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Presidential Documents

Title 3—

The President

Presidential Determination No. 2011–17 of September 30, 2011

Fiscal Year 2012 Refugee Admissions Numbers and Authorizations of In-Country Refugee Status Pursuant to Sections 207 and 101(a)(42), Respectively, of the Immigration and Nationality Act, and Determination Pursuant to Section 2(b)(2) of the Migration and Refugee Assistance Act, as Amended

Memorandum for the Secretary of State

In accordance with section 207 of the Immigration and Nationality Act (the ''Act'') (8 U.S.C. 1157), as amended, and after appropriate consultations with the Congress, I hereby make the following determinations and authorize the following actions:

The admission of up to 76,000 refugees to the United States during Fiscal Year (FY) 2012 is justified by humanitarian concerns or is otherwise in the national interest; provided that this number shall be understood as including persons admitted to the United States during FY 2012 with Federal refugee resettlement assistance under the Amerasian immigrant admissions program, as provided below.

The 76,000 admissions numbers shall be allocated among refugees of special humanitarian concern to the United States in accordance with the following regional allocations (provided that the number of admissions allocated to the East Asia region shall include persons admitted to the United States during FY 2012 with Federal refugee resettlement assistance under section 584 of the Foreign Operations, Export Financing, and Related Programs Appropriations Act of 1988, as contained in section 101(e) of Public Law 100–202 (Amerasian immigrants and their family members)):

Africa	12,000
East Asia	18,000
Europe and Central Asia	2,000
Latin America/Caribbean	5,500
Near East/South Asia	35,500
Unallocated Reserve	3,000

The 3,000 unallocated refugee numbers shall be allocated to regional ceilings, as needed. Upon providing notification to the Judiciary Committees of the Congress, you are hereby authorized to use unallocated admissions in regions where the need for additional admissions arises.

Additionally, upon notification to the Judiciary Committees of the Congress, you are further authorized to transfer unused admissions allocated to a particular region to one or more other regions, if there is a need for greater admissions for the region or regions to which the admissions are being transferred. Consistent with section 2(b)(2) of the Migration and Refugee Assistance Act of 1962 (22 U.S.C. 2601(b)(2)), as amended, I hereby determine that assistance to or on behalf of persons applying for admission to the United States as part of the overseas refugee admissions program will contribute to the foreign policy interests of the United States and designate such persons for this purpose.

Consistent with section 101(a)(42) of the Act (8 U.S.C. 1101(a)(42)), and after appropriate consultation with the Congress, I also specify that, for FY 2012, the following persons may, if otherwise qualified, be considered

refugees for the purpose of admission to the United States within their countries of nationality or habitual residence:

a. Persons in Cuba
b. Persons in Eurasia and the Baltics
c. Persons in Iraq
d. In exceptional circumstances, persons identified by a United States Embassy in any location

You are authorized and directed to report this determination to the Congress immediately and to publish it in the *Federal Register*.

THE WHITE HOUSE,
Washington, September 30, 2011

[FR Doc. 2011–26331
Filed 10–7–11; 8:45 am]
Billing code 4710–10–P

Presidential Documents

Presidential Determination No. 2011–18 of September 30, 2011

Presidential Determination With Respect to Foreign Governments' Efforts Regarding Trafficking in Persons

Memorandum for the Secretary of State

Consistent with section 110 of the Trafficking Victims Protection Act of 2000 (Division A of Public Law 106–386), as amended (the ''Act''), I hereby:

Make the determination provided in section 110(d)(1)(A)(i) of the Act, with respect to Burma, the Democratic Republic of the Congo, Equatorial Guinea, and Zimbabwe, not to provide certain funding for those countries' governments for Fiscal Year 2012, until such governments comply with the minimum standards or make significant efforts to bring themselves into compliance, as may be determined by the Secretary of State in a report to the Congress pursuant to section 110(b) of the Act;

Make the determination provided in section 110(d)(l)(A)(ii) of the Act, with respect to Cuba, the Democratic People's Republic of North Korea (DPRK), Eritrea, Iran, Madagascar, and Venezuela, not to provide certain funding for those countries' governments for Fiscal Year 2012, until such governments comply with the minimum standards or make significant efforts to bring themselves into compliance, as may be determined by the Secretary of State in a report to the Congress pursuant to section 110(b) of the Act;

Determine, consistent with section 110(d)(4) of the Act, with respect to Algeria, the Central African Republic, Guinea-Bissau, Kuwait, Lebanon, Libya, Mauritania, Micronesia, Papua New Guinea, Saudi Arabia, Sudan, Turkmenistan, and Yemen that provision to these countries' governments of all programs, projects, or activities of assistance described in sections 110(d)(l)(A)(i)–(ii) and 110(d)(l)(B) of the Act would promote the purposes of the Act or is otherwise in the national interest of the United States;

Determine, consistent with section 110(d)(4) of the Act, with respect to Burma, that a partial waiver to allow funding for programs described in section 110(d)(1)(A)(i) of the Act to support government labs and offices that work to combat infectious disease and to support government participation in nongovernmental organization-run civil society programs and Association of South East Asian Nations programs addressing vulnerable populations would promote the purposes of the Act or is otherwise in the national interest of the United States;

Determine, consistent with section 110(d)(4) of the Act, with respect to Cuba and Venezuela, that a partial waiver to allow funding for educational and cultural exchange programs described in section 110(d)(1)(A)(ii) of the Act that are related to democracy or the rule of law programming would promote the purposes of the Act or is otherwise in the national interest of the United States;

Determine, consistent with section 110(d)(4) of the Act, with respect to Iran, that a partial waiver to allow funding for educational and cultural exchange programs described in section 110(d)(1)(A)(ii) of the Act would promote the purposes of the Act or is otherwise in the national interest of the United States;

Determine, consistent with section 110(d)(4) of the Act, with respect to the Democratic Republic of the Congo, that assistance and programs described in section 110(d)(1)(A)(i) and 110(d)(1)(B) of the Act, with the exception

of Foreign Military Sales and Foreign Military Financing, would promote the purposes of the Act or is otherwise in the national interest of the United States;

Determine, consistent with section 110(d)(4) of the Act, with respect to Venezuela, that a partial waiver to allow funding for programs described in section 110(d)(1)(A)(i) of the Act to support programs designed to strengthen the democratic process in Venezuela would promote the purposes of the Act or is otherwise in the national interest of the United States;

Determine, consistent with section 110(d)(4) of the Act, with respect to Equatorial Guinea, that a partial waiver to allow funding for programs described in section 110(d)(1)(A)(i) of the Act to support programs to study and combat the spread of infectious diseases and to advance sustainable natural resource management and biodiversity would promote the purposes of the Act or is otherwise in the national interest of the United States;

Determine, consistent with section 110(d)(4) of the Act, with respect to Equatorial Guinea, that assistance described in section 110(d)(1)(B) of the Act would promote the purposes of the Act or is otherwise in the national interest of the United States;

Determine, consistent with section 110(d)(4) of the Act, with respect to Zimbabwe, that a partial waiver to allow funding for programs described in section 110(d)(l)(A)(i) of the Act for assistance for victims of trafficking in persons or to combat such trafficking, and for programs to support the promotion of health, good governance, education, agriculture and food security, poverty reduction, livelihoods, family planning, and macroeconomic growth including anticorruption, and programs that would have a significant adverse effect on vulnerable populations if suspended, would promote the purposes of the Act or is otherwise in the national interest of the United States;

And determine, consistent with section 110(d)(4) of the Act, with respect to Venezuela and Zimbabwe, that assistance described in section 110(d)(1)(B) of the Act, which:

(1) is a regional program, project, or activity under which the total benefit to Venezuela or Zimbabwe does not exceed 10 percent of the total value of such program, project, or activity; or

(2) has as its primary objective the addressing of basic human needs, as defined by the Department of the Treasury with respect to other, existing legislative mandates concerning U.S. participation in the multilateral development banks; or

(3) is complementary to or has similar policy objectives to programs being implemented bilaterally by the United States Government; or

(4) has as its primary objective the improvement of Venezuela or Zimbabwe's legal system, including in areas that impact Venezuela or Zimbabwe's ability to investigate and prosecute trafficking cases or otherwise improve implementation of its anti-trafficking policy, regulations or legislation; or

(5) is engaging a government, international organization, or civil society organization, and seeks as its primary objective(s) to: (a) increase efforts to investigate and prosecute trafficking in persons crimes; (b) increase protection for victims of trafficking through better screening, identification, rescue or removal; aftercare (shelter, counseling) training and reintegration; or (c) expand prevention efforts through education and awareness campaigns highlighting the dangers of trafficking or training and economic empowerment of populations clearly at risk of falling victim to trafficking, would promote the purposes of the Act or is otherwise in the national interest of the United States.

The certification required by section 110(e) of the Act is provided herewith.

You are hereby authorized and directed to submit this determination to the Congress, and to publish it in the *Federal Register*.

THE WHITE HOUSE,
Washington, September 30, 2011

[FR Doc. 2011–26333
Filed 10–7–11; 8:45 am]
Billing code 4710–10–P

Rules and Regulations

Federal Register

Vol. 76, No. 196

Tuesday, October 11, 2011

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. NM465; Special Conditions No. 25–446–SC]

Special Conditions: The Boeing Company, Model 747–8; Upper Deck Occupancy

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Boeing Model 747–8 airplane. These airplanes will have novel or unusual design features associated with upper deck occupancy. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: The effective date of these special conditions is September 28, 2011. We must receive your comments by November 25, 2011.

ADDRESSES: You must mail two copies of your comments to: Federal Aviation Administration, Transport Airplane Directorate, Attn: Rules Docket (ANM–113), Docket No. NM465, 1601 Lind Avenue, SW., Renton, Washington, 98057–3356. You may deliver two copies to the Transport Airplane Directorate at the above address. You must mark your comments: Docket No. NM465. You can inspect comments in the Rules Docket weekdays, except Federal holidays, between 7:30 a.m. and 4:00 p.m.

FOR FURTHER INFORMATION CONTACT: Jayson Claar, FAA, Airframe and Cabin Safety Branch, ANM–115, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–2194 facsimile (425) 227–1232.

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

Comments Invited

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

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

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

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

Background

On November 4, 2005, The Boeing Company applied for an amendment to Type Certificate Number A20WE to include the new Model 747–8 passenger airplane. The Model 747–8 is a derivative of the 747–400. The Model 747–8 is a four-engine jet transport airplane that will have a maximum takeoff weight of 975,000 pounds, new General Electric GEnx–2B67 engines, and the capacity to carry 605 passengers.

The Model 747–8 design offers seating capacity on two separate decks: The main deck with a maximum passenger capacity of 495 and the upper deck with a maximum passenger capacity of 110. Occupants can move between decks via a staircase located near door 2 on the main deck of the airplane in the forward part of the cabin. The staircase is located in the aft end of the upper deck passenger compartment. The regulations do not adequately address a passenger airplane with separate decks for passenger occupancy, thus the FAA considers this to be a novel design, and special conditions are required.

Type Certification Basis

Under the provisions of Title 14 Code of Federal Regulations (14 CFR) 21.101, Boeing must show that the Model 747–8 (hereafter referred to as the 747–8) meets the applicable provisions of 14 CFR part 25, as amended by Amendments 25–1 through 25–117, except for earlier amendments as agreed upon by the FAA. These regulations will be incorporated into Type Certificate No. A20WE after type certification approval of the 747–8.

If the Administrator finds that the applicable airworthiness regulations (i.e., part 25) do not contain adequate or appropriate safety standards for the 747–8 because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design features, or should any other model already included on the same type certificate be modified to incorporate the same novel or unusual design features, these special conditions would also apply to the other model.

In addition to the applicable airworthiness regulations and special conditions, the 747–8 must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the

noise certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in § 11.19, in accordance with § 11.38, and they become part of the type-certification basis under § 21.101.

Novel or Unusual Design Features

The Boeing Model 747–8 will incorporate the following novel or unusual design features: seating capacity on two separate decks, a main deck with a maximum passenger capacity of 495 and an upper deck with a maximum passenger capacity of 110, and a staircase to facilitate occupant movement between the decks.

Discussion

The regulations governing the certification of the 747–8 do not adequately address the certification requirements for a two-deck passenger airplane. The Airbus A380–800 and all of the earlier Boeing 747 passenger airplane models were certified with seating capacity on two separate decks. When the seating capacity of the upper deck of the Boeing 747 exceeded 24 passengers, the FAA issued Special Condition No. 25–61–NW–1 for a maximum seating capacity of 32 passengers on the upper deck for take-off and landing. A second set of special conditions, Special Condition No. 25–71–NW–3, was issued to include airplanes up to a maximum seating capacity of 45 passengers on the upper deck for take-off and landing. The second set of special conditions was modified to address airplanes with a maximum seating capacity of 110 passengers on the upper deck for take-off and landing. Special Conditions No. 25–326–SC for the Airbus A380–800 allowed a seating capacity on two separate decks: The main deck with a maximum passenger capacity of 542 and the upper deck with a maximum passenger capacity of 308. Although these previously issued special conditions provided a starting point for developing the 747–8 special conditions, the 747–8 special conditions are specific to the unique aspects of this airplane's design.

The upper deck of the 747–8 has one pair of exits at station 690, which is located approximately in the forward one-third of the upper deck passenger cabin. The stairway between the main deck and the upper deck is located in the aft end of the upper deck passenger compartment. Depending on the interior arrangement of the upper deck, access to the pair of exits on the upper deck can be reduced. This pair of exits could be rated as Type A, Type C, or Type I exits. These exit configurations and stairway evacuation route are not addressed in the regulations.

Current regulations do not address the design of the emergency lighting system(s) for two-deck airplanes including the separation of the systems between the two decks and the operational requirements of the systems when considering a single transverse vertical separation of the fuselage during a crash landing.

Additionally, with a two-deck airplane, there are concerns with communications between the two decks and between each deck and the flight deck.

The FAA issued a set of special conditions for the 747–8, Special Conditions No. 25–430–SC, specifying the design requirements of the stairway connecting the main and upper decks, including structural design, placement within the airplane, lighting, and signage.

The following special conditions address additional elements to support evacuation between decks of the 747–8 airplane in an in-flight emergency.

Applicability

As discussed above, these special conditions are applicable to the Model 747–8. Should Boeing apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design features, the special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on Model 747–8 airplanes. It is not a rule of general applicability.

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

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

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

The Special Conditions

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Boeing Model 747–8 airplanes.

1. Passenger Emergency Exits

(a) The upper deck passenger occupancy is limited to 110 with one pair of Type A exits. If, due to the interior arrangement, the upper deck exits are rated as Type I, the upper deck passenger occupancy is limited to 45. If, due to the interior arrangement, the upper deck exits are rated as Type C, the upper deck passenger occupancy is limited to 55. The centerline of these exits is located at station 690 on the upper deck.

2. Emergency Lighting System

(a) The upper deck emergency lighting system power supplies must be independent of the main deck emergency lighting system power supplies.

(b) The upper deck emergency lighting system must be designed so that, after any single transverse vertical separation of the fuselage during a crash landing, not more than 25 percent of all required electrically illuminated emergency lights in the upper deck are rendered inoperative, in addition to the upper deck emergency lights that are directly damaged by separation.

3. Inter-deck Communication

(a) An intercom and a two-way alerting means between passenger decks and between each passenger deck and the flightdeck must be provided that meet the following requirements:

(1) They must remain operable in the event of the loss of the main power supply.

(2) They must be capable of providing crewmembers on all decks an immediate indication of emergency situation on any deck.

Issued in Renton, Washington, on September 28, 2011.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–25504 Filed 10–7–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0543; Directorate Identifier 2011–CE–018–AD; Amendment 39–16709; AD 2011–12–02]

RIN 2120–AA64

Airworthiness Directives; Viking Air Limited Model DHC–3 (Otter) Airplanes With Supplemental Type Certificate (STC) SA 09866SC

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: The FAA is correcting an airworthiness directive (AD) that published in the **Federal Register**. That AD applies to Viking Air Limited Model DHC–3 (Otter) airplanes equipped with a Honeywell TPE331–10 or –12JR turboprop engine installed per STC SA09866SC (Texas Turbines Conversions, Inc.). The wording on how the AD is justified and the wording of the temporary placard need clarification. The clarification does not affect the actions of the AD. This document makes this clarification. In all other respects, the original document remains the same.

DATES: This final rule is effective October 11, 2011. The effective date for AD 2011–12–02 remains June 2, 2011.

ADDRESSES: 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: Peter W. Hakala, Aerospace Engineer, Special Certification Office, FAA, Rotorcraft Directorate, 2601 Meacham Blvd., Fort Worth, Texas 76137; phone: (817) 222–5145; fax: (817) 222–5785; e-mail: *peter.w.hakala@faa.gov.*

SUPPLEMENTARY INFORMATION: Airworthiness Directive 2011–12–02, Amendment 39–16709 (76 FR 31800, June 2, 2011), currently requires incorporating revised airspeed limitations and marking the airspeed indicator accordingly for Viking Air Limited Model DHC–3 (Otter) airplanes equipped with a Honeywell TPE331–10 or –12JR turboprop engine installed per STC SA09866SC (Texas Turbines Conversions, Inc.). There is also a requirement for the installation of a temporary placard until the airspeed indicator can be modified but not to exceed a certain period of time.

As published, the wording on justification for the AD and the wording of the temporary placard need clarification. The clarification does not affect the actions of the AD. Only the changed portion of the final rule is being published in the **Federal Register**.

The effective date of this AD remains June 2, 2011.

Correction of Non-Regulatory Text

In the **Federal Register** of June 2, 2011, AD 2011–12–02; Amendment 39–16709 (76 FR 31800, June 2, 2011), is corrected as follows:

On page 31800, in the third column, on line two under Airworthiness Directives; add at the end of the section the phrase ''with Supplemental Type Certificate (STC) SA09866SC.''

On page 31801, in the first column, at the end of the fifth line from the top and beginning of the sixth line from the top, remove the phrase ''as stated in the regulations.''

On page 31801, in the first column, in lines 10 through 12 from the top, replace the phrase ''that exceed the speeds established in the federal aviation regulations for safe operation'' with ''that exceed those determined to be safe by the FAA.''

On page 31801, in the second column, in lines 7 and 8 from the top, remove the phrase ''as stated in the regulations.''

On page 31801, in the second column, in lines 4 through 7 of the first full paragraph, replace the ''with color band markings that do not comply with 14 CFR 23.1505(c). This could result in reduced safety margins that may result in an unsafe condition.'' with ''with color band markings that could result in reduced safety margins and cause an unsafe condition.''

On page 31801, in the second column, in lines 5 through 7 of the third full paragraph, replace the phrase ''that exceed the speeds established in the federal aviation regulations for safe operation'' with ''that exceed those determined to be safe by the FAA.''

Correction of Regulatory Text

§ 39.13 [Corrected]

■ In the **Federal Register** of June 2, 2011, AD 2011–12–02; Amendment 39–16709 (76 FR 31800, June 2, 2011), on page 31802, paragraphs (e) and (f)(2) of AD 2011–12–02 are corrected to read as follows:

(e) This AD was prompted by analysis that showed that airspeed limitations for the affected airplanes are not adjusted for the installation of a turboprop engine. We are issuing this AD to prevent the loss of airplane structural integrity due to the affected airplanes being able to operate at speeds that exceed those determined to be safe by the FAA.

(f)(2) Fabricate a placard using letters of at least ⅛-inch in height with the following words: ''Maximum certificated operating speed is 144 MPH, VMO speed limit for land/ski plane and 134 MPH, VMO speed limit for seaplane.'' Install this placard on the airplane instrument panel next to the airspeed indicator within the pilot's clear view.

Issued in Kansas City, Missouri, on October 3, 2011.

Earl Lawrence,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–26002 Filed 10–7–11; 8:45 am]

BILLING CODE 4910–13–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1450

Virginia Graeme Baker Pool and Spa Safety Act; Interpretation of Unblockable Drain

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule; revocation.

SUMMARY: The Consumer Product Safety Commission (''Commission,'' ''CPSC'' or ''we'') is revoking its interpretation of the term ''unblockable drain'' as used in the Virginia Graeme Baker Pool and Spa Safety Act (''VGB Act'').[1]

DATES: *Effective date:* This rule is effective October 11, 2011.

Compliance date: This revocation does not alter the current requirement that public pools and spas be in compliance with the VGB Act, which became effective December 19, 2008. Any public pools or spas that require *modifications* as a result of this revocation shall comply by May 28, 2012.

Comment dates: Written comments and submissions in response to this

[1] The Commission voted 3–2 to publish this revocation, with changes, in the **Federal Register**. Chairman Inez M. Tenenbaum, Commissioners Robert Adler and Thomas Moore voted to publish the revocation. Commissioners Nancy Nord and Anne Northup voted against publication of this revocation. Chairman Tenenbaum, Commissioner Adler, Commissioner Moore and Commissioner Nord filed statements regarding the vote. The statements may be viewed at *http://www.cpsc.gov/pr/statements.html.*

action must be received by December 12, 2011. The Commission invites written comments regarding the ability of those who have installed VGBA compliant unblockable drain covers as described at 16 CFR 1450.2(b) to come into compliance with our revocation by May 28, 2012.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2011–0071, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. To ensure timely processing of comments, the Commission is no longer accepting comments submitted by electronic mail (e-mail), except through *http://www.regulations.gov.*

Written Submissions

Submit written submissions in the following way:

Mail/Hand delivery/Courier (for paper (preferably in five copies), disk, or CD–ROM submissions), to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to *http://www.regulations.gov*. Do not submit confidential business information, trade secret information, or other sensitive or protected information electronically. Such information should be submitted in writing and noted as such.

Docket: For access to the docket to read background comments or comments received, go to: *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Troy Whitfield, Lead Compliance Officer, Office of Compliance, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814–4408; telephone (301) 504–7548 or e-mail *twhitfield@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

The Virginia Graeme Baker Pool and Spa Safety Act, Pub. L. 110–140, Title XIV (''the VGB Act'') was signed into law on December 19, 2007, and became effective on December 19, 2008. The VGB Act's purpose is to prevent suction entrapment by swimming pool and spa drains and child drowning in swimming pools and spas.

Section 1404(c)(1)(A)(i) of the VGB Act requires that each public pool and spa in the United States be equipped with drain covers that comply with the ASME/ANSI A112.19.8 performance standard or any successor standard. (In the **Federal Register** of August 5, 2011 (76 FR 47436), we published a final rule to incorporate into our regulations ANSI/APSP–16 2011 as the successor standard to ANSI/ASME A112.19.8. The effective date of this incorporation is September 6, 2011, so that drain covers manufactured, distributed, or entered into commerce in the United States must conform to ANSI/APSP–16 2011 as of that date. See 16 CFR 1450.3) Section 1404(c)(1)(A)(ii) of the VGB Act requires that each public pool and spa in the United States with a single main drain, other than an unblockable drain, be equipped, at a minimum, with one or more of the following:

- Safety vacuum release system;
- Suction-limiting vent system;
- Gravity drainage system;
- Automatic pump shut-off system;
- Drain disablement; and/or
- Any other system determined by the Commission to be equally effective as, or better than, the enumerated systems at preventing or eliminating the risk of injury or death associated with pool drainage systems.

For purposes of this preamble, we will refer to these systems collectively as ''secondary anti-entrapment systems.'' Thus, under the VGB Act, each public pool or spa with a single main drain, other than an unblockable drain, must be equipped with a secondary anti-entrapment system. Section 1403(7) of the VGB Act defines an ''unblockable drain'' as ''a drain of any size and shape that a human body cannot sufficiently block to create a suction entrapment hazard.''

On April 27, 2010, the Commission issued a final interpretive rule in the **Federal Register** (75 FR 21985) interpreting ''unblockable drain'' as follows:

> A suction outlet defined as all components, including the sump and/or body, cover/grate, and hardware such that its perforated (open) area cannot be shadowed by the area of the 18″ x 23″ Body Blocking Element of ASME/ANSI A112.19.8–2007 and that the rated flow through the remaining open area (beyond the shadowed portion) cannot create a suction force in excess of the removal force values in Table 1 of that Standard. All suction outlet covers, manufactured or field-fabricated, shall be certified as meeting the applicable requirements of the ASME/ANSI A112.19.8 standard.

This language is codified in 16 CFR 1450.2(b). Under this interpretation, when a drain cover meeting certain specifications was attached to a drain, the covered drain constituted an ''unblockable drain.'' As an unblockable drain, this drain did not require a secondary anti-entrapment system. For the reasons set forth in Part B, the Commission is revoking this interpretation. As a result, a blockable drain cannot be made ''unblockable'' by use of a cover alone.

B. Revised Interpretation

Since the issuance of this interpretive rule, we received 156 letters asking us to reexamine our interpretation of the definition of ''unblockable drain.'' In general, these letters assert that drain covers, regardless of their size, can come off or break over the course of the life of a pool or spa, even when the owners and operators have the best intentions. They claim that for this reason, backup systems are necessary, and a swimming pool or spa with a single main drain cannot be made ''unblockable'' by the simple installation of a drain cover meeting certain requirements. They also claim that our interpretation of the definition of ''unblockable drain'' undermines the law's intent of incorporating several layers of protection into pools and spas. These letters have been made part of the docket.

In light of these letters, we have reconsidered our interpretation of an ''unblockable drain,'' at 16 CFR 1450.2(b) and believe it was in error. Regardless of the size of a drain and its cover, the drain cover can come off, presenting a risk of entrapment. We believe that not requiring an additional layer of protection in the form of a secondary anti-entrapment system thwarts the layers of protection intended by the VGB Act. Accordingly, the Commission is revoking the interpretation of unblockable drain at 16 CFR 1450.2(b).

C. Effect of Revocation of 16 CFR 1450.2(b)

The revocation of this rule means that a drain cover can no longer be used to convert a blockable drain into an unblockable drain. Pursuant to the VGB Act, drains that are blockable require a secondary anti-entrapment system. Section 1404(c)(1)(A)(ii) of the VGB Act. Accordingly, if you have used an unblockable drain cover to create an unblockable drain, the revocation of the interpretative rule means that you must equip your public pool or public spa with a secondary anti-entrapment system as required by the VGB Act. A

drain is ''unblockable'' if the suction outlet, including the sump, has a perforated (open) area that cannot be shadowed by the area of the 18″ x 23″ Body Blocking Element of ANSI/APSP–16 2011 and the rated flow through any portion of the remaining open area (beyond the shadowed portion) cannot create a suction force in excess of the removal force values in Table 1 of that Standard. The Staff Technical Guidance of June 2008 will be updated to clarify that placing a removable, unblockable drain cover over a blockable drain does not constitute an unblockable drain. This revocation corrects the previous interpretation, which the Commission now believes was in error and thwarts the intent of the law to require layers of protection in cases where a drain cover, regardless of its size, can be removed, broken, or otherwise expose a blockable drain and present an entrapment hazard. The Commission has set a compliance date of May 28, 2012, to allow time for firms that require modifications as a result of this revocation to bring their pools into compliance with the statute as written. In addition, the Commission invites written comments regarding the ability of those who have installed VGBA compliant unblockable drain covers as described at 16 CFR 1450.2(b) to come into compliance with our revocation by May 28, 2012.

List of Subjects in 16 CFR Part 1450

Consumer protection, Infants and children, Law enforcement.

For the reasons stated above, the Commission amends part 1450 of title 16 of the Code of Federal Regulations as set forth below:

PART 1450—VIRGINIA GRAEME BAKER POOL AND SPA SAFETY ACT REGULATIONS

■ 1. The authority citation for part 1450 continues to read as follows:

Authority: 15 U.S.C. 2051–2089, 86 Stat. 1207; 15 U.S.C. 8001–8008, 121 Stat. 1794.

§ 1450.2 [Removed and Reserved]

■ 2. Remove and reserve § 1450.2.

Dated: September 29, 2011.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2011–25601 Filed 10–7–11; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[TD 9543]

RIN 1545–BA99

Timely Mailing Treated as Timely Filing

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to final regulations.

SUMMARY: This document contains corrections to final regulations that were published in the **Federal Register** on Tuesday, August 23, 2011, the regulations provide that the proper use of registered or certified mail, or a service of a private delivery service designated under criteria established by the Internal Revenue Service, will constitute prima facie evidence of delivery. The regulations affect taxpayers who mail Federal tax documents to the Internal Revenue service or the United States Tax Court.

DATES: This correction is effective on October 11, 2011 and applies to any payment or document mailed and delivered in accordance with the requirements of § 301.7502–1 in an envelope bearing a postmark dated after September 21, 2004.

FOR FURTHER INFORMATION CONTACT: Steven Karon, (202) 622–4570 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9543) that is the subject of this correction is under sections 301 and 602 of the Internal Revenue Code.

Need for Correction

As published on August 23, 2011 (76 FR 52561), the final regulations (TD 9543) contains errors that may prove to be misleading and is in need of clarification.

Correction of Publication

Accordingly, the final regulations (TD 9543), that were the subject of FR Doc. 2011–21416, are corrected as follows:

1. On page 52561, column 1, in the regulation heading, the CFR Title and part Number, line 3, the phrase ''26 CFR part 301'' is corrected to read ''26 CFR parts 301 and 602''.

2. On page 52561, column 2, in the preamble, under the caption **''FOR FURTHER INFORMATION CONTACT''**, line 1, the phrase ''(202) 622- 4570'' is corrected to read ''(202) 622–4570''.

3. On page 52562, column 3, in the preamble under the caption ''Special Analyses'', lines 6 and 7 from the bottom of the second paragraph, the phrase ''$2.80 and registered mail can be used for as little as $10.60'' is corrected to read ''$2.85 and registered mail can be used for as little as $10.75.''

4. On page 52562, column 3, in the preamble, the caption ''List of Subjects in 26 CFR part 301'' is corrected to read as follows:

List of Subjects

26 CFR Part 301

Employment taxes, Estate taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

5. On page 52562, column 3, in the preamble under the caption ''Adoption of Amendments to the Regulations'', line 1, the phrase ''Accordingly, 26 CFR part 301 is amended as follows:'' is corrected to read ''Accordingly, 26 CFR parts 301 and 602 are amended as follows:''.

Diane O. Williams,

Federal Register Liaison, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).

[FR Doc. 2011–26187 Filed 10–7–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network

31 CFR Part 1060

RIN 1506–AB12

Comprehensive Iran Sanctions, Accountability, and Divestment Reporting Requirements

AGENCY: Financial Crimes Enforcement Network (''FinCEN''), Treasury.

ACTION: Final rule.

SUMMARY: FinCEN, to comply with the congressional mandate to prescribe regulations under section 104(e) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (''CISADA'') and consistent with its statutory mission under 31 U.S.C. 310, is issuing this final rule. The rule requires a U.S. bank that maintains a correspondent account for a foreign bank to inquire of the foreign bank, and report to FinCEN certain information with respect to transactions or other financial services provided by that foreign bank. Under the rule, U.S. banks will only be required to report this

information to FinCEN upon receiving a specific written request from FinCEN. This final rule follows publication of a May 2, 2011 proposed rule, takes into account the public comments received, and adopts the provisions of the proposed rule with minor modifications described in the preamble.

DATES: *Effective Date:* October 11, 2011.

FOR FURTHER INFORMATION CONTACT: The FinCEN regulatory helpline at (800) 949–2732 and select Option 6.

SUPPLEMENTARY INFORMATION:

I. Statutory Provisions

On July 1, 2010, the President signed CISADA [1] into law. Section 104(c) of CISADA requires the Secretary of the Treasury (''the Secretary'') to prescribe regulations to prohibit, or impose strict conditions on, the opening or maintaining in the United States of correspondent accounts and payable-through accounts for foreign financial institutions that the Secretary finds knowingly engage in sanctionable activities described in section 104(c)(2) of CISADA. The relevant statutory language reads as follows:

''(c) PROHIBITIONS AND CONDITIONS WITH RESPECT TO CERTAIN ACCOUNTS HELD BY FOREIGN FINANCIAL INSTITUTIONS.—

(1) IN GENERAL.—Not later than 90 days after the date of the enactment of this Act, the Secretary of the Treasury shall prescribe regulations to prohibit, or impose strict conditions on, the opening or maintaining in the United States of a correspondent account or a payable-through account by a foreign financial institution that the Secretary finds knowingly engages in an activity described in paragraph (2).

(2) ACTIVITIES DESCRIBED.—A foreign financial institution engages in an activity described in this paragraph if the foreign financial institution—

(A) facilitates the efforts of the Government of Iran (including efforts of Iran's Revolutionary Guard Corps or any of its agents or affiliates)—

(i) to acquire or develop weapons of mass destruction or delivery systems for weapons of mass destruction; or

(ii) to provide support for organizations designated as foreign terrorist organizations under section 219(a) of the Immigration and Nationality Act (8 U.S.C. 1189(a)) or support for acts of international terrorism (as defined in section 14 of the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note));

(B) facilitates the activities of a person subject to financial sanctions pursuant to United Nations Security Council Resolution 1737 (2006), 1747 (2007), 1803 (2008), or 1929 (2010), or any other resolution that is agreed to by the Security Council and imposes sanctions with respect to Iran;

(C) engages in money laundering to carry out an activity described in subparagraph (A) or (B);

(D) facilitates efforts by the Central Bank of Iran or any other Iranian financial institution to carry out an activity described in subparagraph (A) or (B); or

(E) facilitates a significant transaction or transactions or provides significant financial services for—

(i) Iran's Revolutionary Guard Corps or any of its agents or affiliates whose property or interests in property are blocked pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.); or

(ii) a financial institution whose property or interests in property are blocked pursuant to that Act in connection with—

(I) Iran's proliferation of weapons of mass destruction or delivery systems for weapons of mass destruction; or

(II) Iran's support for international terrorism.

(3) PENALTIES.—The penalties provided for in subsections (b) and (c) of section 206 of the International Emergency Economic Powers Act (50 U.S.C. 1705) shall apply to a person that violates, attempts to violate, conspires to violate, or causes a violation of regulations prescribed under paragraph (1) of this subsection to the same extent that such penalties apply to a person that commits an unlawful act described in section 206(a) of that Act.''

On August 16, 2010, the Office of Foreign Assets Control (''OFAC') published the Iranian Financial Sanctions Regulations, 31 CFR Part 561 (the ''IFSR''). Section 561.201 of the IFSR implements section 104(c) of CISADA. It states that the Secretary will, consistent with authorities under CISADA, prohibit or impose strict conditions on the opening or maintaining in the United States of correspondent accounts or payable-through accounts for a foreign financial institution that the Secretary finds knowingly engages in one or more of the sanctionable activities described in section 561.201(a) of the IFSR.

Section 104(e) of CISADA requires the Secretary to prescribe regulations to establish one or more specific requirements for U.S. financial institutions maintaining correspondent accounts for foreign financial institutions, in connection with the sanctionable activities described in section 104(c)(2) of CISADA. The relevant statutory language reads as follows:

''(e) REQUIREMENTS FOR FINANCIAL INSTITUTIONS MAINTAINING ACCOUNTS FOR FOREIGN FINANCIAL INSTITUTIONS.—

(1) IN GENERAL.—The Secretary of the Treasury shall prescribe regulations to require a domestic financial institution maintaining a correspondent account or payable-through account in the United States for a foreign financial institution to do one or more of the following:

(A) Perform an audit of activities described in subsection (c)(2) that may be carried out by the foreign financial institution.

(B) Report to the Department of the Treasury with respect to transactions or other financial services provided with respect to any such activity.

(C) Certify, to the best of the knowledge of the domestic financial institution, that the foreign financial institution is not knowingly engaging in any such activity.

(D) Establish due diligence policies, procedures, and controls, such as the due diligence policies, procedures, and controls described in section 5318(i) of title 31, United States Code, reasonably designed to detect whether the Secretary of the Treasury has found the foreign financial institution to knowingly engage in any such activity.

(2) PENALTIES.—The penalties provided for in sections 5321(a) and 5322 of title 31, United States Code, shall apply to a person that violates a regulation prescribed under paragraph (1) of this subsection, in the same manner and to the same extent as such penalties would apply to any person that is otherwise subject to such section 5321(a) or 5322.''

In order to comply with the congressional mandate to prescribe regulations under section 104(e) of CISADA, and consistent with its statutory mission under 31 U.S.C. 310, FinCEN is implementing section 104(e)(1)(B) of CISADA. FinCEN considered implementing any one or more of the options under section 104(e)(1) of CISADA, and determined that implementing section 104(e)(1)(B) is the most useful vehicle for effecting the intent of section 104(e) at this time. Section 104(e)(1)(B) of CISADA authorizes the Secretary to prescribe regulations that require a domestic financial institution maintaining a correspondent account in the United States for a foreign financial institution to report to the Department of the Treasury with respect to transactions or other financial services provided with respect to sanctionable activities described in section 104(c)(2) of CISADA that may be carried out by the foreign financial institution.

FinCEN believes that among the services included within the concept of ''transactions or other financial services provided'' by a foreign financial institution are correspondent accounts the foreign financial institution maintains for other foreign financial institutions and transfers of funds the foreign financial institution processes for or on behalf of other foreign financial institutions, individuals, or entities. A foreign financial institution's provision of correspondent account services and transfer of funds services to a financial institution designated by the U.S. Government in connection with Iran's proliferation of weapons of mass

[1] Public Law No. 111–195, 124 Stat. 1312 (2010).

destruction or delivery systems for weapons of mass destruction, or in connection with Iran's support for international terrorism, may be relevant to the sanctionable activities described under section 104(c)(2) of CISADA. As a result, FinCEN is focusing this reporting requirement on the provision of information relating to such correspondent accounts and transfers of funds.[2] In addition, because a foreign financial institution's provision of transfer of funds services to Iran's Islamic Revolutionary Guard Corps (''IRGC'') or any of its agents or affiliates designated by the U.S. Government may also be relevant to the sanctionable activities described under section 104(c)(2) of CISADA, FinCEN is also focusing this reporting requirement on the provision of information relating to such transfers of funds.[3]

FinCEN is implementing section 104(e)(1)(B) of CISADA by issuing regulations that require a bank, upon receiving a written request from FinCEN, to inquire of a specified foreign bank for which it maintains a correspondent account, and report to FinCEN, with respect to the following: (1) Whether the foreign bank maintains a correspondent account for an Iranian-linked financial institution designated under the International Emergency Economic Powers Act (''IEEPA'');[4] (2) whether the foreign bank has processed one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly,[5] an Iranian-linked financial institution designated under IEEPA, other than through a correspondent account; and (3) whether the foreign bank has processed one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an IRGC-linked person designated under IEEPA.[6]

In addition, the rule requires a bank to request, when making its inquiry of a specified foreign bank, that the foreign bank agree to notify the bank if the foreign bank subsequently establishes a new correspondent account for an Iranian-linked financial institution designated under IEEPA at any time within 365 calendar days from the date of the foreign bank's initial response, and report such information to FinCEN.

The rule also requires a bank to report to FinCEN instances in which the bank does not maintain a correspondent account for a foreign bank specified in a written request from FinCEN. This requirement will only apply when FinCEN specifically requests in writing that the bank report such information. To the extent possible and based on all available information, FinCEN intends to send requests directly to banks that FinCEN believes may maintain correspondent accounts for the specified foreign bank(s). The number of banks that receive a request may vary in each specific case, based on the availability of information to FinCEN and other circumstances.

II. Background Information

A. 31 CFR Part 561 Iranian Financial Sanctions Regulations—Office of Foreign Assets Control

On August 16, 2010, OFAC published the IFSR, 31 CFR part 561. As noted above, section 561.201 of the IFSR implements section 104(c) of CISADA. It states that the Secretary will, consistent with authorities under CISADA, prohibit or impose strict conditions on the opening or maintaining in the United States of correspondent accounts or payable-through accounts for a foreign financial institution that the Secretary finds knowingly engages in one or more of the sanctionable activities described in section 561.201(a) of the IFSR. The names of foreign financial institutions that are found by the Secretary to knowingly engage in such sanctionable activities, and for which U.S. financial institutions may not open or maintain correspondent accounts or payable-through accounts in the United States, will be published in the **Federal Register** and listed in appendix A to the IFSR. If the Secretary decides to impose strict conditions on the opening or maintaining of a correspondent account or a payable-through account for a foreign financial institution, the actual condition(s) to be imposed will be specified upon the identification of the foreign financial institution in an order or regulation published in the **Federal Register.**

B. Use of CISADA Reports

The CISADA reports received as a result of this rulemaking will be used primarily to provide FinCEN with potentially useful information from U.S. banks regarding the nature of foreign bank activities that may be relevant to CISADA. Based on the reports, immediate action may be taken under section 104(c) of CISADA, or, among other things, there may be consultation with those foreign banks that maintain correspondent accounts for Iranian-linked financial institutions designated under IEEPA, that have processed one or more transfers of funds for or on behalf of, directly or indirectly, an Iranian-linked financial institution or an IRGC-linked person designated under IEEPA, or that have been unwilling to respond to inquiries from the banks at which the foreign banks maintain correspondent accounts. An investigation by OFAC into the activities of such foreign banks could result in a finding by the Secretary under section 104(c) of CISADA and section 561.201 of the IFSR. For example, when a bank reports that a foreign bank maintains a correspondent account for an Iranian-linked financial institution designated under IEEPA, or has processed one or more transfers of funds for or on behalf of, directly or indirectly, an Iranian-linked financial institution or an IRGC-linked person designated under IEEPA, OFAC could use the information to corroborate or supplement data derived from other sources and may request further information from the foreign bank to clarify whether the foreign bank is facilitating significant transactions or providing significant financial services for an Iranian-linked financial institution or an IRGC-linked person designated under IEEPA. Such transactions or services can be the basis for prohibiting or imposing strict conditions on the foreign bank's correspondent or payable-through accounts in the United States under section 104(c) of CISADA and section 561.201 of the IFSR.

III. Notice of Proposed Rulemaking

The final rule contained in this document is based on the Notice of Proposed Rulemaking published in the **Federal Register** on May 2, 2011 (''Notice'').[7] With the intent of implementing section 104(e) of CISADA, the Notice proposed to require a U.S. bank that maintains a correspondent account for a foreign bank to inquire of the foreign bank and report to FinCEN certain information with respect to transactions or other financial services provided by that foreign bank. The Notice also proposed that banks would only be required to

[2] *See, e.g.,* CISADA subsection 104(c)(2)(E)(ii), which includes focus on the provision by foreign financial institutions of significant financial services to financial institutions that are of concern under CISADA.

[3] *See, e.g.,* CISADA subsection 104(c)(2)(E)(i), which includes focus on the provision by foreign financial institutions of significant financial services to individuals or entities that are of concern under CISADA.

[4] *See below* Section V. A. for the definition of Iranian-linked financial institution designated under IEEPA.

[5] *See below* Section IV. D. for the rationale for replacing the terminology ''related to'' with ''for or on behalf of, directly or indirectly.''

[6] *See below* Section V. A. for the definition of IRGC-linked person designated under IEEPA.

[7] *See* 76 FR 24410 (May 2, 2011).

report this information to FinCEN upon receiving a specific written request from FinCEN.

IV. Comments on the Notice—Overview and General Issues

The comment period for the Notice ended on June 1, 2011. We received a total of seven comment letters from 14 entities and individuals.[8] Of the seven comment letters, five were submitted by trade groups or associations,[9] one was submitted by a group of seven U.S. Senators, and one was submitted by an advocacy group. The comments were generally supportive of the Notice but sought additional clarification on certain aspects of the Notice. Comments received covered a broad and varied range of topics. Although most of these comments are addressed directly below, a few others are covered in the section-by-section analysis.

Comments on the Notice focused on the following general matters: (A) The approach to implementing section 104(e) of CISADA; (B) the ability of a foreign bank to respond to a CISADA request; (C) the impact of the rule on foreign correspondent account relationships; (D) the scope of information to be reported by a foreign bank; (E) the timeframe for a foreign bank and a U.S. bank to respond to a CISADA request; (F) clarification regarding the proposed model certification; (G) clarification regarding certain definitions and terms; (H) record retention and supporting documentation; (I) sharing information regarding a CISADA request; and (J) estimate of burden.

A. The Approach to Implementing Section 104(e) of CISADA

One of the comments asserted that the Notice was not published in the **Federal Register** until 10 months after the President signed CISADA, which led the commenter to call into question the seriousness of enforcing comprehensive sanctions against Iran. Two commenters urged that the final rule should be implemented as soon as possible. Conversely, another commenter asserted that allowing only a 30-day comment period for the Notice was inadequate. In drafting the Notice, we considered a number of different approaches before settling on the one that we believe will produce the most useful information in the most workable manner. The time it took to publish the Notice reflected the need to craft a rule that would best achieve our policy aims, in a complex and novel context. Because we were mindful of the need to obtain this information expeditiously, we issued the Notice with a 30-day comment period. The quality and scope of the comments convinces us that 30 days was sufficient. We have drafted the final rule as promptly as possible, while taking into consideration all of the comments received and ensuring that we have established a rule that most effectively implements section 104(e) of CISADA.

Section 104(e) of CISADA offers FinCEN four options for rulemaking. One commenter requested clarification regarding how FinCEN determined that implementing section 104(e)(1)(B) would be the most useful way to implement section 104(e) of CISADA. As noted above, FinCEN considered a number of different approaches to implementing section 104(e) of CISADA. We believe that implementing section 104(e)(1)(B) will produce the most useful information in the most workable manner and will best achieve our policy aims. In fact, this belief is echoed in a number of comments FinCEN received. One commenter asserted that section 104(e) of CISADA allows FinCEN to implement any one or more of four requirements, some of which the commenter believes are potentially very burdensome to industry. The commenter believes the proposed requirements appropriately balance the need of the U.S. government to isolate Iran from the global financial system with the need to maintain an effectively functioning correspondent banking system. Another commenter asserted that FinCEN has taken elements of the four options Congress outlined in the statute and incorporated them with existing requirements to develop a rule that considers the costs to industry, the ability of the industry to comply, appropriate use of limited enforcement resources, and the need for information. Yet another commenter asserted that banks providing correspondent relationships in the U.S. are not in a position to speak to the overall activities of their foreign counterparts. The commenter further asserted that as such, if those activities are at issue under section 104(e) of CISADA, it is more appropriate to ask the U.S.-based banks to transmit inquiries to their foreign correspondents than to ask them to conduct independent investigations for which they are ill-suited.

One commenter believes that the proposed rule treats section 104(e) of CISADA as a discretionary provision in which banks will only have to certify they are not doing business with relevant Iranian-linked designated entities and individuals upon a written inquiry from FinCEN. Another commenter suggested that the proposed rule would not meet the requirements of the statute, as domestic financial institutions should be required to provide information to FinCEN, not only when asked, but as soon as they are aware that the foreign financial institution is engaged in a ''prohibited activity.'' FinCEN does not interpret 104(e) to be discretionary. To the contrary, we understand 104(e) to require the Secretary to prescribe regulations mandating that domestic financial institutions take one or more actions, one of which is to provide requested reports to FinCEN, and we believe the final rule reflects this understanding. We also note that the activities described in section 104(c)(2) of CISADA are not ''prohibited activities.'' Instead they are activities that can be grounds for imposing the sanctions described in section 104(c)(1) of CISADA.

FinCEN proposed to target this reporting requirement on those foreign banks that there is some basis to suspect may be engaged in activities that may be sanctionable under section 104(c) of CISADA. We considered requiring every U.S. bank to provide periodic reports from every foreign bank for which they maintain correspondent accounts, but concluded that we would be better served by a rule that focused on those foreign banks that are of interest for purposes of CISADA. By requiring reports from those U.S. banks that maintain correspondent accounts for the specific foreign banks that are of interest for purposes of CISADA implementation, we believe that we will receive the information needed without generating a multitude of unnecessary and uninformative reports.

The reporting requirement in the final rule is scalable. Based on the circumstances, it permits FinCEN to expand the number of U.S. banks that would be required to file reports, as well as the number of foreign banks from whom information would be sought. This means that FinCEN may ask any number of U.S. banks about any number of foreign banks as is necessary, based on the number of foreign banks there is some basis to suspect may be engaged in activities that may be sanctionable under section 104(c) of CISADA.

The targeted approach that FinCEN has proposed is supported by a number of commenters. One commenter strongly recommended incorporating the concept of targeted requests in the final rule. That same commenter noted that it appreciated FinCEN's effort to craft a

[8] All comments to the Notice are available for public viewing at *http://www.regulations.gov.*

[9] One comment letter was submitted on behalf of two trade groups or associations.

regulation that focuses on developing meaningful and properly targeted information. Another commenter expressed support for a request-driven model as an appropriate means of focusing industry and governmental resources on information of value. Yet another commenter asserted that in proposing a reporting requirement that would be imposed only when specifically requested, FinCEN has struck an appropriate balance between the need of the U.S. government to isolate Iran from the global financial system with the need to maintain an effectively functioning correspondent banking system.

One commenter correctly noted that banks are only required to request information from a foreign bank for which they maintain a correspondent account upon receiving a written request from FinCEN regarding that specific foreign bank. This rule does not require a bank to proactively inquire of any one or more of the foreign banks for which it maintains correspondent accounts.

One commenter suggested that under CISADA, a foreign financial institution should be required to report if it has facilitated the activities of a person subject to financial sanctions pursuant to United Nations (''U.N.'') Security Council Resolutions with respect to Iran. The commenter suggested that the proposed rule should be amended to require this additional disclosure. We recognize that foreign banks' transactions involving persons subject to financial sanctions pursuant to U.N. Security Council Resolutions with respect to Iran are among the sanctionable activities described in section 104(c)(2) of CISADA; however, there are other avenues for obtaining information on such transactions and FinCEN has determined that this specific reporting mechanism is not the most efficacious means to obtain such information at this time. However, as FinCEN collects and assesses the information required under this rule, we will continue to consider whether expanding the scope of this rule to include information pertaining to whether a foreign bank has facilitated the activities of a person subject to financial sanctions pursuant to U.N. Security Council Resolutions with respect to Iran would provide additional useful information as it relates to CISADA. If that is determined to be the case, FinCEN will consider proposing an expansion of this reporting requirement to include such information. At this time, FinCEN believes that a focus on foreign banks' transactions involving Iranian-linked financial institutions designated under IEEPA and IRGC-linked persons designated under IEEPA will provide the most beneficial information for purposes of implementing section 104(c) of CISADA.

One commenter suggested that alternative resources might better serve the same purpose as the proposed rule. The commenter encouraged FinCEN to place greater reliance on government-to-government requests given the commenter's belief that such requests are likely to be far more reliable when collecting information to identify sanctions targets. The same commenter asserted that the benefit of an inter-governmental approach is the opportunity to urge other countries to adopt and implement similar sanctions. FinCEN clarifies that this rule is one tool that is being utilized to collect information as it relates to identifying potential sanctions targets under CISADA. As the commenter correctly suggested, additional methods of information collection are being utilized to identify sanctions targets. The commenter also suggested that FinCEN utilize existing Bank Secrecy Act (''BSA'') reporting tools as necessary to implement this reporting requirement. FinCEN agrees, and will leverage existing BSA reporting tools as appropriate.

B. The Ability of a Foreign Bank To Respond to a CISADA Request

Four commenters asserted that privacy legislation in certain jurisdictions may prohibit foreign banks from providing the requested information with respect to individual customer accounts and transactions. Three of these same commenters asserted that under CISADA banks have no legal authority to compel foreign banks to provide the requested information. FinCEN acknowledges that some foreign banks may choose not to respond or may not be able to respond due to their own jurisdictions' privacy legislation. For this reason the rule incorporates an option for U.S. banks to report to FinCEN instances in which they have not received a response from a foreign bank.

Although foreign banks are not necessarily required to respond under CISADA authority, those foreign banks may feel compelled to respond in order to maintain good relationships with the U.S. banks with which they maintain correspondent accounts. Even in instances in which a foreign bank does not respond to a bank's inquiry, that information is still valuable. As noted elsewhere in this rulemaking, based on the reports received, immediate action may be taken under section 104(c) of CISADA, or, among other things, there may be consultation with foreign banks, including those that have been unwilling to respond to inquiries. An investigation by OFAC into the activities of such foreign banks could result in a finding by the Secretary under section 104(c) of CISADA and section 561.201 of the IFSR.

One commenter suggested that the proposed rule should clearly outline the ramifications for foreign banks that fail to provide the required information or provide incorrect information. The commenter suggested that those ramifications should mirror the sanctions outlined in section 104(c)(1) of CISADA. If a foreign bank fails to respond or provides incorrect information an investigation may be conducted into the activities of such foreign bank which could, in turn, result in a finding under section 104(c) of CISADA.

One commenter contended that the proposed rule does not take into account the fact that a foreign bank may conduct legitimate business with an Iranian-linked financial institution designated under IEEPA, through licensed transactions and clearing. The commenter further asserted that for this reason, it would be possible for a U.S. authority to impose a penalty under CISADA on a foreign bank for undertaking transactions which had been licensed by its own competent authority. If a foreign bank wishes to explain that a correspondent account or transfer of funds identified in a certification was licensed by a competent authority in the foreign bank's home jurisdiction, the foreign bank may provide this explanatory information in the certification form. Such explanatory information may be taken into account when the foreign bank's certification is reviewed and it is determined what further action, if any, is appropriate under section 104(c) of CISADA. The model certification has been revised to include language that identifies this type of circumstance as an example of information a foreign bank can include in its certification.

C. The Impact of the Rule on Foreign Correspondent Account Relationships

One commenter requested that FinCEN clarify that a request for information regarding a foreign bank or even a positive report from a foreign bank is not a mandate to close or restrict an account. The commenter asserted that one option under the rule is for a bank to report that it cannot determine to its satisfaction that the foreign bank does not maintain a relevant account or

has not processed relevant transfers of funds. The commenter requested that FinCEN acknowledge in the final rule that this option meets compliance expectations for the bank, and the bank is not expected to take further action. Another commenter similarly suggested that the rule should clarify that a bank that does not receive a response from a foreign bank is merely required to report that and does not have to take any other action, including closing the account.

As explained elsewhere in the rulemaking, this rule does not require a bank to take any steps with respect to the foreign bank other than those relating to the collection of information outlined in the rule, regardless of the response received from the foreign bank. While the rule does not preclude a bank from taking any other action based on the bank's assessment of the facts and bank policy, including restricting or terminating a correspondent account relationship with a foreign bank or filing a suspicious activity report, a bank is not required to take any additional action based solely upon the fact that the bank: (i) Has received a request for information under this regulation; (ii) has received a response from the foreign bank; or (iii) has not received a response from the foreign bank.

If a foreign bank does not respond to an inquiry made by a bank under this rule, the bank will be in compliance with these reporting requirements so long as the bank timely reports to FinCEN that the foreign bank did not respond to the bank's inquiry. In addition, if a bank cannot determine that the foreign bank does not maintain a relevant account or has not processed relevant transfers of funds, the bank will be in compliance with these reporting requirements so long as the bank timely reports such information to FinCEN, together with the reason(s) for this, such as the failure of the foreign bank to respond to the inquiry by or a request from the bank, the failure of the foreign bank to certify its response, or if the bank has information that is inconsistent with the certification.

FinCEN requested comment regarding the impact of this information collection on banks' correspondent account relationships with foreign banks. One commenter suggested that a barrage of requests from the United States could create, over time, an unintended consequence of alienating foreign correspondents. The commenter also asserted that foreign banks might be driven to find alternate ways to direct transactions to avoid dealing with the United States. The commenter sees this as having a two-part negative impact: the immediate detriment to the economy and the decreasing ability of the United States to receive valuable information on international transactions. As stated elsewhere in the rulemaking, FinCEN proposed to target this reporting requirement on those foreign banks that there is some basis to suspect may be engaged in activities that may be sanctionable under section 104(c) of CISADA. We considered requiring every U.S. bank to provide periodic reports from every foreign bank for which they maintain correspondent accounts, but concluded that we would be better served by a rule that focused on those foreign banks that are of interest for purposes of CISADA. We believe that by taking a targeted approach we will avoid alienating foreign banks for which we have no concern regarding sanctionable Iranian-related activities. For these reasons, we believe the commenter's concerns are unfounded.

D. The Scope of Information To Be Reported by a Foreign Bank

FinCEN requested comment as to whether the terminology ''processed one or more transfers of funds'' should be further clarified, and if so, how and what terms should be used in the alternative. A few commenters requested further clarification; however FinCEN did not receive any suggestions regarding alternative terminology.

One commenter asserted that the broad definition of the term ''processed one or more transfers of funds'' appears problematic. The commenter suggested that according to the definition, this term would include each and every transaction, in particular those that do not require using a correspondent account. Another commenter suggested that it would need further clarity regarding the term ''processed one or more transfers of funds'' to identify which transactions FinCEN intends to reach. Another commenter questioned what is meant by the term ''other than through a correspondent account,'' in the context of a request that a foreign bank certify whether it has processed one or more transfers of funds within the preceding 90 calendar days related to an Iranian-linked financial institution designated under IEEPA, ''other than through a correspondent account.''

As explained in the Notice, the terminology ''processed one or more transfers of funds'' is meant to address circumstances through which transfers of funds are made without requiring a correspondent account, specifically including circumstances in which financial institutions are part of a common payments or clearing mechanism that provides for transfers of funds among participants without requiring bilateral correspondent account relationships. If a foreign bank is reporting that it maintains a correspondent account for a specific Iranian-linked financial institution designated under IEEPA, the foreign bank does not also have to report that it has processed transfers of funds for that specific Iranian-linked financial institution, as that is assumed within the context of the reported correspondent account. Alternatively, for example, in instances in which a foreign bank is part of a common payments or clearing mechanism that provides for transfers of funds among participants without requiring bilateral correspondent account relationships, those foreign banks should report whether they have processed transfers of funds for an Iranian-linked financial institution designated under IEEPA through such common payments or clearing mechanisms. This type of example is the reason we used the terminology processed one or more transfers of funds within the preceding 90 calendar days related to an Iranian-linked financial institution designated under IEEPA, ''other than through a correspondent account.'' [10]

[10] As it relates to the model certification, a foreign bank should fill out each section of the model certification by selecting one box in each section of the model certification. For example, if a foreign bank has a correspondent account for an Iranian-linked financial institution designated under IEEPA, the foreign bank will select the second box under section B of the model certification: ''Foreign Bank hereby certifies that it *does* maintain a correspondent account(s) for an Iranian-Linked Financial Institution Designated Under IEEPA.'' The foreign bank will also fill out the corresponding chart in section B of the model certification for each applicable correspondent account. The language in the first box under section C of the model certification states ''Foreign Bank hereby certifies that to its knowledge it *has not processed* one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an Iranian-Linked Financial Institution Designated Under IEEPA, *other than through a correspondent account* detailed above.'' The language ''other than through a correspondent account detailed above'' is intended to direct the foreign bank not to reenter the information that was already entered in section B of the model certification in section C of the model certification. However, regardless of which box the foreign bank selects in section B of the model certification, the foreign bank should also select one box from section C of the model certification. If a foreign bank has not processed any transfers of funds outside of a correspondent account relationship with an Iranian-linked financial institution designated under IEEPA, the foreign bank will select the first box under section C of the model certification. If the foreign bank has processed transfers of funds for or on behalf of, directly or indirectly, an Iranian-linked financial institution designated under IEEPA outside of a correspondent account relationship, the foreign bank will select the second box under section C of the model certification: ''Foreign Bank hereby certifies that it *has processed* one or more transfers of funds within

FinCEN also clarifies that in the context of a request that a foreign bank certify whether it has processed one or more transfers of funds within the preceding 90 calendar days related to an IRGC-linked person designated under IEEPA, the foreign bank should report whether it has processed any transfers of funds related to an IRGC-linked person designated under IEEPA, regardless of whether the transfers of funds were processed through a correspondent account or through some other common payments or clearing mechanism.

One commenter noted that under section 1060.300(b), the foreign bank is requested to certify that it has not ''processed one or more transfers of funds within the preceding 90 calendar days related to an Iranian-linked financial institution'' or ''related to an IRGC-linked person.'' The commenter contended that this concept is broader than can reasonably be expected. The commenter explained that while the foreign bank could reasonably determine whether such relevant designated entities and individuals were parties to a transaction, it has no reliable way of ascertaining whether a transaction with a third party has a relationship to such relevant designated entities and individuals. The commenter provided the following example: if the head office of a foreign bank processes a non-USD-denominated payment from its customer in another country outside the United States to a Middle Eastern trading company, it would have no way of knowing whether the trading company may in turn be acting on behalf of a relevant designated entity or individual. The commenter suggested that the requested certification relate to payments ''to or from'' the relevant designated entities or individuals as opposed to ''related to.''

Another commenter noted that it is conceivable that transactions can be conducted that are settled through correspondent accounts held for other credit institutions where the foreign bank does not or cannot recognize that a relevant transaction is conducted on behalf of or in the interest of an Iranian-linked financial institution designated under IEEPA. The commenter suggested that the certification from the foreign bank, therefore, must at least contain the qualification that it is not aware of, or should not necessarily have been aware of, such circumstance.

In the context of the request that a foreign bank certify whether it has processed one or more transfers of funds within the preceding 90 calendar days ''related to'' an Iranian-linked financial institution designated under IEEPA, other than through a correspondent account, and whether it has processed one or more transfers of funds within the preceding 90 calendar days ''related to'' an IRGC-linked person designated under IEEPA, FinCEN has agreed to replace ''related to'' with ''for or on behalf of, directly or indirectly.'' The terminology ''for or on behalf of, directly or indirectly,'' is meant to include situations where a foreign bank has knowledge that a transfer of funds it is processing is for or on behalf of an Iranian-linked financial institution designated under IEEPA, or an IRGC-linked person designated under IEEPA, but where the designated entity or individual does not appear on the face of the transaction. In other words, the phrase is meant to include those situations in which the processing is being done with knowledge based on a relationship that exists through a third party such as a money exchange or trading house.

Consistent with the above mentioned revision and based on comments received, FinCEN has also incorporated the phrase ''to its knowledge'' into the reporting requirement that upon receiving a written request from FinCEN, a bank shall report to FinCEN, in such format and manner as may be prescribed by FinCEN, the following information for any specified foreign bank the name of any specified foreign bank, for which the bank maintains a correspondent account, that certifies that it does not maintain a correspondent account for an Iranian-linked financial institution designated under IEEPA, that certifies that *to its knowledge* it has not processed one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an Iranian-linked financial institution designated under IEEPA, other than through a correspondent account, and/or that certifies that *to its knowledge* it has not processed one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an IRGC-linked person designated under IEEPA.'' [11] [Emphasis added.]

In order to be consistent with the revisions to the regulation text, FinCEN has also incorporated the phrase ''to its knowledge'' into the model certification in the following places: ''Foreign Bank hereby certifies that *to its knowledge* it has not processed one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an Iranian-Linked Financial Institution Designated Under IEEPA, other than through a correspondent account detailed above;'' [emphasis added] and ''Foreign Bank hereby certifies that *to its knowledge* it has not processed one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an IRGC–Linked Person Designated Under IEEPA.'' [Emphasis added.]

One commenter noted that when inquiring of a foreign bank, the U.S. bank would also be required to ask the foreign bank to agree to report if it establishes a new correspondent account for an Iranian-linked financial institution designated under IEEPA within 365 calendar days after its initial response and that would in turn be reported to FinCEN by the U.S. bank. The commenter believes this is the most difficult element of the proposal. The commenter asserted that a request is based on whether the United States has designated an entity under IEEPA. The commenter further suggested that since IEEPA is a U.S. law, and the IEEPA lists are constantly changing, any affected foreign bank would be required to develop systems to monitor and track whether or not a transaction might be covered. The commenter also suggested that foreign banks would have to sort through the entire OFAC list as a first step to identify which entities are covered and then apply it to its own records. The commenter recommended that FinCEN or OFAC create a special section/list for IEEPA designations that is easily accessed by foreign banks around the world.

FinCEN clarifies that the rule does not call on a foreign bank to report on new transfers of funds processed for a relevant designated entity or individual following its initial response. The rule only calls on a foreign bank to report any new correspondent accounts opened for an Iranian-linked financial institution designated under IEEPA within 365 calendar days after the foreign bank's initial response. Also, as noted elsewhere in the rulemaking and in the model certification, a list of financial institutions that meet the criteria of Iranian-linked financial institutions designated under IEEPA ([IFSR] tags) are included at the following link on OFAC's *Web site: http://www.treasury.gov/resource-*

the preceding 90 calendar days for or on behalf of, directly or indirectly, an Iranian-Linked Financial Institution Designated Under IEEPA, *other than through a correspondent account* detailed above.'' In this case the foreign bank also will fill out the corresponding chart in section C of the model certification for each applicable Iranian-linked financial institution designated under IEEPA. Similarly, the foreign bank will also select one box from section D of the model certification.

[11] *See* section 1060.300(c)(1)(iv).

center/sanctions/Programs/Documents/irgc_ifsr.pdf. As of June 27, 2011, there were 22 financial institutions with IFSR tags, meaning 22 Iranian-linked financial institutions designated under IEEPA.[12] The foreign bank can go to the link to look for updates to the site when they open a new correspondent account. In addition, as part of standard practices, banks globally should perform some type of customer identification or verification, customer due diligence, and/or ''know your customer'' policy in opening new accounts. In light of the global awareness of risks in conjunction with certain transactions related to Iran, it does not appear to be unreasonable to expect that a foreign bank that has received a request under this rulemaking could report on new correspondent accounts within the succeeding 365 calendar days.

The commenter also suggested that FinCEN call on a foreign bank to respond to these requests within 30 calendar days after the foreign bank identifies a new correspondent account with an Iranian-linked financial institution designated under IEEPA. This comment is addressed by text in the model certification, which provides as follows: ''Foreign Bank hereby agrees to notify in writing the Bank if Foreign Bank establishes a new Correspondent Account for an Iranian-Linked Financial Institution Designated Under IEEPA at any time within 365 calendar days from the date of this response. Foreign Bank agrees to provide such notification within 30 calendar days of the establishment of the new correspondent account.''

FinCEN requested comment regarding whether setting a minimum dollar threshold for a foreign bank to report on transfers of funds processed within the preceding 90 calendar days related to an Iranian-linked financial institution designated under IEEPA or related to an IRGC-linked person designated under IEEPA would lessen the reporting obligations, while still providing useful information. FinCEN also requested comment regarding what that minimum dollar threshold should be.

Three commenters suggested that a threshold should be set. Two of these commenters asserted that section 104 of CISADA applies to a ''significant transaction or transactions.'' For this reason, the commenters suggested that a threshold should be set to require foreign banks to only report on significant transactions. As it relates to section 104(c) of CISADA, a determination of significance will be decided on a case-by-case basis. Neither section 104 of CISADA nor the IFSR defines a minimum dollar threshold for ''significant transactions.''[13] Neither of these commenters suggested what the minimum dollar threshold should be.

Only one commenter proposed what that minimum dollar threshold should be. The commenter suggested that FinCEN should apply the $3,000 threshold that exists in some other anti-money laundering rules because monitoring transactions of lesser value can be overly burdensome with little benefit. The commenter also suggested that a threshold for minimum aggregate through-put in a correspondent account can also serve to better focus resources on identifying the riskiest correspondent accounts. However, the commenter further asserted that it is mindful that parsing activity at the margins of the threshold can incur its own compliance costs and therefore thresholds should always be applied permissively and not as technical standards that generate compliance complexities.

Considering the fact that a threshold of $3,000 is unlikely to eliminate a substantial number of responses from foreign banks, and considering the commenter's proposal that utilizing the minimum threshold should be at the foreign bank's discretion due to the potential burden of added compliance costs, FinCEN has determined that it will not set a minimum threshold for reporting on transfers of funds. In addition, for these same reasons, FinCEN will not set a minimum threshold for reporting on correspondent accounts. This rule calls for reports on all correspondent accounts with Iranian-linked financial institutions designated under IEEPA regardless of the volume of transactions conducted through the correspondent accounts.

E. The Timeframe for a Foreign Bank and a U.S. Bank To Respond to a CISADA Request

In the Notice, FinCEN proposed that a bank would be required to report the information required by this rule to FinCEN within 30 calendar days of the date of the written request from FinCEN. In addition, FinCEN proposed that if a bank receives notification from a foreign bank that the foreign bank has established a new correspondent account for an Iranian-linked financial institution designated under IEEPA, the bank is required to report the information required by this rule within 10 calendar days of receiving that notification. FinCEN requested comment as to whether these proposed timeframes were appropriate.

Four commenters contended that 30 calendar days to report the information required by this rule to FinCEN is not sufficient. Three of these commenters proposed that the timeframe be extended to 90 calendar days. Two of these commenters asserted that it will take a foreign bank time to research whether it maintains a correspondent account or has processed transfers of funds in the previous 90 calendar days for the relevant designated entities and individuals. Two of these commenters asserted that foreign banks' responses may be subject to legal review by local regulators prior to submission to the bank. One of these commenters suggested that a bank will have to do some level of due diligence to ''certify'' that it does not know that the foreign bank's certification is incorrect. Another one of these commenters asserted that it would be unfortunate if a U.S. bank had to report to FinCEN that a foreign bank has not replied in time, specifically in instances in which the foreign bank is making efforts to do so, as this could cast a bad and perhaps false light on the foreign bank. Another commenter suggested that a 30-day timeframe to respond will likely produce a significant number of ''no response'' reports to FinCEN.

FinCEN has taken these comments into consideration. For this reason, FinCEN is revising the timeframe to respond to 45 calendar days from the date of the written request from FinCEN. FinCEN acknowledges the concerns raised by the commenters; however, these requests are time-sensitive by nature and extending the timeframe for a response to 90 days is not feasible. In addition, as noted elsewhere in this rulemaking, a U.S. bank is not expected to independently verify the information provided by a foreign bank. This should lessen the amount of time necessary for a U.S. bank to review a foreign bank's response prior to submission to FinCEN.

FinCEN does recognize the possibility that there may be certain situations in which additional time for a foreign bank to respond is needed. For this reason, we are amending the final rule to require that if a U.S. bank receives a certification from a foreign bank after the 45 calendar day deadline, the U.S. bank is required to report that information to FinCEN within 10 calendar days of receiving that certification. This additional obligation does not relieve the U.S. bank of its obligation to report to FinCEN within 45

[12] It is important to note that the list is dynamic and should be referenced regularly to ensure the most up-to-date information.

[13] *See* 31 CFR 561.404 for interpretations of ''significant transaction or transactions.''

calendar days the results of the U.S. bank's inquiry, regardless of whether the foreign bank has responded.

One commenter suggested that a bank should be given 30 days to respond to FinCEN upon receiving a notification from a foreign bank that it has opened a new account with an Iranian-linked financial institution designated under IEEPA. As has been clarified elsewhere in this rulemaking, a U.S. bank is not expected to independently verify the information provided by a foreign bank. For this reason, FinCEN believes that if a bank receives notification from a foreign bank that the foreign bank has established a new correspondent account for an Iranian-linked financial institution designated under IEEPA, the bank will have sufficient time to report the information required by this rule within 10 calendar days of receiving that notification.

F. Clarification Regarding the Proposed Model Certification

FinCEN requested comment as to the effectiveness of the proposed model certification. One commenter noted that under the proposed rule, the person signing on behalf of the U.S. bank would be required to state that he has read and understood the foreign bank's certification, that the statements made are complete and correct, and that the U.S. bank does not know or suspect, or have reason to suspect that the foreign bank's certification is incorrect. The commenter suggested that a statement that the foreign bank's response is complete and correct would require the certifying U.S. officer to have intimate knowledge of the foreign bank's customers and activities, something that the U.S. bank will never have. The commenter also suggested that the terminology ''know, suspect, and reason to suspect'' raises questions about the level of due diligence a U.S. bank is expected to perform under the proposed rule.

Another commenter noted that section 1060.300(c)(1)(v) requires that the reporting U.S. bank identify any specified foreign bank for which the inquiring U.S. bank ''has not been able to establish to its satisfaction'' does not engage in the listed activities and, further, certify to FinCEN that it does not ''know[], suspect[], or ha[ve] reason to suspect'' that any certification provided by the foreign bank is incorrect. With these few words, the commenter suggested, the proposed rule would appear to shift the burden on the inquiring bank from simply acting as a conduit for FinCEN's inquiries to independently investigating and evaluating the truthfulness of the foreign bank's response.

Another commenter noted that a U.S. bank has no ability to verify the information reported by a foreign bank. The commenter recommended that the final rule acknowledge that the only obligation of the U.S. bank is to request the data and pass along the information it receives as received. An additional commenter expressed similar concerns.

FinCEN clarifies that our expectation with regard to knowledge is only knowledge a U.S. bank would have based on the monitoring it already conducts to comply with OFAC requirements and BSA requirements regarding due diligence over foreign correspondent accounts. We also clarify that we do not expect a U.S. bank to independently verify the information provided by a foreign bank. However, we do expect a bank to report if it has information that is inconsistent with the foreign bank's certification. An example of a situation in which information is inconsistent with the certification might involve a scenario where a U.S. bank's transaction monitoring software recently blocked a transaction on behalf of a certain foreign bank, but that foreign bank does not include such transaction in the report provided to the U.S. bank.

To reflect these clarifications in the final rule more clearly, FinCEN has decided to make revisions to section 1060.300(c)(1)(v) and to the portion of the model certification to be completed by the bank. These revisions directly address the recommendations offered by these commenters.

FinCEN is revising the language in section 1060.300(c)(1)(v) of the final rule to clarify our expectations with regard to the U.S. bank's responsibilities as they relate to the information reported by a foreign bank. Section 1060.300(c)(1)(v) proposed that a bank report to FinCEN the following information regarding a specified foreign bank: The name of any specified foreign bank, for which the bank maintains a correspondent account, *about which the bank has not been able to establish to its satisfaction that the foreign bank* does not maintain a correspondent account for an Iranian-linked financial institution designated under IEEPA, has not processed one or more transfers of funds within the preceding 90 calendar days related to an Iranian-linked financial institution designated under IEEPA, other than through a correspondent account, and/or has not processed one or more transfers of funds within the preceding 90 calendar days related to an IRGC-linked person designated under IEEPA, together with the reason(s) for this, such as the failure of the foreign bank to respond to the inquiry by or a request from the bank, the failure of the foreign bank to certify its response, *or if the bank knows, suspects, or has reason to suspect that the certification is incorrect.''* [Emphasis added.]

FinCEN is amending section 1060.300(c)(1)(v) by revising the phrase ''about which the bank has not been able to establish to its satisfaction that the foreign bank'' to read as follows: ''that the bank cannot determine;'' and revising the phrase ''or if the bank knows, suspects, or has reason to suspect that the certification is incorrect'' to read as follows: ''or if the bank has information that is inconsistent with the certification.''

In addition, FinCEN is also revising the corresponding portion of the model certification to be completed by the bank. The proposed language in the model certification stated as follows: ''I, _____ (name of signatory), have read and understand this Certification; the statements made in this Certification are complete and correct, to the best of the knowledge of the Bank; and the Bank does not know, suspect, or have reason to suspect that the Certification made by Foreign Bank is incorrect. I am authorized to submit this document on behalf of the Bank.''

In the final rule, FinCEN is revising the portion of the model certification to be completed by the bank to read as follows: ''I, _____ (name of signatory), have received and reviewed this Certification. To the best of its knowledge, the Bank has no information that is inconsistent with the Certification made by Foreign Bank. I am authorized to submit this document on behalf of the Bank.''

This revision is consistent with the revisions made to section 1060.300(c)(1)(v). FinCEN believes that this revision to the model certification, together with the amendments to section 1060.300(c)(1)(v) discussed above, will alleviate the concerns raised by commenters and more accurately describe FinCEN's expectations with regard to the U.S. bank's obligations as they relate to information received from a foreign bank.

Furthermore, as requested by three commenters, FinCEN clarifies that the individual signing the model certification is only signing on behalf of the relevant bank in his capacity as a duly authorized officer of the bank and not in his personal capacity. As noted in the language in the model certification, the individual signing on behalf of the bank is submitting the ''document on behalf of the Bank.''

Similarly, as requested by one commenter, FinCEN clarifies that the individual signing the model certification is only signing on behalf of the relevant foreign bank in his capacity as a duly authorized officer of the foreign bank and not in his personal capacity. As noted in the language in the model certification, the individual signing on behalf of the foreign bank is ''authorized to execute this certification on behalf of Foreign Bank.''

One commenter requested that FinCEN clarify how foreign banks should convert foreign currency as it relates to the foreign banks' reporting on the approximate value of transactions processed through a correspondent account or transfer(s) of funds processed within the preceding 90 calendar days. FinCEN will not prescribe any specific method or reference rate for the conversion of foreign exchange, but rather leaves it to the foreign bank to convert the sums using a reasonable rate informed by good banking practices. The purpose of this conversion is to help in assessing the significance of the transaction(s) at issue. Examples of reasonable rates may include the rate that the foreign bank would have applied to convert the respective payment into U.S. dollars on the date of the transaction, or, in the case of aggregation of multiple transactions over a time period, the average exchange rate over the applicable time period.

One commenter asserted that while the proposed model certification includes links to websites with information about relevant designated entities and individuals, the commenter believes that the process of responding would be simpler and produce better information if requests to foreign banks also included a list of relevant designated entities and individuals covered by that particular request. The model certification includes a link to the list of relevant designated entities and individuals exclusively applicable to this reporting requirement. FinCEN believes that providing access to this link is sufficient to assist foreign banks in clearly identifying the designated entities and individuals relevant to a request.

As requested by one commenter, FinCEN will consider evaluating the adequacy of the model certification in 12 to 18 months in order to determine if revisions are necessary.

G. Clarification Regarding Certain Definitions and Terms

Refer to Section V.A., below, for clarification regarding the terms bank, correspondent account, and foreign bank.

H. Record Retention and Supporting Documentation

One commenter requested clarification regarding a number of aspects of the record retention requirement, including the record retention period and supporting documentation to be maintained as part of the record retention. The commenter requested that the record retention period be reduced from five years. FinCEN clarifies that the record retention period for this rulemaking will remain five years consistent with FinCEN's other record retention requirements. FinCEN also clarifies that this specific recordkeeping requirement does not serve to change any other applicable recordkeeping requirements. The record retention period will begin on the date the request from FinCEN is issued. If the bank receives notification from a foreign bank that the foreign bank has established a new correspondent account with an Iranian-linked financial institution designated under IEEPA at any time within 365 calendar days from the date of the foreign bank's initial response, this will not affect the beginning of the record retention period. The record retention period with regard to that specific foreign bank will still begin on the date the request from FinCEN was issued.

FinCEN clarifies that supporting documentation related to this rulemaking includes any and all correspondence between the bank and FinCEN, or between the bank and the foreign bank, regarding a request for information under this rulemaking. For example, this would include the initial request from FinCEN to the bank, the request from the bank to the foreign bank, the response from the foreign bank to the bank, the report to FinCEN from the bank, and any correspondence associated with any one of these requests/reports. FinCEN also clarifies that although we will maintain a copy of the report the bank submits to FinCEN, the bank must also maintain a copy of that report in order to confirm compliance with this regulation.

I. Sharing Information Regarding a CISADA Request

One of the commenters questioned in what instances it would be appropriate for a bank to inform others internally or externally that it has received a request from FinCEN regarding a specific foreign bank. To the extent that FinCEN would require a request regarding a specific foreign bank remain confidential, we will explicitly state the requirement for confidentiality in the request sent to the bank.

J. Estimate of Burden

Refer to Section IX., below, for a summary of comments regarding the burden estimates.

V. Section-by-Section Analysis

A. General (§ 1060.300(a))

As proposed, section 31 CFR 1060.300(a) requires that, upon receiving a written request from FinCEN, a bank that maintains a correspondent account for a specified foreign bank shall inquire of the foreign bank, and report to FinCEN with respect to any correspondent account maintained by such foreign bank for an Iranian-linked financial institution designated under IEEPA, any transfer of funds for or on behalf of, directly or indirectly, an Iranian-linked financial institution designated under IEEPA processed by such foreign bank within the preceding 90 calendar days, other than through a correspondent account, and any transfer of funds for or on behalf of, directly or indirectly, an IRGC-linked person designated under IEEPA processed by such foreign bank within the preceding 90 calendar days.

The language in this section of the final rule is substantially the same as proposed. However, for purposes of providing additional clarity as requested by commenters, FinCEN modified the final rule language in the following ways: the phrase ''to the best of the knowledge of the bank'' was removed, consistent with revisions to section 1060.300(c)(1)(v); [14] and ''for or on behalf of, directly or indirectly,'' replaced ''related to.'' [15]

Definitions

Bank

For the purpose of this rule the term ''bank'' is defined in 31 CFR 1010.100(d). A bank includes each agent, agency, branch, or office within the United States of persons doing business in one or more of the following capacities: commercial banks or trust companies, private banks, savings and loan associations, national banks, thrift institutions, credit unions, other organizations chartered under banking laws and supervised by banking supervisors of any State, and banks organized under foreign law.

FinCEN proposed to limit the reporting requirement in this rulemaking to banks, as opposed to all U.S. financial institutions that could fall

[14] *See above* Section IV. F. for the rationale for the revisions to section 1060.300(c)(1)(v).

[15] *See above* Section IV. D. for the rationale for replacing the terminology ''related to'' with ''for or on behalf of, directly, or indirectly.''

within the scope of this rule. FinCEN requested comment as to whether this rulemaking should be expanded to include other types of financial institutions, such as those financial institutions included in FinCEN's definition of ''covered financial institution.'' [16]

Two commenters requested clarification as to why FinCEN proposed to limit this reporting requirement to banks instead of the broader category of U.S. financial institutions as would be permissible under CISADA. One of these commenters also requested clarification as to how FinCEN would determine whether to expand the reporting requirement to other domestic financial institutions.

As explained in the Notice, FinCEN determined that limiting the reporting requirement in this rule to banks will provide useful information as it relates to CISADA, while limiting the obligations of the financial industry. Although there are other financial institutions that could fall within the scope of this rule in light of the breadth of the definition of financial institution in CISADA and the breadth of the definition of correspondent account, this rule focuses on those financial institutions deemed to provide the services most traditionally associated with correspondent banking.

Two trade associations commented on this aspect of the rulemaking. These commenters were in favor of limiting the rulemaking to banks, in order to avoid redundancy and overlapping information. FinCEN did not receive any comments that provided justification for expanding this reporting requirement to include other domestic financial institutions. Based on the comments received, and FinCEN's prior statements regarding the scope of affected U.S. financial institutions, the reporting requirements in the final rule will be limited to banks as proposed.

As FinCEN collects and assesses the information required under this rule, we will continue to consider whether expanding the scope of this rule to include other domestic financial institutions would provide additional useful information as it relates to CISADA. If that is determined to be the case, FinCEN will consider proposing an expansion of this reporting requirement to include other domestic financial institutions.

One commenter requested clarification that the rule will only apply to depository institutions and not to non-depository institutions, even if the two may be within the same bank holding company structure. Another commenter requested clarification regarding whether this rule would apply to U.S. branches of foreign banks. FinCEN clarifies that this rule will only apply to banks as defined in 31 CFR 1010.100(d), and will not apply to any other type of non-bank financial institution that may fall within the same bank holding company structure. In addition, U.S. branches of foreign banks are included within the definition of ''bank'' in 31 CFR 1010.100(d).

Correspondent Account

For the purpose of this rule, the term ''correspondent account'' is defined in 31 CFR 1010.605(c)(1)(ii) and means an account established for a foreign bank to receive deposits from, or to make payments or other disbursements on behalf of, the foreign bank, or to handle other financial transactions related to such foreign bank.[17] Although there is a reference in section 104(e) of CISADA to payable-through accounts, as FinCEN is incorporating this requirement into its regulations, such payable-through accounts are subsumed within the definition of a correspondent account at 31 CFR 1010.610(b)(1)(iii)(B).[18] The definition of correspondent account is being adopted in the final rule as proposed.

Three commenters requested clarification regarding the scope of accounts that are included within the breadth of the definition of the term correspondent account. The definition of correspondent account that is included within this rule is the same definition of correspondent account as in 31 CFR 1010.610—Due diligence programs for correspondent accounts for foreign financial institutions. The same scope of accounts included within the requirements of 31 CFR 1010.610 are included within the requirements of this rulemaking, except that the term only applies to such accounts maintained by any bank for any foreign bank.

Foreign Bank

For the purpose of this rulemaking the term ''foreign bank'' is defined in 31 CFR 1010.100(u) and means a bank organized under foreign law, or an agency, branch, or office located outside the United States of a bank. The term does not include an agent, agency, branch, or office within the United States of a bank organized under foreign law.

FinCEN proposed to limit the reporting requirement in this rulemaking to information pertaining to the activities of foreign banks, as opposed to the activities of all foreign financial institutions that could fall within the scope of this rule. FinCEN requested comment as to whether this rulemaking should be expanded to include information pertaining to the activities of other types of foreign financial institutions, such as those included in FinCEN's definition of ''foreign financial institution,'' [19] or OFAC's definition of ''foreign financial institution'' [20] in the IFSR.

As explained in the Notice, FinCEN has determined that limiting the reporting requirement in this rule to information pertaining to the activities of foreign banks will provide useful information as it relates to CISADA, while limiting the obligations of the financial industry. Although there are other foreign financial institutions that maintain correspondent accounts with U.S. financial institutions that could provide useful information with respect to CISADA-relevant activities, this rule focuses on those foreign financial institutions deemed to receive the services most traditionally associated with correspondent banking.

Two trade associations commented on this aspect of the rule. The commenters asserted that limiting the scope of the rule to inquiries regarding foreign banks was appropriate. FinCEN did not receive any comments that provided justification for expanding this reporting requirement to include information pertaining to the activities of other foreign financial institutions. Based on the comments received, and FinCEN's prior statements regarding the scope of affected foreign financial institutions, the reporting requirements in the final rule will be limited to foreign banks as proposed.

As FinCEN collects and assesses the information required under this rule, we will continue to consider whether expanding the scope of this rule to include information pertaining to the activities of other foreign financial institutions would provide additional useful information as it relates to CISADA. If that is determined to be the

[16] *See* 31 CFR 1010.605(e) (defining a ''covered financial institution'' as any one of a number of specific U.S. financial institutions, including banks, broker-dealers, futures commission merchants, and mutual funds).

[17] This definition of correspondent account is consistent with the rule's focus on U.S. banks' correspondent account relationships with foreign banks.

[18] 31 CFR 1010.610(b)(1)(iii)(B) states ''* * * a payable-through account means a correspondent account maintained by a covered financial institution for a foreign bank by means of which the foreign bank permits its customers to engage, either directly or through a subaccount, in banking activities usual in connection with the business of banking in the United States.''

[19] *See* 31 CFR 1010.605(f).

[20] *See* 31 CFR 561.308.

case, FinCEN will consider proposing an expansion of this reporting requirement to include information pertaining to the activities of other foreign financial institutions.

One commenter asked that FinCEN clarify that the definition of foreign bank excludes U.S. representative offices of foreign banks. The commenter also asked for clarification regarding whether subsidiaries or branches of a single bank operating in different countries are one foreign bank or separate foreign banks for the purpose of a CISADA request. For purposes of this rulemaking, U.S. representative offices are not included within our definition of foreign bank at 31 CFR 1010.100(u), which excludes offices within the United States of a bank organized under foreign law. Although representative offices cannot offer banking services in the United States, they nevertheless are offices of banks organized under foreign law, and therefore are not foreign banks for purposes of the BSA rules. FinCEN will only be sending requests to banks that it knows or believes maintain a correspondent account for the specific foreign bank, specific foreign bank branch, or specific foreign bank subsidiary at issue. This means that the extent of the inquiry will be specific to the correspondent account about which a request is made. In the case of a foreign bank subsidiary, FinCEN would only be requesting information regarding a foreign bank subsidiary if that subsidiary is itself a foreign bank.

Iranian-Linked Financial Institution Designated Under IEEPA

For the purpose of this rule the term ''Iranian-linked financial institution designated under IEEPA'' means a financial institution designated by the United States Government pursuant to IEEPA (or listed in an annex to an Executive order issued pursuant to such Act) in connection with Iran's proliferation of weapons of mass destruction or delivery systems for weapons of mass destruction, or in connection with Iran's support for international terrorism.[21] The definition of ''Iranian-linked financial institution designated under IEEPA'' is being adopted in the final rule as proposed.

IRGC–Linked Person Designated Under IEEPA

For the purpose of this rule the term ''IRGC-linked person designated under IEEPA'' means Iran's Islamic Revolutionary Guard Corps or any of its agents or affiliates designated by the United States Government pursuant to IEEPA (or listed in an annex to an Executive order issued pursuant to such Act).[22] The definition of ''IRGC-linked person designated under IEEPA'' is being adopted in the final rule as proposed.

The names of persons whose property and interests in property are blocked pursuant to IEEPA are published on OFAC's Specially Designated Nationals and Blocked Persons List (''SDN List''). Iranian-linked financial institutions designated under IEEPA are those whose property and interests in property are blocked pursuant to 31 CFR part 544 or 31 CFR part 594 in connection with Iran's proliferation of weapons of mass destruction or delivery systems for weapons of mass destruction or Iran's support for international terrorism and are identified by ''[IFSR]'' tags located at the end of their entries on the SDN List (*e.g.,* [NPWMD][IFSR] or [SDGT][IFSR]). IRGC-linked persons designated under IEEPA are those whose property and interests in property are blocked pursuant to one or more parts of 31 CFR Chapter V and are identified by ''[IRGC]'' tags located at the end of their entries on the SDN List (*e.g.,* [NPWD][IRGC] or [SDGT][IRGC]). OFAC's electronic SDN List can be found at the following URL: *http://www.treasury.gov/resource-center/sanctions/SDN–List/Pages/default.aspx.* The following financial institutions meet the criteria of Iranian-linked financial institutions designated under IEEPA ([IFSR] tags), and the following persons meet the criteria of IRGC-linked persons designated under IEEPA ([IRGC] tags): *http://www.treasury.gov/resource-center/sanctions/Programs/Documents/irgc_ifsr.pdf.* These listings are part of the SDN List, administered by OFAC. Please note that OFAC's SDN List is dynamic and should be reviewed regularly for the most current information regarding Iranian-linked financial institutions designated under IEEPA and IRGC-linked persons designated under IEEPA.

B. Duty To Inquire (§ 1060.300(b))

This section describes a bank's duty to inquire of a specified foreign bank for which the bank maintains a correspondent account, as to whether such foreign bank maintains a correspondent account for an Iranian-linked financial institution designated under IEEPA, and/or has processed one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an Iranian-linked financial institution or an IRGC-linked person designated under IEEPA. Upon receiving a written request from FinCEN, a bank that maintains a correspondent account for a specified foreign bank shall inquire of such foreign bank for the purpose of having such foreign bank certify: (1) Whether it maintains a correspondent account for an Iranian-linked financial institution designated under IEEPA; (2) whether it has processed one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an Iranian-linked financial institution designated under IEEPA, other than through a correspondent account; and (3) whether it has processed one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an IRGC-linked person designated under IEEPA. In addition, when the bank makes its inquiry, the bank shall request that the foreign bank agree to notify the bank if the foreign bank subsequently establishes a new correspondent account for an Iranian-linked financial institution designated under IEEPA at any time within 365 calendar days from the date of the foreign bank's initial response.

The language in this section of the final rule is substantially the same as proposed. However, for purposes of providing additional clarity as requested by commenters, FinCEN modified the final rule language in the following way: ''for or on behalf of, directly or indirectly,'' replaced ''related to.''[23]

To assist a bank in obtaining the required information from a specified foreign bank, FinCEN proposed a model certification format for a bank to provide to a specified foreign bank when the bank makes its inquiry regarding whether the specified foreign bank maintains a correspondent account for an Iranian-linked financial institution designated under IEEPA, and/or has processed one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an Iranian-linked financial institution or an IRGC-linked person designated under IEEPA. The model certification will not appear in the Code of Federal Regulations (''CFR''); however, it is included at Appendix A to this **Federal Register** notice. While the model certification will not be included in the CFR, it is still subject to the Paperwork Reduction Act (''PRA''), and therefore any material changes made to the model certification will go through public notice and comment as required under

[21] *See* CISADA subsection 104(c)(2)(E)(ii).

[22] *See* CISADA subsection 104(c)(2)(E)(i).

[23] *See above* Section IV. D. for the rationale for replacing the terminology ''related to'' with ''for or on behalf of, directly or indirectly.''

the PRA. In addition, FinCEN will use its website to make the model certification available to the public. FinCEN requested comment as to the effectiveness of the proposed model certification.[24]

As part of the model certification, the foreign bank is asked to agree to notify, in writing, the bank at which it maintains a correspondent account if the foreign bank establishes a new correspondent account for an Iranian-linked financial institution designated under IEEPA at any time within 365 calendar days from the date of the foreign bank's response. The model certification sets forth the expectation that the notification shall be due to the bank within 30 calendar days of the establishment of the new correspondent account. If a bank does not utilize the model certification, the bank will need to request separately that the foreign bank provide such information with respect to the establishment of a new correspondent account for an Iranian-linked financial institution designated under IEEPA.

C. Filing Procedures (§ 1060.300(c))

What To File (§ 1060.300(c)(1))

This section describes the filing procedures a bank shall follow to report to FinCEN information required by this rule. Upon receiving a written request from FinCEN, a bank is required to report to FinCEN, in such format and manner as may be prescribed by FinCEN, the following information for any specified foreign bank:

- The name of any specified foreign bank, for which the bank maintains a correspondent account, that certifies that it maintains a correspondent account for an Iranian-linked financial institution designated under IEEPA, together with the name of the Iranian-linked financial institution designated under IEEPA, the full name(s) on the correspondent account and the correspondent account number(s), applicable information regarding whether the correspondent account has been blocked or otherwise restricted, other applicable identifying information for the correspondent account, and the approximate value in U.S. dollars (''USD'') of transactions processed through the correspondent account within the preceding 90 calendar days;
- The name of any specified foreign bank, for which the bank maintains a correspondent account, that certifies that it has processed one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an Iranian-linked financial institution designated under IEEPA, other than through a correspondent account, together with the name of the Iranian-linked financial institution designated under IEEPA, the identity of the system or means by which such transfer(s) of funds was processed, the full name on the account(s) and the account number(s), if applicable, other applicable identifying information for such transfer(s) of funds, and the approximate value in USD of such transfer(s) of funds processed within the preceding 90 calendar days;
- The name of any specified foreign bank, for which the bank maintains a correspondent account, that certifies that it has processed one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an IRGC-linked person designated under IEEPA, together with the name of the IRGC-linked person designated under IEEPA, the identity of the system or means by which such transfer(s) of funds was processed, the full name on the account(s) and the account number(s), if applicable, other applicable identifying information for such transfer(s) of funds, and the approximate value in USD of such transfer(s) of funds processed within the preceding 90 calendar days;
- The name of any specified foreign bank, for which the bank maintains a correspondent account, that certifies that it does not maintain a correspondent account for an Iranian-linked financial institution designated under IEEPA, that certifies that to its knowledge it has not processed one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an Iranian-linked financial institution designated under IEEPA, other than through a correspondent account, and/or that certifies that to its knowledge it has not processed one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an IRGC-linked person designated under IEEPA;
- The name of any specified foreign bank, for which the bank maintains a correspondent account, that the bank cannot determine does not maintain a correspondent account for an Iranian-linked financial institution designated under IEEPA, has not processed one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an Iranian-linked financial institution designated under IEEPA, other than through a correspondent account, and/or has not processed one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an IRGC-linked person designated under IEEPA, together with the reason(s) for this, such as the failure of the foreign bank to respond to the inquiry by or a request from the bank, the failure of the foreign bank to certify its response, or if the bank has information that is inconsistent with the certification;
- The name of any specified foreign bank, for which the bank maintains a correspondent account, that notifies the bank that it has established a new correspondent account for an Iranian-linked financial institution designated under IEEPA at any time within 365 calendar days from the date of the foreign bank's initial response, together with the name of the Iranian-linked financial institution designated under IEEPA, the full name(s) on the correspondent account and the correspondent account number(s), applicable information regarding whether the correspondent account has been blocked or otherwise restricted, and other applicable identifying information for the correspondent account;
- If applicable, confirmation that the bank does not maintain a correspondent account for the specified foreign bank(s), but only in instances in which FinCEN specifically requests that the bank report such information; and
- If applicable, the name of any specified foreign bank, for which the bank maintains a correspondent account, that provides a certification to the bank after the 45 calendar day deadline, along with all applicable related information associated with that certification.

The language in this section of the final rule is substantially the same as proposed. However, for purposes of providing additional clarity as requested by commenters, FinCEN modified the final rule language in the following ways: ''for or on behalf of, directly or indirectly,'' replaced ''related to;''[25] ''that the bank cannot determine'' replaced ''about which the bank has not been able to establish to its satisfaction that the foreign bank;'' and '' if the bank has information that is inconsistent with the certification'' replaced ''if the bank knows, suspects, or has reason to suspect that the certification is incorrect.''[26]

[24] *See above* Section IV. F. for a summary of comments associated with the model certification, along with an explanation of slight revisions to the language in the final model certification.

[25] *See above* Section IV. D. for the rationale for replacing the terminology ''related to'' with ''for or on behalf of, directly or indirectly.''

[26] *See above* Section IV. F. for the rationale for replacing the terminology ''about which the bank

Continued

FinCEN also incorporated the phrase ''to its knowledge'' into the reporting requirement that upon receiving a written request from FinCEN, a bank shall report to FinCEN, in such format and manner as may be prescribed by FinCEN, the following information for any specified foreign bank the name of any specified foreign bank, for which the bank maintains a correspondent account, that certifies that it does not maintain a correspondent account for an Iranian-linked financial institution designated under IEEPA, that certifies that *to its knowledge* it has not processed one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an Iranian-linked financial institution designated under IEEPA, other than through a correspondent account, and/or that certifies that *to its knowledge* it has not processed one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an IRGC-linked person designated under IEEPA.'' [27] [Emphasis added.]

In addition, FinCEN added the following reporting requirement in the final rule in order to provide additional clarity as requested by commenters: Upon receiving a written request from FinCEN, a bank shall report to FinCEN, in such format and manner as may be prescribed by FinCEN, the following information for any specified foreign bank, if applicable, the name of any specified foreign bank, for which the bank maintains a correspondent account, that provides a certification to the bank after the 45-calendar-day deadline, along with all applicable related information associated with that certification.'' [28]

If a bank utilizes the model certification to inquire of a specified foreign bank, the bank can submit the certification from the specified foreign bank to FinCEN in order to comply with this reporting requirement. If a bank does not utilize the model certification to inquire of a specified foreign bank, the bank shall report to FinCEN, in such format and manner as may be prescribed by FinCEN, the information required by this rule.

If a specified foreign bank, for which the bank maintains a correspondent account, does not adequately respond to the bank's inquiry, the bank shall report to FinCEN, in such format and manner as may be prescribed by FinCEN, the information required by this rule. If a bank receives a notification from a specified foreign bank regarding the establishment of a new correspondent account for an Iranian-linked financial institution designated under IEEPA, the bank shall report to FinCEN, in such format and manner as may be prescribed by FinCEN, the information required by this rule. If a bank receives a certification from a specified foreign bank after the 45-calendar-day deadline, the bank shall report to FinCEN, in such format and manner as may be prescribed by FinCEN, the information required by this rule.

If a bank receives a written request from FinCEN regarding a specified foreign bank, for which the bank does not maintain a correspondent account, and FinCEN has specifically requested that the bank report instances in which the bank does not maintain a correspondent account for such specified foreign bank, the bank shall report this information to FinCEN, in such format and manner as may be prescribed by FinCEN.

When To File (§ 1060.300(c)(2))

A bank is required to report the information required by this rule to FinCEN within 45 calendar days of the date of the written request from FinCEN. If a bank receives notification from a foreign bank that the foreign bank has established a new correspondent account for an Iranian-linked financial institution designated under IEEPA, the bank is required to report the information required by this rule within 10 calendar days of receiving that notification. If a bank receives a certification from a foreign bank after the 45-calendar-day deadline, the bank is required to report the information required by this rule within 10 calendar days of receiving that certification.

The language in this section of the final rule is substantially the same as proposed. However, for purposes of providing relief as requested by commenters, FinCEN modified the final rule language in the following way: 45 calendar days replaced 30 calendar days.[29]

In addition, FinCEN added a 10-calendar-day deadline for a bank to report if it receives a certification from a foreign bank after the 45-calendar-day deadline. This corresponds with the following reporting requirement added to the final rule: Upon receiving a written request from FinCEN, a bank shall report to FinCEN, in such format and manner as may be prescribed by FinCEN, the following information for any specified foreign bank, if applicable, the name of any specified foreign bank, for which the bank maintains a correspondent account, that provides a certification to the bank after the 45-calendar-day deadline, along with all applicable related information associated with that certification.'' [30]

D. Record Retention (§ 1060.300(d))

This section describes the recordkeeping requirements applicable to this rule. A bank shall maintain for a period of five years a copy of any report filed and the original or any business record equivalent of any supporting documentation for a report, including a foreign bank certification or other responses to an inquiry under this rule. This section of the final rule is being adopted as proposed.

E. No Other Action Required (§ 1060.300(e))

Paragraph (e) states that ''[n]othing in this section shall be construed to require a bank to take any action, or to decline to take any action, other than the requirements identified in this section, with respect to an account established for, or a transaction engaged in with, a foreign bank. However, nothing in this section relieves a bank of any other applicable regulatory obligation.'' While this paragraph clarifies that the section does not require a bank to take any steps with respect to the foreign bank other than those relating to the collection of information outlined in this section, it also clarifies that this section does not preclude a bank from taking any other action, including restricting or terminating a correspondent account relationship with a foreign bank, or filing a suspicious activity report, based on the bank's assessment of the facts and bank policy. However, a bank is not required to restrict or terminate a correspondent account relationship with a foreign bank, or to file a suspicious activity report, based solely upon the fact that the bank: (i) Has received a request for information under

has not been able to establish to its satisfaction that the foreign bank'' with ''that the bank cannot determine;'' and for the rationale for replacing the terminology ''if the bank knows, suspects, or has reason to suspect that the certification is incorrect'' with ''if the bank has information that is inconsistent with the certification.''

[27] *See* section 1060.300(c)(1)(iv). *Also see above* Section IV. D. for the rationale for incorporating the phrase ''to its knowledge'' into this reporting requirement.

[28] *See* section 1060.300(c)(1)(viii). *Also see above* Section IV. E. for the rationale for implementing this additional reporting requirement.

[29] *See above* Section IV. E. for the rationale for the extension of time to comply with this reporting requirement.

[30] *See* section 1060.300(c)(1)(viii). *Also see above* Section IV. E. for the rationale for implementing this additional reporting requirement, along with the rationale for the corresponding timeframe for reporting.

this regulation; (ii) has received a response from the foreign bank; or (iii) has not received a response from the foreign bank. This section of the final rule is being adopted as proposed.

VI. Executive Order 12866

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. It has been determined that the final rule is 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.

VII. Unfunded Mandates Reform Act of 1995 Statement

Section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), Public Law 104–4 (March 22, 1995), requires that an agency prepare a budgetary impact statement before promulgating a rule that may result in expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. If a budgetary impact statement is required, section 205 of the Unfunded Mandates Act also requires an agency to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. FinCEN has determined that it is not required to prepare a written statement under section 202.

VIII. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (''RFA'') (5 U.S.C. 601 *et seq.*), FinCEN certifies that this final rule will not have a significant economic impact on a substantial number of small entities. The final rule will apply to banks that maintain correspondent accounts for foreign banks. As previously stated in our final rules implementing sections 312,[31] 313,[32] and 319(b)[33] of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001, Public Law 107–56, most banks that maintain correspondent accounts for foreign banks tend to be large banks. We expect that small banks will be less likely to maintain correspondent accounts for foreign banks. In most cases, small banks utilize their domestic correspondent accounts with large banks to conduct transactions with foreign banks.

FinCEN invited comment on the impact of this proposal on small entities. One commenter suggested that FinCEN provided no data to support the conclusion that the regulation would not have a significant economic impact on a substantial number of small entities. However, no other commenters expressed concern that this rule would have a significant economic impact on a substantial number of small entities. The rule applies to banks that maintain correspondent accounts for foreign banks. As stated above, and in our previous rules regarding foreign correspondent accounts, we believe most banks that maintain correspondent accounts for foreign banks are large banks. In addition, as noted elsewhere in this rulemaking, FinCEN estimates that approximately 350 banks maintain correspondent accounts for foreign banks. FinCEN further estimates that on average approximately five percent of banks that maintain correspondent accounts for foreign banks will have an account with any one specific foreign bank about which FinCEN is requesting information. Furthermore, as noted elsewhere in this rulemaking, a bank will only be required to comply with this reporting requirement upon receiving a specific written request from FinCEN. Therefore, a substantial number of small entities would not be affected. Accordingly, a regulatory flexibility analysis is not required.

IX. Paperwork Reduction Act

The collection of information contained in this rule has been approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) under control number 1506–0066. Under the Paperwork Reduction Act, an agency may not conduct or sponsor, and an individual is not required to respond to, a collection of information unless it displays a valid OMB control number.

Reporting Requirements Under Section 104(e) of CISADA

The collection of information in this rule is in 31 CFR 1060.300. The information may be transmitted to one or more departments or agencies of the United States of America for the purpose of fulfilling such departments' and agencies' governmental functions. The collection of information is mandatory. FinCEN is issuing this final rule that will require a bank to report to FinCEN, upon request, certain information regarding certain foreign banks specified by FinCEN.

Description of Affected Financial Institutions: Banks as defined in 31 CFR 1010.100(d).

Estimated Number of Affected Financial Institutions: 350 banks.

FinCEN estimates that approximately 350 banks maintain correspondent accounts for foreign banks.[34] However, FinCEN estimates that on average around five percent of banks that maintain correspondent accounts for foreign banks will have an account with any one specific foreign bank about which FinCEN is requesting information. This smaller proportion of actual affected financial institutions in each case of a request is based on the fact that foreign banks generally only hold a limited number of correspondent

[31] Anti-Money Laundering Programs; Special Due Diligence Programs for Certain Foreign Accounts, 71 FR 496 (Jan. 4, 2006).

[32] Anti-Money Laundering Requirements—Correspondent Accounts for Foreign Shell Banks; Recordkeeping and Termination of Correspondent Accounts for Foreign Banks, 67 FR 60562 (Sept. 26, 2002).

[33] *Id.*

[34] 177 banks reported a balance due as of September 30, 2010 in either line item 3.a. or 3.b. of Schedule RC–A—Cash and Balances Due From Depository Institutions on the Consolidated Reports of Condition and Income for a Bank with Domestic and Foreign Offices—FFIEC 031, or on the Consolidated Reports of Condition and Income for a Bank with Domestic Offices Only—FFIEC 041. Line item 3.a. represents balances due from foreign branches of other U.S. banks and line item 3.b. represents balances due from other banks in foreign countries and foreign central banks. As of September 30, 2010, 7,020 banks, regulated by either the Board of Governors of the Federal Reserve System, the Federal Deposit Insurance Corporation, or the Office of the Comptroller of the Currency, filed either FFIEC 031 or FFIEC 041. 177 of those 7,020 banks reported a balance due for a correspondent account for a foreign bank. These numbers do not include agents, agencies, branches, or offices within the U.S. of a bank organized under foreign law, which are also included within the definition of bank for purposes of this rulemaking. According to the Federal Reserve Board Structure Data for U.S. Banking Offices of Foreign Entities, there are approximately 214 U.S. Offices of Foreign Banking Organizations, as of September 30, 2010. *See http://www.federalreserve.gov/releases/iba/201009/bycntry.htm.* Of those 214 U.S. Offices of Foreign Banking Organizations, approximately 43 only operate in the U.S. as representative offices. *See http://www.federalreserve.gov/releases/iba/201009/bytype.htm.* Representative offices do not maintain correspondent accounts. For this reason, FinCEN is conservatively estimating that it is likely the remaining 171 U.S. Offices of Foreign Banking Organizations do maintain some form of correspondent account for a foreign bank. This results in a total estimate of 348 U.S. banks and foreign banks operating in the U.S. that maintain a correspondent account for a foreign bank.

account relationships with separate U.S. banks. For this reason, the estimated number of financial institutions that may maintain a correspondent account for any one specific foreign bank identified in any one request from FinCEN will be in the range of 18 banks. In order to further reduce the number of affected financial institutions, when possible, FinCEN will rely on information available to help limit the number of banks requested to provide information with respect to the foreign banks that are the subject of specific requests. In turn, FinCEN intends to send requests directly to banks that FinCEN, based on all available information, believes maintain correspondent accounts for the specified foreign bank(s). The number of banks that receive a request may vary in each specific case, based on the availability of information to FinCEN and other circumstances.

Estimated Average Annual Burden Hours per Affected Financial Institution: 31 hours per bank.

The scope of any request may be with respect to one foreign bank or a number of foreign banks (for example, a number of foreign banks operating in the same jurisdiction). FinCEN believes that regardless of the number of requests transmitted, such requests will pertain to approximately 50 foreign banks in any given year.

Financial Institutions That Maintain a Correspondent Account for a Specified Foreign Bank

A bank will only be required to comply with the requirements of this rule if the bank receives a written request from FinCEN. As noted above, FinCEN estimates that on average approximately five percent of the banks that maintain correspondent accounts for foreign banks, *i.e.,* approximately 18 banks, will maintain correspondent accounts for any one specific foreign bank about which FinCEN is requesting information. If FinCEN makes requests with respect to approximately 50 foreign banks per year and on average 18 banks are required to respond, per request, with regard to a correspondent account they maintain for any one specified foreign bank, there will be approximately 900 CISADA-related reports per year.

Each time a bank receives a request from FinCEN regarding a specific foreign bank for which it maintains a correspondent account, it will incur a reporting burden associated with section 1060.300(b) (inquiry); a reporting burden associated with section 1060.300(c) (reporting); and a recordkeeping burden associated with section 1060.300(d) (record retention).

The estimated average reporting burden associated with section 1060.300(b) for one request from FinCEN is one hour per responding U.S. bank with respect to each specific foreign bank about which FinCEN is requesting information. The estimated average reporting burden associated with section 1060.300(c) for one request from FinCEN is one hour per bank. The estimated average recordkeeping burden associated with section 1060.300(d) for one request from FinCEN is one hour per bank. This results in a total estimated average burden of three hours per bank with respect to each foreign bank about which FinCEN is requesting information. In the unlikely scenario in which the same bank were required to respond to FinCEN with respect to each foreign bank about which FinCEN is seeking information in any given year, the estimated annual burden hours would be 150. FinCEN believes that even with respect to the banks that are most active in the provision of correspondent accounts to foreign banks, they are likely to be required to respond to FinCEN with respect to one fifth of the foreign banks about which FinCEN is seeking information, which corresponds to roughly 30 burden hours per year based on the above calculations.

Financial Institutions That Do Not Maintain a Correspondent Account for a Specified Foreign Bank

In certain instances FinCEN may request that if a bank receives a written request from FinCEN regarding a specified foreign bank, and the bank does not maintain a correspondent account for such specified foreign bank, the bank report this information to FinCEN. As noted above, FinCEN intends to send requests to banks that FinCEN is aware have a correspondent account for a specified foreign bank as often as possible. In instances in which FinCEN is not aware of which banks maintain a correspondent account for a specified foreign bank, FinCEN may send requests to those banks FinCEN believes might have a correspondent account for a specified foreign bank.

In instances in which FinCEN is sending a request to a small number of banks that FinCEN believes might maintain a correspondent account for a specified foreign bank, FinCEN may request, in the written request sent to those banks, that the banks that do not maintain a correspondent account for the specified foreign bank report such information to FinCEN. FinCEN believes that we will rarely be sending a request to a large number of banks that we are not certain maintain a correspondent account for the specified foreign bank for which we are requesting information. In those rare cases, FinCEN would most likely not ask those banks to report if they do not maintain a correspondent account for such foreign bank. One commenter noted support for this element of the proposal. The commenter asserted that barring significant need, asking for a written negative confirmation should be unnecessary because banks are subject to extensive supervision and the banking agencies should be able to assess appropriate compliance.

FinCEN believes that the estimated average reporting burden for a bank to report to FinCEN that it does not maintain a correspondent account for the foreign bank specified in a request from FinCEN will be approximately 30 minutes per request. FinCEN also estimates that across the 50 requests FinCEN anticipates making annually, on average two to five banks will receive a request from FinCEN regarding a foreign bank for which they do not maintain a correspondent account, and for which FinCEN requests that they report such information. This means that approximately 250 banks will be required to report that they do not maintain a correspondent account for a foreign bank specified in a request from FinCEN in any given year. This also means that approximately 125 estimated annual burden hours will be expended each year. FinCEN also estimates that no single bank will receive a request from FinCEN more than two times per year regarding a specified foreign bank for which it does not maintain a correspondent account, and for which FinCEN requests that it report such information. This corresponds to roughly one estimated average annual burden hour per bank.

Estimated Total Annual Burden: 2825 total annual burden hours.

Approximately 900 CISADA-related reports anticipated each year (provided by a varying number of banks) multiplied by three burden hours per report. (2700 total annual burden hours). Approximately 250 reports from banks that do not maintain a correspondent account with a specified foreign bank (provided by a varying number of banks) multiplied by 30 minutes of burden per report. (125 total annual burden hours).

In the Notice, FinCEN specifically requested comment concerning the following:

(a) Whether the proposed collection of information is necessary for the proper performance of the functions of FinCEN,

including whether the information will have practical utility.

FinCEN received no specific comments regarding this request.

(b) The accuracy of the estimated burden associated with the proposed collection of information.

One commenter questioned the estimate that of the approximately 350 banks that maintain correspondent accounts for foreign banks, only five percent are likely to have an account affected by any single written request from FinCEN. The commenter contended that there is nothing provided to support the five percent estimate. As noted above, in order to reduce the number of affected financial institutions, when possible, FinCEN will rely on information available to help limit the number of banks requested to provide information with respect to the foreign banks that are the subject of specific requests. The number of banks that receive a request may vary in each specific case, based on the availability of information to FinCEN and other circumstances. This means that although FinCEN has the discretion to send a request to every U.S. bank that maintains a correspondent account for a specific foreign bank, in circumstances in which we feel it is appropriate, we may choose to only send a request to some of the U.S. banks that maintain a correspondent account for a specific foreign bank. For this reason, we can reasonably estimate that on average approximately five percent of banks that maintain correspondent accounts for foreign banks will have an account with the any one specific foreign bank about which FinCEN is requesting information.

The commenter also noted that FinCEN estimates the impact of a request about a specific foreign bank will require no more than three hours for a U.S. bank to comply. The commenter noted that although there is no way to verify these estimates, it believes that this rule has the potential to be burdensome and complex. In order to manage the burden of this reporting requirement, FinCEN has proposed a model certification for a bank to utilize in order to inquire of a foreign bank. The model certification includes language identifying the purpose for which the bank is requesting information from the foreign bank. In addition, the model certification defines the key terms applicable to this reporting request. The model certification clearly outlines the information a foreign bank is requested to report and provides links to the list of relevant designated entities and individuals on which a foreign bank is requested to report. As suggested by the commenter, FinCEN will track and consider reporting on the effectiveness of the reporting mechanism.

The commenter also suggested that the regulatory burden estimates are inadequate and do not seem to be a good faith effort to fulfill requirements to assess adequately the regulatory burden. However the commenter did not provide any alternative burden estimates. In addition, FinCEN did not receive any other comments which raised concerns regarding the adequacy of the burden estimates.

Based on two comments received, FinCEN clarifies that in evaluating the effect of this rule on banks, we estimated that approximately 18 U.S. banks would be required to file reports with FinCEN for each request regarding a single foreign bank. We reached this estimate based on the following calculation: FinCEN estimates that 350 U.S. banks maintain correspondent accounts for foreign banks, and approximately five percent of the U.S. banks that maintain correspondent accounts for foreign banks will have a correspondent account with any given foreign bank about which FinCEN is requesting information. Five percent of 350 is 18 (rounded up). In any given request, the actual number of U.S. banks that would be required to report will, of course, vary.

(c) How the quality, utility, and clarity of the information to be collected may be enhanced.

FinCEN received various comments regarding clarification associated with the collection of information. Those comments are addressed throughout the preamble of this rulemaking.

(d) How the burden of complying with the proposed collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology.

One commenter requested that FinCEN utilize e-filing to collect the required information from banks. At this time, FinCEN cannot utilize e-filing for this collection of information. This is something we may consider in the future. FinCEN will prescribe the format and manner in which information will be collected from banks in the requests FinCEN sends to those banks.

X. Effective Date

Publication of a substantive rule not less than 30 days before its effective date is required by the Administrative Procedure Act except as otherwise provided by the agency for good cause.[35] In order to comply with the congressional mandate to prescribe regulations under section 104(e) of CISADA, which will work in tandem with the regulations implementing section 104(c) of CISADA, FinCEN finds that there is good cause for making this amendment effective on October 11, 2011. Regulations implementing section 104(c) of CISADA were required to be prescribed within 90 days of the enactment of the Act on July 1, 2010. As noted above, on August 16, 2010, OFAC published the IFSR. Section 561.201 of the IFSR implements section 104(c) of CISADA. The reports received as a result of this regulation will assist in the implementation of the IFSR.

In finding good cause, FinCEN considered the possible effect of providing less than 30 days notice to affected persons. FinCEN determined that immediate implementation would not unfairly burden these persons because, as explained above, U.S. banks will only be required to report to FinCEN upon receiving a specific written request from FinCEN. As also noted above, FinCEN will only request reports from those U.S. banks that maintain correspondent accounts for the specific foreign banks that are of interest for purposes of CISADA implementation, and as a result we believe that we will receive the information needed without generating a multitude of unnecessary and uninformative reports.

List of Subjects in 31 CFR Part 1060

Banks, Banking, Counter-terrorism, Foreign banking, Reporting and recordkeeping requirements, Terrorism.

Authority and Issuance

For the reasons set forth above, 31 CFR part 1060 is added to read as follows:

PART 1060—PROVISIONS RELATING TO THE COMPREHENSIVE IRAN SANCTIONS, ACCOUNTABILITY, AND DIVESTMENT ACT OF 2010

Sec.
1060.100 [Reserved]
1060.200 [Reserved]
1060.300 Reporting obligations on foreign bank relationships with Iranian-linked financial institutions designated under IEEPA and IRGC-linked persons designated under IEEPA.
1060.400 [Reserved]
1060.500 [Reserved]
1060.600 [Reserved]
1060.700 [Reserved]
1060.800 Penalties

Authority: Pub. L. 111–195, 124 Stat. 1312.

[35] 5 U.S.C. 553(d).

§ 1060.100 [Reserved]

§ 1060.200 [Reserved]

§ 1060.300 Reporting obligations on foreign bank relationships with Iranian-linked financial institutions designated under IEEPA and IRGC-linked persons designated under IEEPA.

(a) *General.*

(1) Upon receiving a written request from FinCEN, a bank (as defined in 31 CFR 1010.100(d)) that maintains a correspondent account (as defined in 31 CFR 1010.605(c)(1)(ii)) for a specified foreign bank (as defined in 31 CFR 1010.100(u)) shall inquire of the foreign bank, and report to FinCEN, with respect to any correspondent account maintained by such foreign bank for an Iranian-linked financial institution designated under IEEPA; any transfer of funds for or on behalf of, directly or indirectly, an Iranian-linked financial institution designated under IEEPA processed by such foreign bank within the preceding 90 calendar days, other than through a correspondent account; and any transfer of funds for or on behalf of, directly or indirectly, an IRGC-linked person designated under IEEPA processed by such foreign bank within the preceding 90 calendar days.

(2) For the purposes of this section, an ''Iranian-linked financial institution designated under IEEPA'' means a financial institution designated by the United States Government pursuant to the International Emergency Economic Powers Act (or listed in an annex to an Executive order issued pursuant to such Act) in connection with Iran's proliferation of weapons of mass destruction or delivery systems for weapons of mass destruction, or in connection with Iran's support for international terrorism. For the purposes of this section, an ''IRGC-linked person designated under IEEPA'' means Iran's Islamic Revolutionary Guard Corps or any of its agents or affiliates designated by the United States Government pursuant to the International Emergency Economic Powers Act (or listed in an annex to an Executive order issued pursuant to such Act).

Note to paragraph (a)(2): Section 104(c) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (''CISADA''), Public Law 111–195, 124 Stat. 1312, provides the Secretary of the Treasury with authority to prohibit, or impose strict conditions on, the opening or maintaining in the United States of a correspondent account or a payable-through account by a foreign financial institution that the Secretary finds knowingly engages in certain specified activities. Those specified activities include facilitating a significant transaction or transactions or providing significant financial services for a financial institution whose property or interests in property are blocked pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) in connection with Iran's proliferation of weapons of mass destruction or delivery systems for weapons of mass destruction, or in connection with Iran's support for international terrorism, or for Iran's Islamic Revolutionary Guard Corps or any of its agents or affiliates whose property or interests in property are blocked pursuant to that Act.

(b) *Duty to inquire.* Upon receiving a written request from FinCEN, a bank that maintains a correspondent account for a specified foreign bank shall inquire of such foreign bank for the purpose of having such foreign bank certify: whether it maintains a correspondent account for an Iranian-linked financial institution designated under IEEPA; whether it has processed one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an Iranian-linked financial institution designated under IEEPA, other than through a correspondent account; and whether it has processed one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an IRGC-linked person designated under IEEPA. Upon such inquiry, a bank shall request that the foreign bank agree to notify the bank if the foreign bank subsequently establishes a new correspondent account for an Iranian-linked financial institution designated under IEEPA at any time within 365 calendar days from the date of the foreign bank's initial response.

(c) *Filing Procedures.*

(1) *What to file.* Upon receiving a written request from FinCEN, a bank shall report to FinCEN, in such format and manner as may be prescribed by FinCEN, the following information for any specified foreign bank:

(i) The name of any specified foreign bank, for which the bank maintains a correspondent account, that certifies that it maintains a correspondent account for an Iranian-linked financial institution designated under IEEPA, and the following related information:

(A) The name of the Iranian-linked financial institution designated under IEEPA;

(B) The full name(s) on the correspondent account and the correspondent account number(s);

(C) Applicable information regarding whether the correspondent account has been blocked or otherwise restricted;

(D) Other applicable identifying information for the correspondent account; and

(E) The approximate value in U.S. dollars of transactions processed through the correspondent account within the preceding 90 calendar days;

(ii) The name of any specified foreign bank, for which the bank maintains a correspondent account, that certifies that it has processed one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an Iranian-linked financial institution designated under IEEPA, other than through a correspondent account, and the following related information:

(A) The name of the Iranian-linked financial institution designated under IEEPA;

(B) The identity of the system or means by which such transfer(s) of funds was processed;

(C) The full name on the account(s) and the account number(s), if applicable;

(D) Other applicable identifying information for such transfer(s) of funds; and

(E) The approximate value in U.S. dollars of such transfer(s) of funds processed within the preceding 90 calendar days;

(iii) The name of any specified foreign bank, for which the bank maintains a correspondent account, that certifies that it has processed one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an IRGC-linked person designated under IEEPA, and the following related information:

(A) The name of the IRGC-linked person designated under IEEPA;

(B) The identity of the system or means by which such transfer(s) of funds was processed;

(C) The full name on the account(s) and the account number(s), if applicable;

(D) Other applicable identifying information for such transfer(s) of funds; and

(E) The approximate value in U.S. dollars of such transfer(s) of funds processed within the preceding 90 calendar days;

(iv) The name of any specified foreign bank, for which the bank maintains a correspondent account, that certifies that it does not maintain a correspondent account for an Iranian-linked financial institution designated under IEEPA, that certifies that to its knowledge it has not processed one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an Iranian-linked financial institution designated under IEEPA, other than through a correspondent account, and/

or that certifies that to its knowledge it has not processed one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an IRGC-linked person designated under IEEPA;

(v) The name of any specified foreign bank, for which the bank maintains a correspondent account, that the bank cannot determine does not maintain a correspondent account for an Iranian-linked financial institution designated under IEEPA, has not processed one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an Iranian-linked financial institution designated under IEEPA, other than through a correspondent account, and/or has not processed one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an IRGC-linked person designated under IEEPA, together with the reason(s) for this, such as the failure of the foreign bank to respond to the inquiry by or a request from the bank, the failure of the foreign bank to certify its response, or if the bank has information that is inconsistent with the certification;

(vi) The name of any specified foreign bank, for which the bank maintains a correspondent account, that notifies the bank that it has established a new correspondent account for an Iranian-linked financial institution designated under IEEPA at any time within 365 calendar days from the date of the foreign bank's initial response, and the following related information:

(A) The name of the Iranian-linked financial institution designated under IEEPA;

(B) The full name(s) on the correspondent account and the correspondent account number(s);

(C) Applicable information regarding whether the correspondent account has been blocked or otherwise restricted; and

(D) Other applicable identifying information for the correspondent account;

(vii) If applicable, confirmation that the bank does not maintain a correspondent account for the specified foreign bank(s), but only in instances in which FinCEN specifically requests that the bank report such information; and

(viii) If applicable, the name of any specified foreign bank, for which the bank maintains a correspondent account, that provides a certification to the bank after the 45-calendar-day deadline, along with all applicable related information associated with that certification.

(2) *When to file.* (i) A bank shall report to FinCEN within 45-calendar-days of the date of the request from FinCEN.

(ii) Reports based on subsequent notifications received from a foreign bank regarding the establishment of a new correspondent account for an Iranian-linked financial institution designated under IEEPA shall be due within 10 calendar days of receipt of the notification.

(iii) Reports based on certifications received from a foreign bank after the 45 calendar day deadline shall be due within 10 calendar days of receipt of the certification.

(d) *Retention of records.* A bank shall maintain for a period of five years a copy of any report filed and the original or any business record equivalent of any supporting documentation for a report, including a foreign bank certification or other responses to an inquiry under this section.

(e) *No other action required.* Nothing in this section shall be construed to require a bank to take any action, or to decline to take any action, other than the requirements identified in this section, with respect to an account established for, or a transaction engaged in with, a foreign bank. However, nothing in this section relieves a bank of any other applicable regulatory obligation.

§ 1060.400 [Reserved]

§ 1060.500 [Reserved]

§ 1060.600 [Reserved]

§ 1060.700 [Reserved]

§ 1060.800 Penalties.

A person violating any requirement under this part is subject to the penalties provided for in sections 5321(a) and 5322 of title 31, United States Code, in the same manner and to the same extent as such penalties would apply to any person that is otherwise subject to such section 5321(a) or 5322.

Dated: October 3, 2011.

James H. Freis, Jr.,

Director, Financial Crimes Enforcement Network.

Note: This appendix will not appear in the Code of Federal Regulations; however, FinCEN will use its website to make this model certification available to the public.

Appendix A

Certification for Purposes of Section 104(e) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 and 31 CFR § 1060.300

[OMB Control Number 1506-0066]

The information contained in this Certification is sought for purposes of Section 104(e) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 ("CISADA") (Public Law 111-195). This Certification will be used to provide the Department of the Treasury, through the Financial Crimes Enforcement Network ("FinCEN"), with information regarding the nature of foreign bank activities that may be relevant to CISADA.

This Certification may be completed by a **foreign bank** that maintains a **correspondent account** with a U.S. **bank** (see definitions below). An entity that is not a foreign bank is not required to complete this Certification.

A **Foreign Bank** is a bank organized under foreign law, or an agency, branch, or office located outside the United States of a bank (see definition at 31 CFR § 1010.100(u)). A **Bank** includes each agent, agency, branch, or office within the United States of persons doing business in one or more of the following capacities: commercial banks or trust companies, private banks, savings and loan associations, national banks, thrift institutions, credit unions, other organizations chartered under banking laws and supervised by banking supervisors of any State, and banks organized under foreign law (see definition at 31 CFR § 1010.100(d)).

A **Correspondent Account** for a foreign bank is an account established for a foreign bank to receive deposits from, or to make payments or other disbursements on behalf of, the foreign bank, or to handle other financial transactions related to such foreign bank (see definition at 31 CFR § 1010.605(c)(1)(ii)).

An Iranian-Linked Financial Institution Designated Under IEEPA is a financial institution designated by the United States Government pursuant to the International Emergency Economic Powers Act ("IEEPA") (or listed in an annex to an Executive order issued pursuant to such Act) in connection with Iran's proliferation of weapons of mass destruction or delivery systems for weapons of mass destruction, or in connection with Iran's support for international terrorism. Iranian-Linked Financial Institutions Designated Under IEEPA are identified by "[IFSR]" tags located at the end of their entries on the Specially Designated Nationals and Blocked Persons List ("SDN List") (e.g., [NPWMD][IFSR] or [SDGT][IFSR]). The Office of Foreign Assets Control's ("OFAC") electronic SDN List can be found at the following URL: http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx. The following financial institutions meet the criteria of Iranian-Linked Financial Institutions Designated Under IEEPA ([IFSR] tags): http://www.treasury.gov/resource-center/sanctions/Programs/Documents/irgc_ifsr.pdf. These listings are part of the SDN List, administered by OFAC. Please note that OFAC's SDN List is dynamic and should be reviewed

regularly for the most current information regarding Iranian-Linked Financial Institutions Designated Under IEEPA.

An IRGC-Linked Person Designated Under IEEPA is Iran's Islamic Revolutionary Guard Corps or any of its agents or affiliates designated by the United States Government pursuant to IEEPA (or listed in an annex to an Executive order issued pursuant to such Act). IRGC-Linked Persons Designated Under IEEPA are identified by "[IRGC]" tags located at the end of their entries on the SDN List (e.g., [NPWMD][IRGC] or [SDGT][IRGC]). OFAC's electronic SDN List can be found at the following URL: http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx. The following persons meet the criteria of IRGC-Linked Persons Designated Under IEEPA ([IRGC] tags): http://www.treasury.gov/resource-center/sanctions/Programs/Documents/irgc_ifsr.pdf. These listings are part of the SDN List, administered by OFAC. Please note that OFAC's SDN List is dynamic and should be reviewed regularly for the most current information regarding IRGC-Linked Persons Designated Under IEEPA.

A. The undersigned financial institution, _____ ("**Foreign Bank**") hereby certifies as follows: (**Note:** Foreign Bank should check one box in each of sections B, C, and D in order to complete the Certification).

B. Correspondent Account maintained for an Iranian-Linked Financial Institution Designated Under IEEPA: Check **one** box to certify.

☐ Foreign Bank hereby certifies that it **does not** maintain a correspondent account(s) for an Iranian-Linked Financial Institution Designated Under IEEPA.

☐ Foreign Bank hereby certifies that it **does** maintain a correspondent account(s) for an Iranian-Linked Financial Institution Designated Under IEEPA. (If this box has been selected please fill out the below information for each correspondent account maintained for an Iranian-Linked Financial Institution Designated Under IEEPA).

	Iranian-Linked Financial Institution Designated Under IEEPA	Full Name(s) on Correspondent Account	Correspondent Account Number(s)	Applicable Information regarding whether the Correspondent Account has been Blocked or Otherwise Restricted *	Other Applicable Identifying Information for the Correspondent Account	Approximate Value in U.S. Dollars ("USD") of Transactions Processed through the Correspondent Account Within Preceding 90 Calendar Days
1						
2						
3						
4						
5						

(Add more rows as needed)
* Please include other applicable information such as whether the account(s) has been restricted or blocked in accordance with laws or policies, whether the account(s) is dormant, or whether the account(s) activity has been subject to specific exceptions to otherwise applicable restrictions, such as an account(s) licensed by a competent authority in the foreign bank's home jurisdiction.

C. Processed one or more transfers of funds for or on behalf of, directly or indirectly, an Iranian-Linked Financial Institution Designated Under IEEPA, other than through a correspondent account: Check **one** box to certify.

□ Foreign Bank hereby certifies that to its knowledge it **has not processed** one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an Iranian-Linked Financial Institution Designated Under IEEPA, **other than through a correspondent account** detailed above.

□ Foreign Bank hereby certifies that it **has processed** one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an Iranian-Linked Financial Institution Designated Under IEEPA, **other than through a correspondent account** detailed above. (If this box has been selected please fill out the below information for each Iranian-Linked Financial Institution Designated Under IEEPA).

	Iranian-Linked Financial Institution Designated Under IEEPA	Identify System or Means by Which Transfer(s) of Funds Was Processed	Full Name on Account(s) (if applicable)	Account Number(s) (if applicable)	Other Applicable Identifying Information for the Transfer(s) of Funds *	Approximate Value in USD of Transfer(s) of Funds Processed (other than through a Correspondent Account) Within Preceding 90 Calendar Days
1						
2						
3						
4						
5						

(Add more rows as needed)
* Please include other applicable information such as whether the transfer(s) of funds has been subject to specific exceptions to otherwise applicable restrictions, such as a transfer(s) of funds licensed by a competent authority in the foreign bank's home jurisdiction.

D. Processed one or more transfers of funds for or on behalf of, directly or indirectly, an IRGC-Linked Person Designated Under IEEPA: Check **one** box to certify.

□ Foreign Bank hereby certifies that to its knowledge it **has not processed** one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an IRGC-Linked Person Designated Under IEEPA.

□ Foreign Bank hereby certifies that it **has processed** one or more transfers of funds within the preceding 90 calendar days for or on behalf of, directly or indirectly, an IRGC-Linked Person Designated Under IEEPA. (If this box has been selected please fill out the below information for each IRGC-Linked Person Designated Under IEEPA).

	IRGC-Linked Person Designated Under IEEPA	Identify System or Means by Which Transfer(s) of Funds Was Processed	Full Name on Account(s) (if applicable)	Account Number(s) (if applicable)	Other Applicable Identifying Information for the Transfer(s) of Funds *	Approximate Value in USD of Transfer(s) of Funds Processed Within Preceding 90 Calendar Days
1						
2						
3						
4						
5						

(Add more rows as needed)

* Please include other applicable information such as whether the transfer(s) of funds has been subject to specific exceptions to otherwise applicable restrictions, such as a transfer(s) of funds licensed by a competent authority in the foreign bank's home jurisdiction.

E. General

Foreign Bank hereby agrees to notify in writing the Bank if Foreign Bank establishes a new correspondent account for an Iranian-Linked Financial Institution Designated Under IEEPA at any time within 365 calendar days from the date of this response. Foreign Bank agrees to provide such notification within 30 calendar days of the establishment of the new correspondent account.

Foreign Bank understands that the Bank will provide a copy of this Certification to FinCEN, a bureau of the U.S. Department of the Treasury. Foreign Bank further understands that the statements contained in this Certification may be transmitted to one or more departments or agencies of the United States of America for the purpose of fulfilling such departments' and agencies' governmental functions.

I, _____(name of signatory), certify that I have read and understand this Certification, that the statements made in this Certification are complete and correct, and that I am authorized to execute this Certification on behalf of Foreign Bank.

_____
[Name of Foreign Bank]

_____
[Signature]

_____
[Printed Name]

_____
[Title]

Executed on this _____day of _____, 20___.

To be completed by the Bank:

I, _____(name of signatory), have received and reviewed this Certification. To the best of its knowledge, the Bank has no information that is inconsistent with the Certification made by Foreign Bank. I am authorized to submit this document on behalf of the Bank.

_____
[Name of Bank]

_____
[Signature]

_____
[Printed Name]

_____
[Title]

Submitted on this _____day of _____, 20___.

[FR Doc. 2011–26204 Filed 10–7–11; 8:45 am]
BILLING CODE 4810–02–P

CENTRAL INTELLIGENCE AGENCY

32 CFR Part 1902

Information Security Regulations

AGENCY: Central Intelligence Agency.

ACTION: Final rule.

SUMMARY: The Central Intelligence agency is removing certain information security regulations which have become outdated. The Executive Order upon which the regulations are based has been superseded, and the regulations are no longer needed.

DATES: Effective October 11, 2011.

FOR FURTHER INFORMATION CONTACT: Joseph W. Lambert, (703) 613–1379.

SUPPLEMENTARY INFORMATION: Under the authority of Executive Order 13526, the CIA is removing and reserving 32 CFR part 1902. This part relies on authority that is no longer in force and established criteria and procedures that are superseded by Executive Order 13526. This rule is being issued as final rule without prior notice of proposed rulemaking as allowed by the Administrative Procedures Act, 5 U.S.C. 533(b)(3)(A) for rules of agency procedure and interpretation and Section 6 of the CIA Act as amended, 50 U.S.C. 403g.

List of Subjects in 32 CFR Part 1902

Information security regulations.

PART 1902 [REMOVED AND RESERVED]

§ 1902.13 [Removed and Reserved]

■ Accordingly, under the authority of Executive Order 13526, the CIA removes and reserves part 32 CFR part 1902.

Dated: September 19, 2011.

Joseph W. Lambert,

Director, Information Management Services.

[FR Doc. 2011–25546 Filed 10–7–11; 8:45 am]

BILLING CODE 6310–02–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Part 334

Archers Creek, Ribbon Creek, and Broad River; U.S. Marine Corps Recruit Depot, Parris Island, SC; Danger Zone

AGENCY: United States Army Corps of Engineers, Department of Defense.

ACTION: Final rule.

SUMMARY: The U.S. Army Corps of Engineers (Corps) is amending its regulations by modifying two existing danger zones that are located adjacent to the rifle range and pistol range at the U.S. Marine Corps Recruit Depot Parris Island in Beaufort County, South Carolina. The amendments include reformatting the regulations for clarity, modifying the boundaries of both danger zones, and modifying the hours of range operations from 6:30 a.m. to 5 p.m. to 6 a.m. to 5 p.m. Monday through Friday. These amendments will enhance the ability of the U.S. Marine Corps to provide for the safe operation of the existing rifle and pistol ranges.

DATES: *Effective date:* November 10, 2011.

ADDRESSES: U.S. Army Corps of Engineers, Attn: CECW–CO (David B. Olson), 441 G Street NW., Washington, DC 20314–1000.

FOR FURTHER INFORMATION CONTACT: Mr. David B. Olson, Headquarters, Operations and Regulatory Community of Practice, Washington, DC at 202–761–4922 or Mr. Nathaniel I. Ball, U.S. Army Corps of Engineers, Charleston District, Regulatory Division, at 843–329–8047.

SUPPLEMENTARY INFORMATION: Pursuant to its authorities in Section 7 of the Rivers and Harbors Act of 1917 (40 Stat 266; 33 U.S.C. 1) and chapter XIX of the Army Appropriations Act of 1919 (40 Stat 892; 33 U.S.C. 3) the Corps is amending the regulations at 33 CFR part 334 to provide for the safe operation of the existing rifle and pistol ranges at the U.S. Marine Corps Recruit Depot Parris Island. The modifications to the regulations are described below.

The modifications include reformatting the regulations to describe the areas, the regulations, and enforcement. This format is consistent with other danger zone regulations and provides greater clarity. The boundaries of both danger zones have been modified to incorporate modern methods of measuring ballistic footprints and design criteria for range construction. Since these changes to the boundaries of the areas are relatively minor, the existing live fire warning signs will continue to be used to ensure safe navigation in the vicinity of the rifle and pistol ranges.

These regulations allow the Commanding General, U.S. Marine Corps Recruit Depot Parris Island to restrict passage of persons, vessels and other watercraft in navigable waters adjacent to the existing rifle range and pistol range between the hours of 6 a.m. and 5 p.m. Monday through Friday, and from 6 a.m. to 12 p.m. on Saturdays, National holidays excepted, and at other times as designated and properly published by the U.S. Marine Corps Recruit Depot Parris Island. The public will continue to be able to use these portions of Archers Creek, Ribbon Creek, and the Broad River when the rifle and pistol ranges are not in use.

The proposed rule was published in the June 17, 2011, edition of the **Federal Register** (76 FR 35379) with the docket number COE–2011–0010. No comments were received.

Procedural Requirements

a. *Review Under Executive Order 12866.* This regulation is issued with respect to a military function of the Department of Defense and the provisions of Executive Order 12866 do not apply.

b. *Review Under the Regulatory Flexibility Act.* This regulation has been reviewed under the Regulatory Flexibility Act (Pub. L. 96–354) which requires the preparation of a regulatory flexibility analysis for any regulation that will have a significant economic impact on a substantial number of small entities (*i.e.,* small businesses and small governments). The Corps determined that this regulation would have little or no economic impact on the public nor would it result in any anticipated navigational hazard or interference with existing waterway traffic. This regulation will have no significant economic impact on small entities.

c. *Review Under the National Environmental Policy Act.* Due to the administrative nature of this action and because there is no intended change in the use of the area, this regulation will not have a significant impact to the quality of the human environment and, therefore, preparation of an environmental impact statement is not required. An environmental assessment has been prepared. It may be reviewed at the district office listed at the end of **FOR FURTHER INFORMATION CONTACT,** above.

d. *Unfunded Mandates Act.* This regulation does not impose an enforceable duty among the private sector and, therefore, is not a Federal private sector mandate and is not subject to the requirements of Section 202 or 205 of the Unfunded Mandates Reform Act (Pub. L. 104–4, 109 Stat. 48, 2 U.S.C. 1501 *et seq.*). We have also found under Section 203 of the Act, that small governments will not be significantly or uniquely affected by this regulation.

List of Subjects in 33 CFR Part 334

Danger zones, Navigation (water), Restricted areas, Waterways.

For the reasons set out in the preamble, the Corps amends 33 CFR Part 334 as follows:

PART 334—DANGER ZONE AND RESTRICTED AREA REGULATIONS

■ 1. The authority citation for part 334 continues to read as follows:

Authority: 40 Stat. 266 (33 U.S.C. 1) and 40 Stat. 892 (33 U.S.C. 3).

■ 2. Revise § 334.480 to read as follows:

§ 334.480 Archers Creek, Ribbon Creek, and Broad River; U.S. Marine Corps Recruit Depot, Parris Island, South Carolina; danger zones.

(a) *The areas.* (1) The danger zone on Archers Creek (between the Broad River and Beaufort River), Ribbon Creek, and the Broad River shall encompass all navigable waters of the United States, as defined at 33 CFR part 329, adjacent to the existing rifle range. This area is bounded by a line connecting the following coordinates: Commencing from the shoreline at the southernmost portion of the area, at latitude 32°19′59″ N, longitude 80°42′54″ W, thence to a point at latitude 32°20′05″ N, longitude 80°43′16″ W, thence to a point at latitude 32°21′40″ N, longitude 80°44′54″ W, thence to a point at latitude 32°22′20″ N, longitude 80°43′52″ W, thence to a point on the shoreline at latitude 32°21′34″ N, longitude 80°42′48″ W, thence follow the mean high water line southwesterly around Horse Island approximately 2.3 nautical miles to a point at latitude 32°21′22″ N, longitude 80°42′30″ W, thence to a point on the shoreline at latitude 32°20′56″ N, longitude 80°41′50″ W, thence follow the mean high water line southwesterly approximately 2.2 nautical miles to terminate at the southernmost portion of the area (the starting point).

(2) The danger zone on the Broad River shall encompass all navigable waters of the United States, as defined at 33 CFR part 329, adjacent to the existing pistol range. This area is bounded by a line connecting the following coordinates: Commencing from the shoreline at the easternmost portion of the area, at latitude 32°19′36″ N, longitude 80°42′34″ W, thence to a point at latitude 32°19′23″ N, longitude 80°42′50″ W, thence to a point at latitude 32°19′06″ N, longitude 80°43′31″ W, thence to a point at latitude 32°19′28″ N, longitude 80°43′54″ W, thence to a point at latitude 32°19′59″ N, longitude 80°43′28″ W, thence to a point on the shoreline at latitude 32°20′10″ N, longitude 80°43′10″ W, and thence follow the mean high water line southeasterly approximately 0.75 nautical miles to terminate at the easternmost portion of the area (the starting point).

(b) *The regulations.* (1) All persons, vessels, or other watercraft are prohibited from entering, transiting, anchoring, or drifting within the danger zones described in paragraph (a) of this section when the adjacent rifle or pistol ranges on U.S. Marine Corps Recruit Depot Parris Island are in use.

(2) Firing over these ranges will normally take place between the hours of 6 a.m. and 5 p.m., Monday through Friday, and from 6 a.m. to 12 p.m. on Saturday, National holidays excepted, and at other times as designated and properly published by the Commanding General, U.S. Marine Corps Recruit Depot Parris Island.

(3) Warning signs indicating the periods when the rifle range is in use will be posted by the entrances to Archers Creek and Ribbon Creek. In addition, warning signs will be placed along the shoreline on the Broad River near the upstream and downstream boundaries of both the rifle range and the pistol range.

(4) Warning flags shall be flown from the top of the lookout tower and on the rifle range and pistol range during actual firing. In addition, a sentry lookout will be on duty during actual firing and a patrol boat will be accessible for clearing the area and warning all approaching vessels of the danger zone and the schedule of firing.

(5) During storms or similar emergencies these areas shall be opened to vessels to reach safety without undue delay for the preservation of life and property.

(c) *Enforcement.* The regulations in this section shall be enforced by the Commanding General, U.S. Marine Corps Recruit Depot Parris Island and/or such persons or agencies as he/she may designate.

Dated: September 29, 2011.

Michael G. Ensch,

Chief, Operations and Regulatory, Directorate of Civil Works.

[FR Doc. 2011–26195 Filed 10–7–11; 8:45 am]

BILLING CODE 3720–58–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

36 CFR Part 1258

[NARA–11–0002]

RIN 3095–AB71

NARA Records Reproduction Fees

AGENCY: National Archives and Records Administration.

ACTION: Final rule.

SUMMARY: The National Archives and Records Administration (NARA) is changing its regulations to add the methodology for creating and changing records reproduction fees, to remove records reproduction fees found in its regulations, and to provide a notification process for the public of new or proposed fees. This final rule covers reproduction of Federal or Presidential records accessioned, donated, or transferred to NARA. Note that there are no proposed changes to fees at any NARA facility at this time.

DATES: This rule is effective November 10, 2011.

FOR FURTHER INFORMATION CONTACT: Stuart Culy on (301) 837–0970.

SUPPLEMENTARY INFORMATION: On July 22, 2011, NARA published a proposed rule in the **Federal Register** (76 FR 43960) for a 60-day public comment period. This proposed rule changed NARA's regulations to add the methodology for creating and changing records reproduction fees, to remove records reproduction fees found in its regulations, and to provide a notification process for the public of new or proposed fees. The public comment period closed on September 20, 2011. NARA received no comments.

This final rule is not a significant regulatory action for the purposes of Executive Order 12866 and has not been reviewed by the Office of Management and Budget. As required by the Regulatory Flexibility Act, I certify that this rule will not have a significant impact on a substantial number of small entities because it affects Federal agencies and individual researchers. This regulation does not have any federalism implications.

List of Subjects in 36 CFR Part 1258

Archives and records.

■ For the reasons set forth in the preamble, NARA revises 36 CFR part 1258 to read as follows:

PART 1258—FEES

Sec.
1258.1 [Reserved]
1253.2 What definitions apply to the regulations in this part?
1258.4 What costs make up the NARA fees?
1258.6 How does NARA calculate fees for individual products?
1258.8 How does NARA change fees for existing records reproductions?
1258.10 How does NARA develop and publicize new records reproduction fees?
1258.12 When does NARA provide records reproductions without charge?
1258.14 What is NARA's payment policy?
1258.16 What is NARA's refund policy?
1258.18 Where can I find NARA's current fees and information on how to order reproductions?

Authority: 44 U.S.C. 2116(c) and 44 U.S.C. 2307.

§ 1258.1 [Reserved]

§ 1258.2 What definitions apply to the regulations in this part?

Accession means the method of acquiring archival records or donated materials from various Governmental bodies.

Archival records means records that have been accessioned into the legal custody of NARA, donated historical materials in the legal custody of NARA and its Presidential libraries, and Congressional, Supreme Court, and other historical materials in NARA's physical custody and for which NARA has a formal agreement for their permanent retention.

Certification means affixing a seal to copies certifying the copies are a valid reproduction of a file; this service is available for an additional fee.

Cost means the total amount of money spent by the NATF for providing services including, but not limited to, salaries; benefits; rent; communication and utilities; printing and reproductions; consulting and other services; payments to other agencies/funds; supplies and materials; depreciation; system upgrades/replacements; *etc.*

Custodial units mean NARA's Federal Records Centers, National Personnel Records Center, archival reference operations nationwide, and Presidential Libraries.

Fee means the price researchers pay for reproductions of records. Certification of records is also a reproduction fee.

Records center records means Federal records in the physical custody of NARA records centers, but still in the legal custody of the agencies that created and maintained them.

§ 1258.4 What costs make up the NARA fees?

(a) 44 U.S.C. 2116(c) allows the NATF to recover all of its costs for providing records reproduction services to the public. The vast majority of materials that are reproduced are from the holdings of NARA, which require special handling, due to the age, condition and historical significance. Examples of special handling include the following:

(1) *The placement of each record by hand on the reproduction equipment.* Many of the records are fragile and have historical uniqueness; reproduction equipment operators must take great care in handling these records. For example, each page of a document must be carefully placed by hand on the reproduction equipment, a copy made, the page removed, and the process re-started.

(2) *Clarity and legibility of the reproduced records.* Older records may be handwritten and darkened from age, which requires extra time to make sure we produce copies that are as clear and legible as possible.

(3) *Inability to use automatic document feeders.* Because of the requirements in paragraph (a)(1) of this section, automatic document feeders cannot be used for the duplication of paper materials. This adds time and cost to the price of copying these irreplaceable documents.

(b) The NATF costs, at a minimum, include:

(1) Salaries and benefits of the NATF staff involved in all aspects of the records reproduction process (includes, but is not limited to, compensation for full- and part-time employees, temporary appointments, overtime, awards, Civil Service Retirement Service and Federal Employees' Retirement System contributions, health benefits, life insurance benefits and Thrift Savings Plan contributions).

(2) Travel and transportation (includes, but is not limited to, travel and transportation of persons, transportation of things, and contract mail service).

(3) Rent, communications and utilities (includes, but is not limited to, telecommunications, equipment rental, and postage).

(4) Printing and reproductions (includes, but is not limited to, commercial printing, advertising, and printing of forms).

(5) Consulting and other services (includes, but is not limited to, management and professional services, contract labor, work performed in support of reproduction orders, and maintenance of equipment).

(6) Payments to other agencies/funds (includes, but is not limited to, reimbursements and payments to other agencies and other funds within NARA). Specifically, the NATF ''hires'' the NARA custodial units to do reproduction work. In return, the NATF reimburses the custodial units for the cost of salaries and benefits.

(7) Supplies and materials (includes, but is not limited to, general supplies, and materials and parts).

(8) Depreciation (spreading the cost of an asset over the span of several years).

(9) System upgrades/replacement (includes, but is not limited to, installation of operating equipment, software upgrades, and system changes).

§ 1258.6 How does NARA calculate fees for individual products?

NARA calculates the fees for individual products using the following:

(a) *Cost summary.* A summary of all costs incurred by the NATF in providing records reproduction services.

(b) *Percent of revenue.* The percentage of the total NATF revenue represented by sales of a product. This is determined and used where a more accurate percentage based upon actual usage is not available. To calculate this percentage, an analysis is made to determine the current percent of NATF sales revenue represented by each product line. The sales volume is then reviewed with the custodial units to determine if this represents anticipated sales.

(c) *Actual cost percent calculation.* Using the information calculated in the Cost Summary, the actual revenue cost percentage is determined. In some cases, the actual percentage of cost can be calculated from available data or known constraints of the product line. For example, if the contractor responsible for providing copy support does not support the reproduction of a given product line then zero (0) percent of the contractor's costs would be allocated to that product line.

(d) *Forecasted volume.* The prediction of a product's sales volume in future year(s). These estimates are made by working with the custodial units and taking into account historical sales volume. An annual percent change is then estimated

(e) *Reimbursements to the custodial units.* The amount paid to the custodial units for records reproductive services in support of NATF customer orders. The NATF reimburses the custodial units for services rendered to the NATF for the reproduction of NARA holdings. To determine the reimbursement per copy for an item, past reimbursement fees are changed by the compounded annual Government salary changes as issued by the Office of Personnel Management for the fiscal years being projected. The new rates are reviewed with custodial unit personnel and adjustments are made as required.

(f) *Additional cost allocation.* The costs unique to a given product line. Each product line is evaluated to determine the costs that are unique to that product line, such as purchase and installation costs of specialty equipment, replacement costs for aging equipment, copier leases and maintenance costs, etc. These costs are then allocated against those product lines that use the equipment. Where costs cross product lines, the allocations are apportioned based upon the percent of the estimated copy volume for each product line.

(g) *Fee calculation.* The product fee is calculated by the following formula: {[(Percent of Revenue * NATF Overhead Costs) + Reimbursement + Additional Costs]/Projected Sales Volume}

This calculation is completed for each product.

(h) *Final review.* After the suggested new fees are calculated, NATF reviews them to establish the final fees. Fees may be adjusted across product lines to ensure that the NATF can succeed in total cost recovery.

§ 1258.8 How does NARA change fees for existing records reproductions?

(a) The NATF conducts periodic reviews of its fees to ensure that the costs of providing services to the public are properly recovered.

(b) Existing records reproduction fees may be adjusted annually based on the following factors:

(1) Inflation.

(2) The Office of Personnel Management (OPM) salary changes.

(3) Reallocation of shared costs across product lines using the methodology described in § 1258.6.

(4) The projected sales volume for the product.

(5) The actual sales volume for the product.

(6) The approval of the Archivist of the United States.

(d) NARA will place a notice on our Web site (*http://www.archives.gov*) annually when announcing that records reproduction fees will be adjusted in accordance with this regulation.

§ 1258.10 How does NARA develop and publicize new records reproduction fees?

(a) Custodial units prepare a justification proposal for a proposed records reproduction service and send the justification to the custodial unit office head, through appropriate channels, for concurrence and forwarding to NATF. The justification proposal includes, at a minimum, the following information:

(1) Estimated monthly volume of product orders based on available historical data;

(2) Identification of the equipment and supplies required to provide the product and service;

(3) Brief description of the process required to provide the product and service, including the amount of time for each number and grade level of staff.

(4) Identification of any services or products that will be replaced by the proposed products and services;

(5) Identification of other NARA units that may have a demand for the proposed services; and

(6) Any other relevant information.

(b) After receiving the proposal, NATF staff:

(1) Assesses the potential customer base for the proposed products and services, consulting other NARA offices.

(2) If the potential demand does not warrant establishing fees for new records reproduction products and services, NATF notifies the proposing office that the new product and service are not approved and the reasons why.

(3) If the potential demand warrants, NATF prepares a cost analysis following the methodology in § 1258.6 and develops a proposed recommended fee for review by NARA's Financial Resources Division and approval by the Archivist of the United States.

(c) Notification of new records reproduction services and trial periods:

(1) The public will be notified of new records reproduction services, including the business case for determining initial fee, on-line at *http://www.archives.gov,* by press releases, and through NARA's social media outlets.

(2) New records reproduction services fees have an initial trial period of one year. During this time, the public is encouraged to provide feedback to NARA about the new records reproduction services and their fees as directed in the notification of the new services.

(3) Prior to the expiration of a trial period, NATF will assess the validity of the fees for the new records reproduction products and services, and make one of three determinations:

(i) Retain products, services and fees;

(ii) Retain products or services but adjust fees up or down; or

(iii) Discontinue products or services.

(d) The public will be notified of NATF determination, including business case for determination, in NARA research rooms nationwide, on-line at *http://www.archives.gov,* press releases, and through NARA's social media outlets.

§ 1258.12 When does NARA provide records reproductions without charge?

At the discretion of the Secretary of the NATF, customers are not charged a fee for records reproductions or certifications in the instances described in this section.

(a) When NARA furnishes copies of records to other elements of the Federal Government. However, a fee may be charged if the appropriate director determines that the service cannot be performed without reimbursement;

(b) When NARA wishes to disseminate information about its activities to the general public through press, radio, television, and newsreel representatives;

(c) When the reproduction is to furnish the donor of a document or other gift with a copy of the original;

(d) When the reproduction is for individuals or associations having official voluntary or cooperative relations with NARA in its work;

(e) When the reproduction is for a foreign, State, or local government or an international agency and furnishing it without charge is an appropriate courtesy; and

(f) For records of other Federal agencies in NARA Federal records centers only:

(1) When furnishing the service free conforms to generally established business custom, such as furnishing personal reference data to prospective employers of former Government employees;

(2) When the reproduction of not more than one copy of the document is required to obtain from the Government financial benefits to which the requesting person may be entitled (*e.g.,* veterans or their dependents, employees with workmen's compensation claims, or persons insured by the Government);

(3) When the reproduction of not more than one copy of a hearing or other formal proceeding involving security requirements for Federal employment is requested by a person directly concerned in the hearing or proceeding; and

(4) When the reproduction of not more than one copy of a document is for a person who has been required to furnish a personal document to the Government (*e.g.,* a birth certificate required to be given to an agency where the original cannot be returned to the individual).

§ 1258.14 What is NARA's payment policy?

Fees may be paid:

(a) By check or money order made payable to the *National Archives Trust Fund.*

(b) By selected credit cards.

(c) Payments from outside the United States must be made by international money order payable in U.S. dollars or a check drawn on a U.S. bank.

(d) In cash (note that some locations do not accept cash).

§ 1258.16 What is NARA's refund policy?

Due to the age, original media type, and general condition of many of the items in NARA's holdings, it is occasionally difficult to make a legible reproduction. NARA staff will notify customers if they anticipate that the original will result in a reproduction of questionable legibility before requesting the reproduction and after approval of the customer. After a records reproduction is completed, the product undergoes a review to determine if it is an accurate representation of the original item. Because of the preapproval process, NARA does not provide refunds except in special cases. If a customer requests a refund, a review is made of the order to determine if the customer was properly notified of the questionable nature of the original and if the product is a true representation of the original. If the customer authorized proceeding and the product is a true representation of the original, no refund will be issued.

§ 1258.18 Where can I find NARA's current fees and information on how to order reproductions?

(a) NARA's fee schedule and ordering portal are located at *http://www.archives.gov.*

(b) Fee schedules for reproductions made from the holdings of Presidential libraries may differ because of regional cost variations. Presidential library fee schedules are available at *http://www.archives.gov/presidential-libraries/.* Some services may not be available at all NARA facilities.

(c) In order to preserve certain records which are in poor physical condition, NARA may restrict customers to photographic or other kinds of duplication instead of electrostatic copies.

Dated: October 4, 2011.

David S. Ferriero,

Archivist of the United States.

[FR Doc. 2011–26167 Filed 10–7–11; 8:45 am]

BILLING CODE 7515–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2010–0160; FRL–9477–6]

Approval and Promulgation of Air Quality Implementation Plans; Commonwealth of Virginia; Section 110(a)(2) Infrastructure Requirements for the 1997 8-Hour Ozone and the 1997 and 2006 Fine Particulate Matter National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving submittals from the Commonwealth of Virginia pursuant to the Clean Air Act (CAA) sections 110(k)(2) and (3). These submittals address the infrastructure elements specified in CAA section 110(a)(2), necessary to implement, maintain, and enforce the 1997 8-hour ozone and fine particulate matter ($PM_{2.5}$) national ambient air quality standards (NAAQS) and the 2006 $PM_{2.5}$ NAAQS. This final rule is limited to the following infrastructure elements which were subject to EPA's completeness findings pursuant to CAA section 110(k)(1) for the 1997 8-hour ozone NAAQS dated March 27, 2008 and the 1997 $PM_{2.5}$ NAAQS dated October 22, 2008: 110(a)(2)(A), (B), (C), (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M), or portions thereof; and the following infrastructure elements for the 2006 $PM_{2.5}$ NAAQS: 110(a)(2)(A), (B), (C), (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M), or portions thereof.

DATES: *Effective Date:* This final rule is effective on November 10, 2011.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2010–0160. All documents in the docket are listed in the *http://www.regulations.gov* Web site. Although listed in the electronic docket, some information is not publicly available, *i.e.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as 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 through *http://www.regulations.gov* or in hard copy for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia 23219.

FOR FURTHER INFORMATION CONTACT: Marilyn Powers, (215) 814–2308, or by e-mail at *powers.marilyn@epa.gov*.

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

I. Background

On July 14, 2011 (76 FR 41444), EPA published a notice of proposed rulemaking (NPR) for the Commonwealth of Virginia. The NPR proposed approval of Virginia submittals that provide the basic program elements specified in CAA section 110(a)(2)(A), (B), (C), (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M), or portions thereof, necessary to implement, maintain, and enforce the 1997 8-hour ozone and $PM_{2.5}$ NAAQS and the 2006 $PM_{2.5}$ NAAQS. The formal submittals by the Commonwealth of Virginia on December 10, 2007, December 13, 2007, June 8, 2010, and June 9, 2010 addressed the section 110(a)(2) requirements for the 1997 8-hour ozone NAAQS; the submittals dated July 10, 2008, September 2, 2008, June 8, 2010, June 9, 2010, and August 30, 2010 addressed the section 110(a)(2) requirements for the 1997 $PM_{2.5}$ NAAQS; and the submittals dated August 30, 2010 and April 1, 2011 addressed the section 110(a)(2) requirements for the 2006 $PM_{2.5}$ NAAQS.

II. Scope of Action on Infrastructure Submissions

EPA is currently acting on State Implementation Plans (SIPs) that address the infrastructure requirements of CAA section 110(a)(1) and (2) for the ozone and $PM_{2.5}$ NAAQS for various states across the country. Commenters on EPA's recent proposals for some states raised concerns about EPA statements that it was not addressing certain substantive issues in the context of acting on those infrastructure SIP submissions.[1] Those commenters specifically raised concerns involving provisions in existing SIPs and with EPA's statements in other proposals that it would address two issues separately and not as part of actions on the infrastructure SIP submissions: (i) Existing provisions related to excess emissions during periods of start-up, shutdown, or malfunction (SSM) at sources, that may be contrary to the CAA and EPA's policies addressing such excess emissions; and (ii) existing provisions related to ''director's variance'' or ''director's discretion'' that purport to permit revisions to SIP approved emissions limits with limited public process or without requiring further approval by EPA, that may be contrary to the CAA. EPA notes that there are two other substantive issues for which EPA likewise stated in other proposals that it would address the issues separately: (i) Existing provisions for minor source new source review (''minor source NSR'') programs that may be inconsistent with the requirements of the CAA and EPA's regulations that pertain to such programs and (ii) existing provisions for Prevention of Significant Deterioration (PSD) programs that may be inconsistent with current requirements of EPA's ''Final NSR Improvement Rule,'' (67 FR 80186, December 31, 2002), as amended by the NSR Reform Rule (72 FR 32526, June 13, 2007) (NSR Reform). In light of the comments, EPA now believes that its statements in various proposed actions on infrastructure SIPs with respect to these four individual issues should be explained in greater depth.

EPA intended the statements in the other proposals concerning these four issues merely to be informational and to provide general notice of the potential existence of provisions within the existing SIPs of some states that might require future corrective action. EPA did not want states, regulated entities, or members of the public to be under the misconception that EPA's approval of the infrastructure SIP submission of a given state should be interpreted as a reapproval of certain types of provisions that might be contained in the larger existing SIP for such state. Thus, for example, EPA explicitly noted that we believe that some states may have existing SIP approved SSM provisions that are contrary to the CAA and EPA policy, but that ''in this rulemaking, EPA is not proposing to approve or disapprove any existing State provisions with regard to excess emissions during SSM of operations at facilities.'' EPA further explained, for informational purposes, that ''EPA plans to address such State regulations in the future.'' EPA made similar statements, for similar reasons, with respect to the director's discretion, minor source NSR, and NSR Reform issues. EPA's objective

[1] See, Comments of Midwest Environmental Defense Center, dated May 31, 2011. Docket # EPA–R05–OAR–2007–1179 (adverse comments on proposals for three states in Region 5). EPA notes that these public comments on another proposal are not relevant to this rulemaking and do not have to be directly addressed in this rulemaking. EPA will respond to these comments in the appropriate rulemaking action to which they apply.

was to make clear that approval of an infrastructure SIP for these ozone and $PM_{2.5}$ NAAQS should not be construed as explicit or implicit reapproval of any existing provisions that relate to these four substantive issues.

The commenters and others evidently interpreted these statements to mean that EPA considered action upon the SSM provisions and the other three substantive issues to be integral parts of acting on an infrastructure SIP submission, and therefore that EPA was merely postponing taking final action on the issue in the context of the infrastructure SIPs. This was not EPA's intention. To the contrary, EPA only meant to convey its awareness of the potential for certain types of deficiencies in existing SIPs and to prevent any misunderstanding that it was reapproving any such existing provisions. EPA's intention was to convey its position that the statute does not require that infrastructure SIPs address these specific substantive issues in existing SIPs and that these issues may be dealt with separately, outside the context of acting on the infrastructure SIP submission of a state. To be clear, EPA did not mean to imply that it was not taking a full final agency action on the infrastructure SIP submission with respect to any substantive issue that EPA considers to be a required part of acting on such submissions under section 110(k) or under section 110(c). Given the confusion evidently resulting from EPA's statements in those proposals, however, we want to explain more fully EPA's reasons for concluding that these four potential substantive issues in existing SIPs may be addressed separately.

The requirement for the SIP submissions at issue arises out of CAA section 110(a)(1). That provision requires that states must make a SIP submission ''within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national primary ambient air quality standard (or any revision thereof)'' and that these SIPs are to provide for the ''implementation, maintenance, and enforcement'' of such NAAQS. Section 110(a)(2) includes a list of specific elements that ''[e]ach such plan'' submission must meet. EPA has historically referred to these particular submissions that states must make after the promulgation of a new or revised NAAQS as ''infrastructure SIPs.'' This specific term does not appear in the statute, but EPA uses the term to distinguish this particular type of SIP submission designed to address basic structural requirements of a SIP from other types of SIP submissions designed to address other different requirements, such as ''nonattainment SIP'' submissions required to address the nonattainment planning requirements of part D, ''regional haze SIP'' submissions required to address the visibility protection requirements of CAA section 169A, new source review permitting program submissions required to address the requirements of part D, and a host of other specific types of SIP submissions that address other specific matters.

Although section 110(a)(1) addresses the timing and general requirements for these infrastructure SIPs and section 110(a)(2) provides more details concerning the required contents of these infrastructure SIPs, EPA believes that many of the specific statutory provisions are facially ambiguous. In particular, the list of required elements provided in section 110(a)(2) contains a wide variety of disparate provisions, some of which pertain to required legal authority, some of which pertain to required substantive provisions, and some of which pertain to requirements for both authority and substantive provisions.[2] Some of the elements of section 110(a)(2) are relatively straightforward, but others clearly require interpretation by EPA through rulemaking, or recommendations through guidance, in order to give specific meaning for a particular NAAQS.[3]

Notwithstanding that section 110(a)(2) states that ''each'' SIP submission must meet the list of requirements therein, EPA has long noted that this literal reading of the statute is internally inconsistent, insofar as section 110(a)(2)(I) pertains to nonattainment SIP requirements that could not be met on the schedule provided for these SIP submissions in section 110(a)(1).[4] This illustrates that EPA must determine which provisions of section 110(a)(2) may be applicable for a given infrastructure SIP submission. Similarly, EPA has previously decided that it could take action on different parts of the larger, general ''infrastructure SIP'' for a given NAAQS without concurrent action on all subsections, such as section 110(a)(2)(D)(i), because EPA bifurcated the action on these latter ''interstate transport'' provisions within section 110(a)(2) and worked with states to address each of the four prongs of section 110(a)(2)(D)(i) with substantive administrative actions proceeding on different tracks with different schedules.[5] This illustrates that EPA may conclude that subdividing the applicable requirements of section 110(a)(2) into separate SIP actions may sometimes be appropriate for a given NAAQS where a specific substantive action is necessitated, beyond a mere submission addressing basic structural aspects of the state's SIP. Finally, EPA notes that not every element of section 110(a)(2) would be relevant, or as relevant, or relevant in the same way, for each new or revised NAAQS and the attendant infrastructure SIP submission for that NAAQS. For example, the monitoring requirements that might be necessary for purposes of section 110(a)(2)(B) for one NAAQS could be very different than what might be necessary for a different pollutant. Thus, the content of an infrastructure SIP submission to meet this element from a state might be very different for an entirely new NAAQS, versus a minor revision to an existing NAAQS.[6]

Similarly, EPA notes that other types of SIP submissions required under the statute also must meet the requirements of section 110(a)(2), and this also demonstrates the need to identify the applicable elements for other SIP submissions. For example, nonattainment SIPs required by part D

[2] For example, section 110(a)(2)(E) provides that states must provide assurances that they have adequate legal authority under state and local law to carry out the SIP; section 110(a)(2)(C) provides that states must have a substantive program to address certain sources as required by part C of the CAA; section 110(a)(2)(G) provides that states must have both legal authority to address emergencies and substantive contingency plans in the event of such an emergency.

[3] For example, section 110(a)(2)(D)(i) requires EPA to be sure that each state's SIP contains adequate provisions to prevent significant contribution to nonattainment of the NAAQS in other states. This provision contains numerous terms that require substantial rulemaking by EPA in order to determine such basic points as what constitutes significant contribution. See, *e.g.,* ''Rule To Reduce Interstate Transport of Fine Particulate Matter and Ozone (Clean Air Interstate Rule); Revisions to Acid Rain Program; Revisions to the nitrogen oxides (NO_x) SIP Call; Final Rule,'' (70 FR 25162, May 12, 2005) (defining, among other things, the phrase ''contribute significantly to nonattainment'').

[4] See, *e.g., Id.,* (70 FR 25162, at 63–65, May 12, 2005) (explaining relationship between timing requirement of section 110(a)(2)(D) versus section 110(a)(2)(I)).

[5] EPA issued separate guidance to states with respect to SIP submissions to meet section 110(a)(2)(D)(i) for the 1997 ozone and 1997 $PM_{2.5}$ NAAQS. See, ''Guidance for State Implementation Plan (SIP) Submissions to Meet Current Outstanding Obligations Under Section 110(a)(2)(D)(i) for the 8-Hour Ozone and $PM_{2.5}$ National Ambient Air Quality Standards,'' from William T. Harnett, Director Air Quality Policy Division OAQPS, to Regional Air Division Director, Regions I–X, dated August 15, 2006.

[6] For example, implementation of the 1997 $PM_{2.5}$ NAAQS required the deployment of a system of new monitors to measure ambient levels of that new indicator species for the new NAAQS.

likewise have to meet the relevant subsections of section 110(a)(2) such as section 110(a)(2)(A) or (E). By contrast, it is clear that nonattainment SIPs would not need to meet the portion of section 110(a)(2)(C) that pertains to part C, *i.e.,* the PSD requirements applicable in attainment areas. Nonattainment SIPs required by part D also would not need to address the requirements of section 110(a)(2)(G) with respect to emergency episodes, as such requirements would not be limited to nonattainment areas. As this example illustrates, each type of SIP submission may implicate some subsections of section 110(a)(2) and not others.

Given the potential for ambiguity of the statutory language of section 110(a)(1) and (2), EPA believes that it is appropriate for EPA to interpret that language in the context of acting on the infrastructure SIPs for a given NAAQS. Because of the inherent ambiguity of the list of requirements in section 110(a)(2), EPA has adopted an approach in which it reviews infrastructure SIPs against this list of elements ''as applicable.'' In other words, EPA assumes that Congress could not have intended that each and every SIP submission, regardless of the purpose of the submission or the NAAQS in question, would meet each of the requirements, or meet each of them in the same way. EPA elected to use guidance to make recommendations for infrastructure SIPs for these NAAQS.

On October 2, 2007, EPA issued guidance making recommendations for the infrastructure SIP submissions for both the 1997 8-hour ozone NAAQS and the 1997 $PM_{2.5}$ NAAQS.[7] Within this guidance document, EPA described the duty of states to make these submissions to meet what EPA characterized as the ''infrastructure'' elements for SIPs, which it further described as the ''basic SIP requirements, including emissions inventories, monitoring, and modeling to assure attainment and maintenance of the standards.''[8] As further identification of these basic structural SIP requirements, ''attachment A'' to the guidance document included a short description of the various elements of section 110(a)(2) and additional information about the types of issues that EPA considered germane in the context of such infrastructure SIPs. EPA emphasized that the description of the basic requirements listed on attachment A was not intended ''to constitute an interpretation of'' the requirements and was merely a ''brief description of the required elements.''[9] EPA also stated its belief that with one exception, these requirements were ''relatively self explanatory, and past experience with SIPs for other NAAQS should enable states to meet these requirements with assistance from EPA Regions.''[10] For the one exception to that general assumption, however, *i.e.,* how states should proceed with respect to the requirements of section 110(a)(2)(G) for the 1997 $PM_{2.5}$ NAAQS, EPA gave much more specific recommendations. But for other infrastructure SIP submittals, and for certain elements of the submittals for the 1997 $PM_{2.5}$ NAAQS, EPA assumed that each state would work with its corresponding EPA regional office to refine the scope of a state's submittal based on an assessment of how the requirements of section 110(a)(2) should reasonably apply to the basic structure of the state's SIP for the NAAQS in question.

On September 25, 2009, EPA issued guidance to make recommendations to states with respect to the infrastructure SIPs for the 2006 $PM_{2.5}$ NAAQS.[11] In the 2009 Guidance, EPA addressed a number of additional issues that were not germane to the infrastructure SIPs for the 1997 8-hour ozone and 1997 $PM_{2.5}$ NAAQS, but were germane to these SIP submissions for the 2006 $PM_{2.5}$ NAAQS, *e.g.,* the requirements of section 110(a)(2)(D)(i) that EPA had bifurcated from the other infrastructure elements for those specific 1997 ozone and $PM_{2.5}$ NAAQS.

Significantly, neither the 2007 Guidance nor the 2009 Guidance explicitly referred to the SSM, director's discretion, minor source NSR, or NSR Reform issues as among specific substantive issues EPA expected states to address in the context of the infrastructure SIPs, nor did EPA give any more specific recommendations with respect to how states might address such issues even if they elected to do so. The SSM and director's discretion issues implicate section 110(a)(2)(A), and the minor source NSR and NSR Reform issues implicate section 110(a)(2)(C). In the 2007 Guidance, however, EPA did not indicate to states that it intended to interpret these provisions as requiring a substantive submission to address these specific issues in the context of the infrastructure SIPs for these NAAQS. Instead, EPA's 2007 Guidance merely indicated its belief that the states should make submissions in which they established that they have the basic SIP structure necessary to implement, maintain, and enforce the NAAQS. EPA believes that states can establish that they have the basic SIP structure, notwithstanding that there may be potential deficiencies within the existing SIP. Thus, EPA's other proposals mentioned these issues not because EPA considers them issues that must be addressed in the context of an infrastructure SIP as required by section 110(a)(1) and (2), but rather because EPA wanted to be clear that it considers these potential existing SIP problems as separate from the pending infrastructure SIP actions.

EPA believes that this approach to the infrastructure SIP requirement is reasonable, because it would not be feasible to read section 110(a)(1) and (2) to require a top to bottom, comprehensive, review of each and every provision of an existing SIP merely for purposes of assuring that the state in question has the basic structural elements for a functioning SIP for a new or revised NAAQS. Because SIPs have grown by accretion over the decades as statutory and regulatory requirements under the CAA have evolved, they may include some outmoded provisions and historical artifacts that, while not fully up to date, nevertheless may not pose a significant problem for the purposes of ''implementation, maintenance, and enforcement'' of a new or revised NAAQS when EPA considers the overall effectiveness of the SIP. To the contrary, EPA believes that a better approach is for EPA to determine which specific SIP elements from section 110(a)(2) are applicable to an infrastructure SIP for a given NAAQS, and to focus attention on those elements that are most likely to need a specific SIP revision in light of the new or revised NAAQS. Thus, for example, EPA's 2007 Guidance specifically directed states to focus on the requirements of section 110(a)(2)(G) for the 1997 $PM_{2.5}$ NAAQS because of the absence of underlying EPA regulations for emergency episodes for this NAAQS and an anticipated absence of relevant provisions in existing SIPs.

[7] See, ''Guidance on SIP Elements Required Under Section 110(a)(1) and (2) for the 1997 8-hour Ozone and $PM_{2.5}$ National Ambient Air Quality Standards,'' from William T. Harnett, Director Air Quality Policy Division, to Air Division Directors, Regions I—X, dated October 2, 2007 (the ''2007 Guidance'').

[8] *Id.,* at page 2.

[9] *Id.,* at attachment A, page 1.

[10] *Id.,* at page 4. In retrospect, the concerns raised by commenters with respect to EPA's approach to some substantive issues indicates that the statute is not so ''self explanatory,'' and indeed is sufficiently ambiguous that EPA needs to interpret it in order to explain why these substantive issues do not need to be addressed in the context of infrastructure SIPs and may be addressed at other times and by other means.

[11] See, ''Guidance on SIP Elements Required Under Sections 110(a)(1) and (2) for the 2006 24-Hour Fine Particle ($PM_{2.5}$) National Ambient Air Quality Standards (NAAQS),'' from William T, Harnett, Director Air Quality Policy Division, to Regional Air Division Directors, Regions I—X, dated September 25, 2009 (the ''2009 Guidance'').

Finally, EPA believes that its approach is a reasonable reading of section 110(a)(1) and (2) because the statute provides other avenues and mechanisms to address specific substantive deficiencies in existing SIPs. These other statutory tools allow EPA to take appropriate tailored action, depending upon the nature and severity of the alleged SIP deficiency. Section 110(k)(5) authorizes EPA to issue a ''SIP call'' whenever EPA determines that a state's SIP is substantially inadequate to attain or maintain the NAAQS, to mitigate interstate transport, or otherwise to comply with the CAA.[12] Section 110(k)(6) authorizes EPA to correct errors in past actions, such as past approvals of SIP submissions.[13] Significantly, EPA's determination that an action on the infrastructure SIP is not the appropriate time and place to address all potential existing SIP problems does not preclude EPA's subsequent reliance on provisions in section 110(a)(2) as part of the basis for action at a later time. For example, although it may not be appropriate to require a state to eliminate all existing inappropriate director's discretion provisions in the course of acting on the infrastructure SIP, EPA believes that section 110(a)(2)(A) may be among the statutory bases that EPA cites in the course of addressing the issue in a subsequent action.[14]

III. Summary of SIP Revision

The submittals referenced in the Background section above address the infrastructure elements specified in the CAA section 110(a)(2). These submittals refer to the implementation, maintenance, and enforcement of the 1997 8-hour ozone NAAQS, the 1997 $PM_{2.5}$ NAAQS, and the 2006 $PM_{2.5}$ NAAQS. The rationale supporting EPA's proposed action is explained in the NPR and the technical support document (TSD) and will not be restated here. The TSD is available online at *http://www.regulations.gov,* Docket ID number EPA–R03–OAR–2010–0160. No public comments were received on the NPR.

IV. General Information Pertaining to SIP Submittals from the Commonwealth of Virginia

In 1995, Virginia adopted legislation that provides, subject to certain conditions, for an environmental assessment (audit) ''privilege'' for voluntary compliance evaluations performed by a regulated entity. The legislation further addresses the relative burden of proof for parties either asserting the privilege or seeking disclosure of documents for which the privilege is claimed. Virginia's legislation also provides, subject to certain conditions, for a penalty waiver for violations of environmental laws when a regulated entity discovers such violations pursuant to a voluntary compliance evaluation and voluntarily discloses such violations to the Commonwealth and takes prompt and appropriate measures to remedy the violations. Virginia's Voluntary Environmental Assessment Privilege Law, Va. Code Sec. 10.1–1198, provides a privilege that protects from disclosure documents and information about the content of those documents that are the product of a voluntary environmental assessment. The Privilege Law does not extend to documents or information (1) That are generated or developed before the commencement of a voluntary environmental assessment; (2) that are prepared independently of the assessment process; (3) that demonstrate a clear, imminent and substantial danger to the public health or environment; or (4) that are required by law.

On January 12, 1998, the Commonwealth of Virginia Office of the Attorney General provided a legal opinion that states that the Privilege Law, Va. Code Sec. 10.1–1198, precludes granting a privilege to documents and information ''required by law,'' including documents and information ''required by Federal law to maintain program delegation, authorization or approval,'' since Virginia must ''enforce Federally authorized environmental programs in a manner that is no less stringent than their Federal counterparts. * * *'' The opinion concludes that ''[r]egarding § 10.1–1198, therefore, documents or other information needed for civil or criminal enforcement under one of these programs could not be privileged because such documents and information are essential to pursuing enforcement in a manner required by Federal law to maintain program delegation, authorization or approval.''

Virginia's Immunity Law, Va. Code Sec. 10.1–1199, provides that ''[t]o the extent consistent with requirements imposed by Federal law,'' any person making a voluntary disclosure of information to a state agency regarding a violation of an environmental statute, regulation, permit, or administrative order is granted immunity from administrative or civil penalty. The Attorney General's January 12, 1998 opinion states that the quoted language renders this statute inapplicable to enforcement of any Federally authorized programs, since ''no immunity could be afforded from administrative, civil, or criminal penalties because granting such immunity would not be consistent with Federal law, which is one of the criteria for immunity.''

Therefore, EPA has determined that Virginia's Privilege and Immunity statutes will not preclude the Commonwealth from enforcing its program consistent with the Federal requirements. In any event, because EPA has also determined that a state audit privilege and immunity law can affect only state enforcement and cannot have any impact on Federal enforcement authorities, EPA may at any time invoke its authority under the CAA, including, for example, sections 113, 167, 205, 211 or 213, to enforce the requirements or prohibitions of the state plan, independently of any state enforcement effort. In addition, citizen enforcement under section 304 of the CAA is likewise unaffected by this, or any, state audit privilege or immunity law.

V. Final Action

EPA is approving the Commonwealth of Virginia's submittals that provide the basic program elements specified in CAA sections 110(a)(2)(A), (B), (C), (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M), or portions thereof, necessary to implement, maintain, and enforce the 1997 8-hour ozone and $PM_{2.5}$ NAAQS and the 2006 $PM_{2.5}$ NAAQS.

EPA made completeness findings for the 1997 8-hour ozone NAAQS on March 27, 2008 (73 FR 16205) and on October 22, 2008 (73 FR 62902) for the 1997 $PM_{2.5}$ NAAQS. These findings pertained only to whether the submissions were complete, pursuant to section 110(k)(1)(A), and did not

[12] EPA has recently issued a SIP call to rectify a specific SIP deficiency related to the SSM issue. See, ''Finding of Substantial Inadequacy of Implementation Plan; Call for Utah State Implementation Plan Revision,'' (74 FR 21639, April 18, 2011).

[13] EPA has recently utilized this authority to correct errors in past actions on SIP submissions related to PSD programs. See, ''Limitation of Approval of Prevention of Significant Deterioration Provisions Concerning Greenhouse Gas Emitting-Sources in State Implementation Plans; Final Rule,'' (75 FR 82536, Dec. 30, 2010). EPA has previously used its authority under CAA 110(k)(6) to remove numerous other SIP provisions that EPA determined it had approved in error. See, *e.g.,* (61 FR 38664, July 25, 1996) and (62 FR 34641, June 27, 1997) (corrections to American Samoa, Arizona, California, Hawaii, and Nevada SIPs); (69 FR 67062, November 16, 2004) (corrections to California SIP); and (74 FR 57051, November 3, 2009) (corrections to Arizona and Nevada SIPs).

[14] EPA has recently disapproved a SIP submission from Colorado on the grounds that it would have included a director's discretion provision inconsistent with CAA requirements, including section 110(a)(2)(A). See, *e.g.,* (75 FR 42342- 42344, July 21, 2010) (proposed disapproval of director's discretion provisions); (76 FR 4540, Jan. 26, 2011) (final disapproval of such provisions).

constitute EPA approval or disapproval of such submissions. The Virginia submittals, described above and in the technical support document, addressed these findings, with the exception of the part C PSD permit program.

EPA has taken separate action on the portions of section 110(a)(2)(C) and (J) for the 1997 8-hour ozone NAAQS as they relate to Virginia's part C PSD permit program. With respect to this permit program, on November 29, 2005 (70 FR 71612), EPA promulgated a change that made NO_X a precursor for ozone in the part C regulations at 40 CFR 51.166 and 40 CFR 52.21. In the March 27, 2008 completeness findings, EPA determined that Virginia failed to submit a SIP revision to its part C PSD permit program to fully incorporate NO_X as a precursor for ozone. On June 7, 2010, Virginia submitted revisions to it PSD regulation, 9VAC5 Chapter 80, to include NO_X as a precursor for ozone. EPA has approved this PSD SIP revision and element 110(a)(2)(C) and (J) as it pertains to the PSD permit program for the 1997 8-hour ozone NAAQS was addressed in this separate action (76 FR 54706, September 2, 2011).

Two elements identified in section 110(a)(2) are not governed by the three year submission deadline of section 110(a)(1) because SIPs incorporating necessary local nonattainment area controls are not due within three years after promulgation of a new or revised NAAQS, but rather are due at the time the nonattainment area plan requirements are due pursuant to section 172. This action does not cover these specific elements. This action also does not address the requirements of section 110(a)(2)(D)(i) for the 1997 8-hour ozone and $PM_{2.5}$ NAAQS and the 2006 $PM_{2.5}$ NAAQS. The 110(a)(2)(D)(i)(I) requirements have been addressed by separate findings issued by EPA (70 FR 21147, April 25, 2005 and 75 FR 32673, June 9, 2010), and a federal implementation plan (FIP) (75 FR 45210, August 2, 2010). The 110(a)(2)(D)(i)(II) portion of these requirements are addressed through 110(a)(2) SIP submittals that EPA will take separate action on.

VI. Statutory and Executive Order Reviews

A. General Requirements

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

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 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 the requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

B. Submission to Congress and the Comptroller General

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).

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by December 12, 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 pertaining to Virginia's section 110(a)(2) infrastructure SIP submittals for the 1997 8-hour ozone and $PM_{2.5}$ NAAQS, and the 2006 $PM_{2.5}$ NAAQS, 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, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: September 27, 2011.

W. C. Early,

Acting Regional Administrator, Region III.

40 CFR Part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for 40 CFR part 52 continues to read as follows:

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

Subpart VV—Virginia

■ 2. In § 52.2420, the table in paragraph (e) is amended by adding entries at the end of the table for Section 110(a)(2) Infrastructure Requirements for the 1997 8–Hour Ozone NAAQS, Section 110(a)(2) Infrastructure Requirements for the 1997 $PM_{2.5}$ NAAQS, and Section 110(a)(2) Infrastructure Requirements for the 2006 $PM_{2.5}$ NAAQS. The amendments read as follows:

§ 52.2420 Identification of plan.

* * * * *

(e) * * *

Name of non-regulatory SIP revision	Applicable geographic area	State submittal date	EPA approval date	Additional explanation
*	*	*	*	*
Section 110(a)(2) Infrastructure Requirements for the 1997 8–Hour Ozone NAAQS.	Statewide	12/10/07 12/13/07 6/8/10 6/9/10	10/11/11 *[Insert page number where the document begins]*.	This action addresses the following CAA elements or portions thereof: 110(a)(2)(A), (B), (C), (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M).
Section 110(a)(2) Infrastructure Requirements for the. 1997 $PM_{2.5}$ NAAQS	Statewide	7/10/08 9/2/08 6/8/10 6/9/10 4/1/08	10/11/11 *[Insert page number where the document begins]*.	This action addresses the following CAA elements or portions thereof: 110(a)(2)(A), (B), (C), (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M).
Section 110(a)(2) Infrastructure Requirements for the 2006 $PM_{2.5}$ NAAQS.	Statewide	8/30/10 4/1/11	10/11/11 *[Insert page number where the document begins]*.	This action addresses the following CAA elements or portions thereof: 110(a)(2)(A), (B), (C), (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M).

[FR Doc. 2011–26095 Filed 10–7–11; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2011–0454; FRL9477–5]

Approval and Promulgation of Air Quality Implementation Plans; West Virginia; Determination of Attainment and Determination of Clean Data for the Annual 1997 Fine Particle Standard for the Charleston Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is making two determinations regarding the Charleston, West Virginia fine particulate matter ($PM_{2.5}$) nonattainment area (hereafter referred to as ''Charleston Area'' or ''Area''). First, EPA is determining that the Area has attained the 1997 annual average $PM_{2.5}$ National Ambient Air Quality Standard (NAAQS). This determination of attainment is based upon complete, quality-assured, and certified ambient air monitoring data for the 2007–2009 period showing that the Charleston Area has attained the 1997 annual $PM_{2.5}$ NAAQS and data available to date for 2010 in EPA's Air Quality System (AQS) database that show the area continues to attain. EPA's determination releases the Charleston Area from the requirements to submit attainment demonstrations and associated reasonably available control measures (RACM), a reasonable further progress (RFP) plan, contingency measures, and other planning State Implementation Plan (SIP) revisions related to attainment of the standard for so long as the Area continues to attain the annual $PM_{2.5}$ NAAQS. Second, EPA is determining based on quality-assured and certified monitoring data for the 2007–2009 monitoring period that the area has attained the 1997 annual $PM_{2.5}$ NAAQS, by its applicable attainment date of April 5, 2010.

DATES: *Effective Date:* This final rule is effective on November 10, 2011.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2011–0454. All documents in the docket are listed in the *http://www.regulations.gov* website. Although listed in the electronic docket, some information is not publicly available, *i.e.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as 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 through *http://www.regulations.gov* or in hard copy for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

FOR FURTHER INFORMATION CONTACT: Asrah Khadr, (215) 814–2071, or by e-mail at *khadr.asrah@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What actions is EPA taking?
II. What are the effects of these actions?
III. Statutory and Executive Order Reviews.

I. What actions is EPA taking?

In accordance with section 179(c)(1) of the Clean Air Act (CAA), 42 U.S.C. section 7509(c)(1), and 40 Code of Federal Regulations (CFR) section 51.1004(c), EPA is determining that the Charleston Area (composed of Kanawha and Putnam Counties) has attained the 1997 annual $PM_{2.5}$ NAAQS. This action is based upon complete, quality-assured, and certified ambient air monitoring data for the 2007–2009 monitoring period that show that the Area has monitored attainment of the 1997 annual $PM_{2.5}$ NAAQS and data available to date for 2010 that show the Area continues to attain. EPA is also determining, in accordance with EPA's $PM_{2.5}$ Implementation Rule of April 25, 2007 (72 FR 20664), that the Charleston Area has attained the 1997 annual $PM_{2.5}$ NAAQS by its applicable attainment date of April 5, 2010.

EPA published in the **Federal Register** its proposed determination for the Charleston Area on July 15, 2011 (76 FR 41739). A discussion of the rationale behind this determination and the effect of the determination was included in the notice of proposed rulemaking. EPA received no comments on this notice of proposed rulemaking.

II. What are the effects of these actions?

In determining the Charleston Area attained the 1997 annual $PM_{2.5}$ standard by its applicable attainment date (April 5, 2010), EPA has met its requirement pursuant to 179(c)(1) of the CAA to make a determination based on the Area's air quality data as of the attainment date whether the Area attained the standard by that date. This action does not constitute a redesignation of the Area to attainment of the 1997 annual $PM_{2.5}$ NAAQS under section 107(d)(3) of the CAA. Further, this action does not involve approving maintenance plans for the Area as required under section 175A of the CAA, nor does it find that the Area has met all other requirements for redesignation. Even after a determination of attainment by EPA, the designation status of the Charleston Area is nonattainment for the 1997 annual $PM_{2.5}$ NAAQS until such time as EPA determines that the Area meets the CAA requirements for redesignation to

attainment and takes action to redesignate the Charleston Area.

EPA's clean data determination releases the Charleston Area from the requirement to submit an attainment demonstration and associated RACM, a RFP plan, contingency measures, and any other planning SIPs related to attainment of the 1997 annual $PM_{2.5}$ NAAQS for so long as the Charleston Area continues to attain the 1997 annual $PM_{2.5}$ NAAQS. *See* 40 CFR 51.1004(c).

After a final clean data determination, if EPA determines that the Area has violated the 1997 annual $PM_{2.5}$ NAAQS, the basis for the suspension of the specific requirements would no longer exist for the Charleston Area and it would thereafter have to address the applicable requirements. *See* 40 CFR 51.1004(c). The two actions regarding the Charleston Area's attainment are only with respect to the 1997 annual $PM_{2.5}$ NAAQS. Today's actions do not address the 24-hour $PM_{2.5}$ NAAQS.

III. Statutory and Executive Order Reviews

A. General Requirements

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

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

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

B. Submission to Congress and the Comptroller General

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).

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by December 12, 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 pertaining to the determination of attainment and clean data determination for the Charleston Area 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, Particulate matter, Reporting and recordkeeping requirements.

Dated: September 27, 2011.

W. C. Early,

Acting, Regional Administrator, Region III.

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 XX—West Virginia

■ 2. In § 52.2526, paragraph (e) is added to read as follows:

§ 52.2526 Control strategy: Particulate matter.

* * * * *

(e) Determination of Attainment. EPA has determined, as of October 11, 2011, that based on 2007 to 2009 ambient air quality data, the Charleston nonattainment area has attained the 1997 annual $PM_{2.5}$ NAAQS. This determination, in accordance with 40 CFR 52.1004(c), suspends the requirements for this area to submit an attainment demonstration, associated reasonably available control measures, a reasonable further progress plan, contingency measures, and other planning SIPs related to attainment of the standard for as long as this area continues to meet the 1997 annual $PM_{2.5}$ NAAQS.

■ 3. In § 52.2527, paragraph (c) is added to read as follows:

§ 52.2527 Determination of attainment.

* * * * *

(c) Based upon EPA's review of the air quality data for the 3-year period 2007–2009, EPA determined that the Charleston fine particle ($PM_{2.5}$) nonattainment area attained the 1997 annual $PM_{2.5}$ National Ambient Air Quality Standard (NAAQS) by the applicable attainment date of April 5, 2010. Therefore, EPA has met the requirement pursuant to CAA section 179(c) to determine, based on the area's air quality as of the attainment date, whether the area attained the standard. EPA also determined that the Charleston $PM_{2.5}$ nonattainment area is not subject to the consequences of failing to attain pursuant to section 179(d).

[FR Doc. 2011–26093 Filed 10–7–11; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 11–1432]

Digital Broadcast Television Redistribution Control; Corrections

AGENCY: Federal Communications Commission.

ACTION: Technical amendment.

SUMMARY: The Federal Communications Commission (FCC) is correcting a final rule that appeared in the **Federal Register** of September 9, 2011 [76 FR 55817]. The document removed broadcast flag rules that are without current legal effect and are obsolete. The document inadvertently removed unrelated rules contained in Subpart L of Part 73 of the Commission's rules. This document corrects that error.

DATES: Effective October 11, 2011.

FOR FURTHER INFORMATION CONTACT: For additional information on this proceeding, contact Katie Costello, *Katie.Costello@fcc.gov* of the Media Bureau, Policy Division, (202) 418–2233.

SUPPLEMENTARY INFORMATION: FR Doc. 2011–23010 published in the **Federal Register** on Friday, September 9, 2011, 76 FR 55817, inadvertently removed rules contained in Subpart L of Part 73. The following correcting amendments are made to restore those rules.

List of Subjects in 47 CFR Part 73

Incorporation by reference, Radio, Television.

Accordingly, 47 CFR part 73 is corrected by making the following correcting amendments:

PART 73—RADIO BROADCAST SERVICES

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

Authority: 47 U.S.C. 154, 303, 334, 336 and 339.

■ 2. Add Subpart L to read as follows:

Subpart L—Incorporated Standards

§ 73.8000 Incorporation by reference.

(a) The materials listed in this section are incorporated by reference in this part. These incorporations by reference were approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. These materials are incorporated as they exist on the date of the approval, and notice of any change in these materials will be published in the **Federal Register**. The materials are available for inspection at the Federal Communications Commission (FCC), 445 12th St., SW., Reference Information Center, Room CY–A257, Washington, DC 20554 and 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.*

(b) The following materials are available from Advanced Television Systems Committee (ATSC), 1750 K Street, NW., Suite 1200, Washington, DC 20006, or at the ATSC Web site: *http://www.atsc.org/standards.html.*

(1) ATSC A/52: ''ATSC Standard Digital Audio Compression (AC–3),'' 1995, IBR approved for § 73.682.

(2) ATSC A/53 Parts 1–4 and 6: 2007 ''ATSC Digital Television Standard,'' (January 3, 2007) and ATSC A/53 Part 5: 2010 ''ATSC Digital Television Standard: Part 5—AC–3 Audio System Characteristic,'' (July 6, 2010), as listed below:

(i) A/53, Part 1:2007, ''Digital Television System'' (January 3, 2007), IBR approved for § 73.682.

(ii) A/53, Part 2:2007, ''RF/Transmission System Characteristics'' (January 3, 2007), IBR approved for § 73.682.

(iii) A/53, Part 3:2007, ''Service Multiplex and Transport Subsystem Characteristics'' (January 3, 2007), IBR approved for § 73.682.

(iv) A/53, Part 4:2007, ''MPEG–2 Video System Characteristics'' (January 3, 2007), IBR approved for § 73.682, except for § 6.1.2 of A/53 Part 4: 2007, and the phrase ''see Table 6.2'' in section 6.1.1 Table 6.1 and section 6.1.3 Table 6.3.

(v) A/53, Part 5: 2010, ''AC–3 Audio System Characteristics'' (July 6, 2010), IBR approved for § 73.682.

(vi) A/53, Part 6:2007, ''Enhanced AC–3 Audio System Characteristics'' (January 3, 2007), IBR approved for § 73.682.

(3) [Reserved]

(4) ATSC A/65C: ''ATSC Program and System Information Protocol for Terrestrial Broadcast and Cable, Revision C With Amendment No. 1 dated May 9, 2006,'' (January 2, 2006), IBR approved for §§ 73.682.

(c) [Reserved]

(d) The following materials are available at the FCC, 445 12th St., SW., Reference Information Center, Room CY–A257, Washington, DC 20554, or at the FCC's Office of Engineering and Technology (OET) Web site: *http://www.fcc.gov/oet/info/documents/bulletins/.*

(1) OET Bulletin No. 69: ''Longley-Rice Methodology for Evaluating TV Coverage and Interference'' (February 6, 2004), IBR approved for § 73.616.

(2) [Reserved]

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

[FR Doc. 2011–25797 Filed 10–7–11; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

RIN 0648–XA694

Fisheries of the Northeastern United States; Tilefish Fishery; 2012 Tilefish Fishing Quota Specification

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

ACTION: Quota specification.

SUMMARY: NMFS announces that the overall annual tilefish quota for the 2012 fishing year will remain the same as it was in fishing year 2011. Regulations governing these fisheries require NMFS to notify the public in the **Federal Register** of the overall annual quota levels for tilefish if the previous year's quota specifications remain unchanged.

DATES: Effective November 1, 2011, through October 31, 2012.

FOR FURTHER INFORMATION CONTACT: Jason Berthiaume, Fishery Management Specialist, (978) 281–9177; fax (978) 281–9135.

SUPPLEMENTARY INFORMATION: The tilefish regulations at 50 CFR 648.292 specify that, in the absence of a new stock assessment or recommendation from the Tilefish Monitoring Committee, the previous year's tilefish specifications will remain effective for the following fishing year. The most recent tilefish stock assessment was completed in 2009, and the Tilefish Monitoring Committee has not taken any action to change the tilefish quota levels; therefore, the tilefish total allowable landings (TAL) for the 2012 fishing year will remain the same as the fishing year 2011 TAL of 1.995 million lb (904,917 kg). Five percent of the TAL (99,750 lb (45,246 kg)) is allocated to incidental catch, leaving 1,895,250 lb

(859,671 kg) to be allocated to Individual Fishing Quota holders.

Classification

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

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

Dated: October 4, 2011.

Steven Thur,

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

[FR Doc. 2011–26202 Filed 10–7–11; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 76, No. 196
Tuesday, October 11, 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.

DEPARTMENT OF ENERGY

10 CFR Part 430

Request To Consider Automatic Termination Controls

AGENCY: Office of the General Counsel, Department of Energy (DOE).

ACTION: Petition for rulemaking; request for comment.

SUMMARY: On September 8, 2011, the Department of Energy received a joint petition submitted by the Association of Home Appliance Manufacturers and the Appliance Standards Awareness Project, on behalf of a number of named parties requesting that the clothes dryer test procedure be amended to address the effectiveness of automatic termination controls such as moisture and temperature sensor controls. Public comment is requested on whether DOE should grant the petition and consider the proposal contained in the petition.

DATES: Comments must be postmarked no later than December 12, 2011.

ADDRESSES: Any comments submitted must reference the petition for rulemaking. Comments may be submitted using any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail: ResCDPetition-2011-PET-0062@ee.doe.gov.* Include ''Petition for Rulemaking'' in the subject line of the message.
- *Postal Mail:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, Mailstop EE–2J, 1000 Independence Avenue, SW., Washington, DC, 20585–0121. If possible, please submit all items on a CD. It is not necessary to include printed copies.
- *Hand Delivery/Courier:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, 950 L'Enfant Plaza, SW., Suite 600, Washington, DC, 20024. Telephone: (202) 586–2945. If possible, please submit all items on a CD. It is not necessary to include printed copies.

FOR FURTHER INFORMATION CONTACT: Stephen L.Witkowski, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Program, EE–2J, 1000 Independence Avenue, SW., Washington, DC, 20585–0121, (202) 586–7463, e-mail: *stephen.witkowski@ee.doe.gov.*

Ms. Elizabeth Kohl or Ms. Sarah Butler, U.S. Department of Energy, Office of General Counsel, GC–71, 1000 Independence Avenue, SW., Washington, DC, 20585–0121, (202) 586–7796, e-mail: *Elizabeth.Kohl@hq.doe.gov* or *Sarah.Butler@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: The Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.,* provides among other things, that ''[each] agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.'' (5 U.S.C. 553(e)). Pursuant to this provision of the APA, the Association of Home Appliance Manufacturers and the Appliance Standards Awareness Project, on behalf of a number of named parties, petitioned DOE to amend the test procedure for residential clothes dryers to include provisions related to automatic termination controls, as set forth below. In promulgating this petition for public comment, the DOE is seeking views on whether it should grant the petition and consider the proposal contained in the petition. By seeking comment on whether to grant this petition, the DOE takes no position at this time regarding the merits of the suggested amendment.

The proposed amendment sought in the petition would institute a procedure that addresses the effectiveness of automatic termination controls such as moisture and temperature sensor controls. The petitioners request that DOE test the full cycle of clothes dryers, including cool-down. The petitioners also request that the DOE modify the ending remaining moisture content (RMC) to require that the RMC be no more than 2 percent when testing units equipped with automatic termination controls using the DOE test load. This petition also requests that the DOE revise the relevant energy conservation standards under section 323 of the Energy Policy and Conservation Act to reflect the requested test procedure. The DOE seeks public comment on whether it should grant the petition.

DOE notes that it issued a Request for Information (RFI) to further investigate the effects of automatic cycle termination on the energy efficiency of clothes washers. (76 FR 50145, Aug. 12, 2011). The petition also served as a response to DOE's RFI.

Issued in Washington, DC, on October 4, 2011.

Sean A. Lev,

Acting General Counsel.

Set forth below is the full text of the Association of Home Appliance Manufacturers and the Appliance Standards Awareness Project petition:

Joint Petition to Amend the Test Procedure for Residential Clothes Dryers to Include Provisions Related to Automatic Termination Controls Docket No. EERE–2008–BT–TP–0010; RIN 1904–AC02 and Docket No. EERE–2011–BT–TP–0054, RIN 1904–AC63

September 8, 2011

Association of Home Appliance Manufacturers[1]
American Council for an Energy-Efficient Economy
Natural Resources Defense Council
Alliance to Save Energy
Alliance for Water Efficiency Appliance Standards Awareness Project Northwest Power and Conservation Council Northeast
Energy Efficiency Partnerships Consumer Federation of America
National Consumer Law Center

I. Introduction and Overview

As part of the agreement between the Joint Commenters on federal minimum energy conservation standards for five products, including residential clothes dryers, and related test procedures, ENERGY STAR, and financial incentive provisions, the Joint Commenters agreed that the Department of Energy (DOE) should amend the clothes dryer test procedure to address the effectiveness of automatic termination controls such as

[1] Representing the following companies who are members of the Major Appliance Division: Whirlpool, General Electric, Electrolux, LG Electronics, BSH, Alliance Laundry, Viking Range, Sub-Zero Wolf, Friedrich A/C, U–Line, Samsung, Sharp Electronics, Miele, Heat Controller, AGA Marvel, Brown Stove, Haier, Fagor America, Airwell Group, Arcelik, Fisher & Paykel, Scotsman Ice, Indesit, Kuppersbusch, Kelon, and DeLonghi.

moisture and temperature sensor controls. In its final test procedure, however, DOE declined to adopt proposed amendments to address automatic termination controls. The Joint Commenters estimate that energy savings of approximately 1.1 quads over 30 years can be achieved through a test procedure revision that accounts for such controls, and thus petition DOE to amend the clothes dryer test procedure to account for the effectiveness of automatic termination controls.[2] This petition also serves as joint comments in response to DOE's Request for Information on Test Procedures for Residential Clothes Dryers, Docket No. EERE–2011–BT–TP–0054, RIN 1904–AC63, 76 Fed Reg. 50145 (Aug. 12, 2011).

II. The Joint Stakeholders to and Supporters of the Agreement

The American Council for an Energy Efficient Economy (ACEEE) is a nonprofit, non-partisan, organization dedicated to advancing energy efficiency as a means of promoting economic prosperity, energy security, and environmental protection. ACEEE fulfills its mission by conducting in-depth technical and policy assessments; advising policymakers and program managers; working collaboratively with businesses, public interest groups, and other organizations; publishing books, conference proceedings, and reports; organizing conferences and workshops; and educating consumers and businesses.

The Association of Home Appliance Manufacturers (AHAM) represents manufacturers of major, portable and floor care home appliances, and suppliers to the industry. AHAM's membership includes over 150 companies throughout the world. In the U.S., AHAM members employ tens of thousands of people and produce more than 95% of the household appliances shipped for sale. The factory shipment value of these products is more than $30 billion annually. The home appliance industry, through its products and innovation, is essential to U.S. consumer lifestyle, health, safety and convenience. Through its technology, employees and productivity, the industry contributes significantly to U.S. jobs and economic security. Home appliances also are a success story in terms of energy efficiency and environmental protection. New appliances often represent the most effective choice a consumer can make to reduce home energy use and costs. AHAM represents the manufacturers of virtually all affected clothes dryers manufactured and/or sold in the United States.

The Alliance to Save Energy (ASE) is a coalition of prominent business, government, environmental, and consumer leaders who promote the efficient and clean use of energy worldwide to benefit consumers, the environment, economy, and national security. Established as an NGO in 1977, to carry out its mission, the Alliance undertakes research, educational programs, and policy advocacy, designs and implements energy-efficiency projects, promotes technology development and deployment, and builds public-private partnerships, in the U.S. and other countries.

The Alliance for Water Efficiency is a stakeholder-based 501(c)(3) non-profit organization dedicated to the efficient and sustainable use of water, with 317 member organizations from water utilities, government agencies, businesses, industry, plumbing, appliance and irrigation manufacturers, retailers, environmental and energy efficiency advocates, and other stakeholders. Located in Chicago, the Alliance serves as a North American advocate for water efficient products and programs, and provides information and assistance on water conservation efforts.

The Appliance Standards Awareness Project (ASAP) is a coalition group dedicated to advancing cost-effective energy efficiency standards for appliances and equipment. ASAP works at both the state and federal levels and is led by a Steering Committee with representatives from consumer groups, utilities, state government, environmental groups, and energy-efficiency groups.

The Consumer Federation of America is an association of nearly 300 nonprofit consumer groups that was established in 1968 to advance the consumer interest through research, advocacy, and education.

The National Consumer Law Center®, a nonprofit corporation founded in 1969, assists consumers, advocates, and public policy makers nationwide on consumer law issues. NCLC works toward the goal of consumer justice and fair treatment, particularly for those whose poverty renders them powerless to demand accountability from the economic marketplace. NCLC has provided model language and testimony on numerous consumer law issues before federal and state policy makers. NCLC publishes an 18-volume series of treatises on consumer law, and a number of publications for consumers.

The Natural Resources Defense Council (NRDC) is a national environmental advocacy organization with over 1.3 million members and online activists. NRDC has spent decades working to build and improve DOE's federal appliance standards programs because of the important energy, environmental, consumer, and reliability benefits of appliance efficiency standards. NRDC participated in the enactment of the first federal legislation establishing efficiency standards, and has been active in all significant rulemakings since then.

Northeast Energy Efficiency Partnerships (NEEP) is a non-profit organization that facilitates regional partnerships to advance the efficient use of energy in homes, buildings and industry in the Northeast U.S. NEEP works to leverage knowledge, capability, learning and funding through regionally coordinated policies, programs and practices. As a regional organization that collaborates with policy makers, energy efficient program administrators, and business, NEEP is a leader in the movement to build a cleaner environment and a more reliable and affordable energy system.

The Northwest Power and Conservation Council is an interstate compact between the states of Idaho, Montana, Oregon and Washington authorized by the Northwest Power Act of 1980 (PL96–501). The Council is charged with ensuring that the Northwest's electric power system will provide adequate and reliable energy at the lowest economic and environmental cost to its citizens.

Other supporters include the California Energy Commission, Demand Response and Smart Grid Coalition, and Earthjustice.

III. Background

DOE proposed to amend DOE's test procedure for clothes dryers to incorporate the individual test procedures for timer dryers and automatic termination control dryers in AS/NSZ Standard 2442 with a few modifications. DOE sought comment on the adequacy of AS/NSZ Standard 2442, along with proposed definitions and clarifications, to measure energy consumption for timer and automatic termination control clothes dryers to account for over-drying energy consumption. The Joint Commenters supported DOE's proposal to account for the effectiveness of automatic termination controls because it would have provided an incentive to

[2] EPCA section 323(b)(2) provides the process which DOE must follow in replying to a petition for a test procedure revision. The Administrative Procedure Act requires that ''[e]ach agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.'' 5 U.S.C. § 553(e).

manufacturers to design products that avoid over-drying. Although the Joint Stakeholders generally promote harmonization with international standards, the Joint Stakeholders did not agree that AS/NSZ Standard 2442 provided the best methods and procedures to account for the amount of over- drying associated with automatic termination control dryers beyond a specified RMC.

Instead, the Joint Stakeholders proposed that the procedure should be to test the *full cycle, including cool-down.* This procedure is more representative of consumer usage because it includes all of the energy use in a cycle. It is also reproducible and repeatable because it does not require any ''guesswork'' as to when the cool-down will begin. On the other hand, DOE's original proposal to stop the dryer when the heater switches off for the final time at the end of the drying cycle, i.e., immediately before the cool-down period begins, entails some guesswork that introduces variability into the test. The procedure the Joint Stakeholders' proposed is also less burdensome because it does not require the manufacturers to conduct multiple tests in order to determine the point immediately before cool-down for each model. Thus, the Joint Stakeholders argued that their proposal improved upon DOE's proposal in addressing over-drying by including cool-down.

Furthermore, for dryers that have both an automatic termination control cycle and a timer cycle, the Joint Stakeholders argued that only the automatic termination cycle should be tested.

Finally, the Joint Stakeholders argued that if DOE adopted the Joint Stakeholders' proposed test procedure, i.e., to test the full cycle including cool-down, it must also revise the relevant energy conservation standards to reflect the new test procedure, ensuring that for dryers with effective automatic termination controls, there is no change in the stringency of the standards, per section 323 of the Energy Policy and Conservation Act. Specifically, the Joint Stakeholders argued, the procedures in section 323(e)(2) should be used, with the clarification that for the purposes of establishing a representative sample of products, DOE should choose a sample of minimally compliant dryers which automatically terminate the drying cycle at no less than four percent RMC.

In the final test procedure, DOE declined to adopt the amendments it had proposed with regard to automatic termination controls (with or without the modifications proposed by the Joint Stakeholders). DOE determined, based on test results, that

given the load specified in the current DOE test procedure, the proposed automatic cycle termination control procedures may not adequately measure clothes dryer performance * * *. DOE believes that, although automatic termination control dryers may be measured as having a lower efficiency than a comparable dryer with only time termination control if tested according to the proposed test procedure, automatic termination control dryers may in fact be drying the clothing to approximately 5-percent RMC in real world use. DOE believes that automatic termination control dryers reduce energy consumption (by reducing over-drying) compared to timer dryers based on analysis of the AHAM field use survey and analysis of the field test data conducted by NIST. (76 Fed. Reg. 972, 1000 (Jan. 6, 2011)).

DOE also stated that if data were available to develop a test procedure that accurately measures the energy consumption of clothes dryers equipped with automatic termination controls, it could consider revised amendments to the test procedure. (Id.).

IV. **Proposal**

The Joint Stakeholders now present data to assist in the development of a test procedure that accurately measures the energy consumption of clothes dryers equipped with automatic termination controls, and request that DOE amend the clothes dryer test procedure to include procedures to account for automatic termination controls.

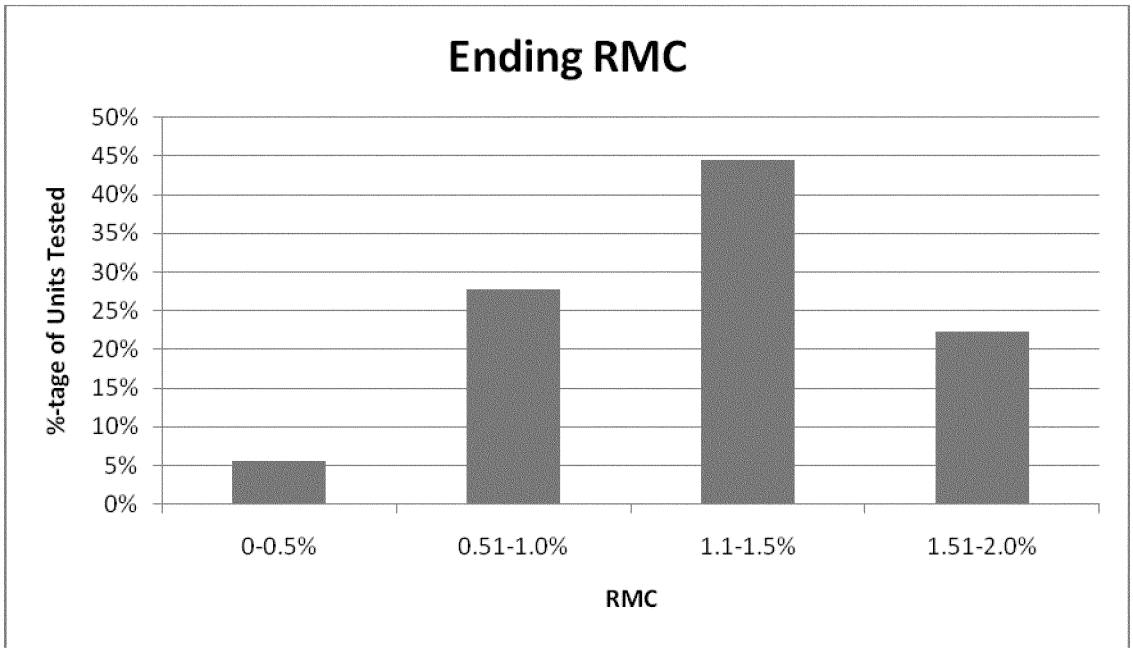
DOE was concerned that the proposed test procedure may not properly measure the effectiveness of automatic termination controls, particularly in light of data that suggested that automatic termination control dryers may in fact be drying clothing to approximately five percent remaining moisture content (RMC) in the real world. The Joint Stakeholders determined that the best way to address DOE's concern was to account for the fact that the test procedure has inherent differences from consumer use that are necessary for repeatability and reproducibility. The most significant difference between the test procedure and consumer use is the DOE test cloth, which does not represent a variety of cloth used by consumers. The DOE test cloth is uniform, whereas a consumer load contains items of varying weights, composition, and size. Thus, the DOE test cloth likely dries faster and more uniformly than an actual consumer load.

AHAM members conducted testing on clothes dryers with automatic termination controls that are currently on the market—the clothes dryers tested represent about 60 percent of shipments. Because there are few consumer complaints that clothes dryers equipped with automatic termination controls do not dry clothes, the testing assumed that the current market ending RMC is appropriate. The testing was conducted per the following conditions which closely approximated DOE's proposed test procedure, except that the entire cycle was tested, including cool-down:

- Test procedure: Existing DOE test procedure, not including most recent amendments.
- Starting RMC: 70% ± 3.5%.
- Test load: DOE load.
- Test runs: Three tests on each machine, average ending RMC reported to AHAM.
- Program: A ''normal'' program (cycle) shall be selected. Where the dryness level can be chosen independently of the program, the ''normal'' level shall be selected. Where the drying temperature (setting) can be chosen independently of the program, it shall be set to the maximum.
- Tests were run until the automatic termination controls stopped the clothes dryer (i.e., cool-down was included).
- Data was de-identified and aggregated by AHAM.

The test results, shown in Table 1, demonstrated that an ending RMC of two percent using the DOE test cloth best approximates the maximum, consumer accepted, ending RMC.

Figure 1



Based on this data, the Joint Stakeholders request that DOE adopt the test procedure amendments it previously proposed except that it should modify the proposal to state that testing will include the full cycle, including cool-down. As the Joint Stakeholders previously commented, and is discussed in more detail in Section III above, testing the entire cycle including cool-down is more representative of actual consumer use and is less of a test burden for manufacturers than DOE's original proposal to stop the dryer when the heater switches off for the final time at the end of the drying cycle. In addition, DOE should modify its original proposal to state that ending RMC when testing units equipped with automatic termination controls shall be no more than two percent when testing with the DOE test load. That maximum percentage, according to the data above, is representative of clothes dryers currently on the market. Consistent with DOE's proposal, but substituting two percent ending RMC for five percent ending RMC, any test cycle in which the final RMC is two percent or less should be considered valid. If the final RMC is greater than two percent, the test would be invalid and a new run would be conducted using the highest dryness level setting.

V. **Revision of Standards**

If DOE adopts the Joint Stakeholders' proposals in this petition, which would test the full cycle, including cool-down, and result in a change in measured energy, it must also revise the relevant energy conservation standards to reflect the new test procedure, ensuring that for dryers with effective automatic termination controls, there is no change in the stringency of the standards, per section 323 of the Energy Policy and Conservation Act. Specifically, the procedures in section 323(e)(2) should be used, with the clarification that for the purposes of establishing a representative sample of products, DOE should choose a sample of minimally compliant dryers which automatically terminate the drying cycle at 1.5 to 2 percent RMC. By selecting products that terminate at 1.5 to 2 percent, DOE will assure that the revised standard is based upon dryers which do not over-dry. This approach will also assure that the tested sample yields valid results under both the current and proposed revised test procedure.

We note that in the test procedures SNOPR, DOE stated that for the purposes of determining the effects of an amended test procedure on the measured efficiency of clothes dryers, the measurement of only clothes dryers that terminate the drying cycle at no less than a particular RMC would not constitute a representative sample.[3] If DOE continues to hold this view, the test procedure proposal in this petition should still be adopted. In that case, DOE could revise the standards without limiting the representative sample of dryers based on automatic termination performance. As described in the next section, that alternate approach would reduce, but not eliminate, the benefits from this test procedure change and, therefore, we urge DOE to reconsider its position.

VI. **Energy Savings Potential**

If DOE adopts the Joint Stakeholders' proposals in this petition, manufacturers will have an incentive to refine their automatic termination feature to terminate very close to two percent maximum ending RMC using the DOE test load. As Figure 1 demonstrates, a large percentage of clothes dryers currently on the market dry to levels below the proposed two percent ending RMC. As manufacturers make these refinements, two things will happen—the measured energy efficiency of the dryer will improve and the ''real world'' energy consumption of the dryer will be reduced. This is exactly what should happen as the result of such a change in the test procedure towards conditions that more closely replicate consumer use.

To estimate energy savings from the proposals for a test procedure amendment and a revision to the standards presented in this petition, we assume that the AHAM test load is representative of consumer loads. The DOE test data presented in the test procedures SNOPR showed that the maximum ending RMC using the

[3] 76 Fed. Reg. 1026 (January 6, 2011).

AHAM test load was five percent.[4] As noted above, the AHAM test data suggest that an ending RMC of two percent using the DOE test load best approximates the maximum, consumer accepted, ending RMC. We assume that an ending RMC of two percent with the DOE test load translates to an ending RMC of five percent using the AHAM test load, and we also assume that the average ending RMC using the DOE test load translates to the average ending RMC using the AHAM test load. The SNOPR data showed that the average over-drying energy consumption (i.e. energy consumed after the dryer reaches an RMC of five percent) using the AHAM test load based on the four models tested with a ''normal cycle'' and ''normal dryness'' was 0.18 kWh per cycle.[5] Based on this data, we estimate that a test procedure change and a revision to the standards as proposed in this petition would result in average per-unit energy savings of 0.18 kWh per cycle, or 51 kWh per year, and cumulative national energy savings of approximately 1.1 quads over 30 years.[6]

If DOE determines that it cannot limit the representative sample to dryers that terminate within a 1.5 to 2 percent RMC range for purposes of revising the standard levels, national energy savings would be reduced, but significant savings would still be achieved. Dryers with automatic termination controls that perform worse than average would need to improve such that they consume no more energy than an average dryer. DOE noted in the test procedures SNOPR that there is an exponential trend in the plot of energy consumption as a function of RMC below an RMC of about five percent likely because it becomes more difficult to remove the lesser amounts of moisture remaining in the load.[7] This exponential trend suggests that dryers that currently terminate at very low RMCs consume significant amounts of over-drying energy and that requiring dryers with poor automatic termination controls to improve such that they perform as well as an average dryer represents a significant savings opportunity.

We recognize that there are significant uncertainties in estimating energy savings from the proposed test procedure in this petition. However, energy savings will certainly be achieved by encouraging use of better automatic termination controls to reduce over-drying energy consumption. In addition, an amended test procedure as proposed in this petition would capture all the energy use of a dryer cycle, which would better represent real-world dryer energy consumption and allow manufacturers more options for improving rated dryer efficiency.

VII. **Timing**

We recommend that test procedure and standards revisions adopted in response to this petition take effect on January 1, 2015. Our goal is to have a single round of standards and test procedure changes take effect. Thus, these test procedure and related standards amendments would replace the final test procedure issued in January 2011 and the dryer standards contained in the Direct Final Rule issued in April 2011.

In order to give manufacturers adequate time to prepare for a revised test procedure and standards, we urge DOE to complete and finalize the test procedure and standards revisions as soon as possible, but no later than December 31, 2011. We suggest that DOE propose the modifications to the standards required by Section 323(e) in parallel to modifications to the test procedure. Parallel revisions to the test procedure and standards will provide stakeholders the clearest understanding of the impacts of the changes and enable the fastest resolution of the issues raised in this petition. The timing suggested in this petition is contingent on DOE providing adequate lead-in time for manufacturers to develop products that will comply with the revised standard per the revised test procedure that more effectively accounts for automatic termination controls. In order to provide adequate lead-in time, it is necessary that the test procedures and standards are completed and final no later than December 31, 2011.

VIII. **Conclusion**

Because data is now available to support a test procedure that accurately measures the effectiveness of automatic termination controls, the Joint Commenters request that DOE amend the clothes dryer test procedure to account for the effectiveness of automatic termination controls as discussed in Section IV above. Such amendments to account for the effectiveness of automatic termination controls will help to prevent over-drying and will, thus, result in energy savings. If DOE adopts procedures to amend the test procedure to measure the effectiveness of automatic termination controls, it must also revise the relevant energy conservation standards to reflect the new test procedure, ensuring that for dryers with effective automatic termination controls, there is no change in the stringency of the standards, per section 323 of the Energy Policy and Conservation Act.

JOINT STAKEHOLDERS

Manufacturers

Kevin Messner
Vice President, Government Relations
Association of Home Appliance Manufacturers

Members of Major Appliance Division:
Whirlpool
General Electric
Electrolux
LG Electronics
Council BSH
Alliance Laundry
Viking Range
Sub-Zero
Wolf

Advocates

Andrew deLaski
Executive Director
Appliance Standards Awareness Project

On Behalf of—

American Council for an Energy-Efficient Economy
Natural Resources Defense Council
Alliance to Save Energy
Alliance for Water Efficiency
Northwest Power and Conservation
Northeast Energy Efficiency Partnerships
Consumer Federation of America
National Consumer Law Center

[4] 75 Fed. Reg. 37618 (June 29, 2010).

[5] Reich, Judith. Navigant Consulting, Inc. 2010. Personal communication to Joanna Mauer. June 22, 2010.

[6] Per-unit annual energy savings based on 283 cycles per year. Cumulative national energy savings calculated using the affected stock values and heat rates from the DOE NIA spreadsheet.

[7] 75 FR 37618.

JOINT STAKEHOLDERS—Continued

Manufacturers	Advocates
Friedrich	
A/C U-Line	
Samsung	
Sharp Electronics	
Miele	
Heat	
Controller	
AGA Marvel	
Brown Stove	
Haier	
Fagor	
America	
Airwell	
Group	
Arcelik Fisher & Paykel	
Scotsman Ice	
Indesit	
Kuppersbusch	
Kelon	
DeLonghi	

[FR Doc. 2011–26169 Filed 10–7–11; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2006–25001; Directorate Identifier 2006–NM–079–AD]

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: Supplemental notice of proposed rulemaking (NPRM); reopening of comment period.

SUMMARY: We are revising an earlier proposed airworthiness directive (AD) for the products listed above. That second supplemental NPRM proposed a one-time inspection to determine the part numbers of the aero/fire seals of the blocker doors on the thrust reverser torque boxes on the engines, and replacing affected aero/fire seals with new, improved aero/fire seals. That second supplemental NPRM was prompted by a report that the top 3 inches of the aero/fire seals of the blocker doors on the thrust reverser torque boxes are not fireproof. This action revises the second supplemental NPRM by prohibiting installation of certain non-fireproof thrust reverser seals. We are proposing this third supplemental NPRM to prevent a fire in the fan compartment (a fire zone) from migrating through the seal to a flammable fluid in the thrust reverser actuator compartment (a flammable fluid leakage zone), which could result in an uncontrolled fire. Since these actions impose an additional burden over that proposed in the second supplemental NPRM, we are reopening the comment period to allow the public the chance to comment on these proposed changes.

DATES: We must receive comments on this supplemental NPRM by November 25, 2011.

ADDRESSES: You may send comments by any of the following methods:

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

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 proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (*phone:* 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Chris Parker, Aerospace Engineer, Propulsion Branch, ANM–140S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, Washington 98057–3356; *phone:* 425–917–6496; *fax:* 425–917–6590; *e-mail: chris.r.parker@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2006–25001; Directorate Identifier 2006–NM–079–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We issued a second supplemental NPRM to amend 14 CFR part 39 to include an airworthiness directive (AD) that would apply to all Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes. That second supplemental NPRM was published in the **Federal Register** on July 16, 2009 (74 FR 34518). That second supplemental NPRM proposed to require a one-time inspection to determine the part numbers of the aero/fire seals of the blocker doors on the thrust reverser torque boxes on the engines, and replacing affected aero/fire seals with new, improved aero/fire seals. That second supplemental NPRM also proposed to reduce the compliance time for the replacement of the affected aero/fire seals.

Actions Since Second Supplemental NPRM Was Issued

Since we issued the second supplemental NPRM (74 FR 34518, July 16, 2009), we have determined that it is necessary to propose to prohibit installation of certain non-fireproof thrust reverser seals in this third supplemental NPRM, because we have received information indicating that some thrust reversers with non-fireproof seals could be installed on certain airplanes.

Comments

We gave the public the opportunity to comment on the second supplemental NPRM (74 FR 34518, July 16, 2009). The following presents the comments received on the second supplemental NPRM and the FAA's response to each comment.

Request To Include Parts Installation Paragraph

Boeing requested that the second supplemental NPRM (74 FR 34518, July 16, 2009) be revised to address spare thrust reverser halves being installed on any Model 737 Next Generation airplane. Boeing explained that some spare thrust reverser halves could be equipped with non-fireproof seals and that if these spare units are installed after the inspection, some airplanes will have non-fireproof seals.

We partially agree. While we explained in the first supplemental NPRM (73 FR 51382, September 3, 2008) that we understood affected spare assemblies had been purged from the parts supply system, we have now received information that thrust reverser interchangeability instructions might allow older thrust reverser seals having part number (P/N) 315A2245–1 or 315A2245–2 to be installed on newly delivered airplanes. While we cannot apply the inspections proposed by this third supplemental NPRM to spare parts, we can require that parts being installed on the airplane be compliant with this third supplemental NPRM. We have added paragraph (i) to this third supplemental NPRM to prohibit installation of non-fireproof thrust reverser seals.

Requests To Extend Compliance Time for Replacement

The Air Transport Association (ATA), on behalf of two member airlines (Air Tran Airways and American Airlines), and Boeing requested that we change the proposed compliance time for the replacement of the aero/fire seals specified in paragraph (h) of the second supplemental NPRM (74 FR 34518, July 16, 2009).

Air Tran Airways (Air Tran) explained that the second supplemental NPRM (74 FR 34518, July 16, 2009) proposed to allow up to 60 months or 8,200 flight cycles after the effective date of the AD to comply with the proposed inspection specified in paragraph (g) of the second supplemental NPRM. However, Air Tran pointed out that if a non-fireproof aero/fire seal is found on a thrust reverser, the seal must be changed prior to further flight. Air Tran reasoned that the second supplemental NPRM should allow a more realistic time frame to have the seal replaced. Air Tran provided no technical justification for this request.

Boeing explained that the compliance time from the original NPRM (71 FR 34025, June 13, 2006) should be used, regardless of when the inspection for aero/fire seals of the thrust reverser torque boxes on the engines was done. Boeing stated that the second supplemental NPRM (74 FR 34518, July 16, 2009) would likely ground airplanes because operators would only accomplish the inspections if they have replacement seals on hand; Boeing only carries limited quantities of the seals and the re-order lead time for these seals is approximately 20 weeks.

We agree to revise this third supplemental NPRM to change the proposed compliance time specified in paragraph (h) of this third supplemental NPRM. However, we are revising the compliance time in paragraph (h) of this third supplemental NPRM to specify that operators have within 6 months after doing the inspection in paragraph (g) of this third supplemental NPRM to replace a non-fireproof seal. Under the provisions of paragraph (k) of this third supplemental NPRM, we will consider requests for approval of an alternative method of compliance (AMOC) that provides an acceptable level of safety, if parts availability becomes a problem. We have determined that replacement of the non-fireproof seal within 6 months after doing the inspection in paragraph (g) of this third supplemental NPRM will not adversely affect safety. We have revised this third supplemental NPRM accordingly.

Request To Specify Terminating Action

The ATA, on behalf of its member American Airlines, requested that the replacement of the non-fireproof seal be done in accordance with Boeing Special Attention Service Bulletin 737–78–1074, Revision 1, dated September 15, 2005, and that the proposed AD state that this replacement is terminating action.

We agree that the replacement of the non-fireproof seals can be done in accordance with Boeing Special Attention Service Bulletin 737–78–1074, Revision 1, dated September 15, 2005, and that the replacement of the non-fireproof seals is terminating action for the inspection required by paragraph (g) of this third supplemental NPRM. We have added this information to paragraph (h) of this AD.

Requests To Apply AD to Part Rather Than Airplane

The ATA, on behalf of its member Air Tran, and Boeing requested that the second supplemental NPRM (74 FR 34518, July 16, 2009) apply only to thrust reverser assemblies having certain part numbers as opposed to applying to the airplane.

Air Tran explained that thrust reversers are rotable, line replaceable unit assemblies, which may be uninstalled, stand-alone spares, and can be rotated among other airplanes. For this reason, Air Tran suggested that the applicability of the second supplemental NPRM (74 FR 34518, July 16, 2009) should be against thrust reverser assembly part numbers rather than the airplane.

Boeing explained that the proposed applicability in the second supplemental NPRM (74 FR 34518, July 16, 2009) is open-ended and would apply to new Model 737 airplanes that are already compliant. Boeing explained further that thrust reversers having part number (P/Ns) 315A2295–195 through

315A2295–500 were delivered with seals with a fireproof section, and that interchangeability definitions for thrust reversers having P/Ns 315A2245–7 and 315A2245–8 (fireproof section) do not allow these seals to be replaced with seals having P/Ns 315A2245–1 and 315A2245–2 (non-fireproof). Boeing recommended limiting the proposed applicability to thrust reversers having P/Ns 315A2295–3 through 315A2295–194, and P/Ns 315A2295–503 through 315A2295–694.

We disagree to change the applicability of this third supplemental NPRM to apply to thrust reversers having certain part numbers. The seal is not integral to the thrust reverser and is replaceable. Therefore, a non-fireproof seal could be used on any thrust reverser—even a thrust reverser originally built with a compliant fireproof seal. It is the operator's responsibility to maintain compliance once an AD has been accomplished. The operator must ensure that the thrust reversers on its airplanes have been inspected and are using a fireproof seal. If an operator replaces a thrust reverser, the thrust reverser must be inspected to ensure compliance with this third supplemental NPRM. We have not changed the applicability of this third supplemental NPRM in this regard.

However, we have determined that the inspection required by paragraph (g) of this third supplemental NPRM is only necessary for certain airplanes. Therefore, we have revised paragraph (g) of this third supplemental NPRM to specify that only the following airplanes are subject to the requirements of that paragraph: ''For airplanes having an original airworthiness certificate issued before the effective date of this AD, and for airplanes on which the date of issuance of the original export certificate of airworthiness is before the effective date of this AD * * *.''

Request for Clarification of Use of Illustrated Parts Catalog (IPC) as Maintenance Record

All Nippon Airways (ANA) requested that we clarify if their IPC can be used as a form of maintenance record to identify if the airplane has the fireproof seal installed. ANA explained that the seals are not controlled by any type of part-control system, and that operators visually verify the stamped part number instead. ANA stated that since the stamped part number is often unreadable, the operator would be forced to replace the seal in order to remain in compliance with the AD, regardless if the seal was already a fireproof seal. ANA asserted that replacing a possible fireproof seal (to remain in compliance with the proposed AD) simply because the part number is unreadable, is an unreasonable action.

We disagree to allow use of the IPC as a maintenance record. If the required maintenance records, which do not include the IPC, are not available to show that the correct fireproof seal has been installed, and the part number is worn off the aero/fire seals, it is still possible to verify that the correct part is installed by visually inspecting the seal for color content, as specified in paragraph (g) of the second supplemental NPRM. We have not changed this third supplemental NPRM in this regard.

Request for Clarification of the Difference in the Applicability Between the Original NPRM and the Second Supplemental NPRM

ANA also requested that we clarify the difference in the applicability between the original NPRM (71 FR 34025, June 13, 2006) and the second supplemental NPRM (74 FR 34518, July 16, 2009). ANA explained that the applicability in the original NPRM was for all Model 737–600, –700,–700C, –800, and –900 series airplanes, which is what is listed in Boeing Special Attention Service Bulletin 737–78–1074, Revision 1, dated September 15, 2005 (referenced in the original NPRM as the source of service information for replacing aero/fire seals).

We agree to clarify differences in the applicability of the various NPRMs. The applicability of the original NPRM (71 FR 34025, June 13, 2006) referenced that service bulletin for affected airplanes. After we issued the original NPRM, we received information on the interchangeability of the affected aero/fire seals. The applicability of the first supplemental NPRM (73 FR 51382, September 3, 2008) was revised to specify ''all'' Model 737 airplanes (including Model 737–900ER series airplanes, which had been added to the U.S. type certificate data sheet), since all of these airplanes could be affected by the interchangeability of the seals. No change to this third supplemental NPRM is necessary in this regard.

Explanation of Change Made to This Proposed AD

We have revised this proposed AD to identify the legal name of the manufacturer as published in the most recent type certificate data sheet for the affected airplane models.

FAA's Determination

We are proposing this third supplemental NPRM because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of these same type designs. Certain changes described above expand the scope of the second supplemental NPRM (74 FR 34518, July 16, 2009). As a result, we have determined that it is necessary to reopen the comment period to provide additional opportunity for the public to comment on this third supplemental NPRM.

Explanation of Change to Costs of Compliance

Since issuance of the original NPRM (71 FR 34025, June 13, 2006), we have increased the labor rate used in the Costs of Compliance from $80 per work-hour to $85 per work-hour. The Costs of Compliance information, below, reflects this increase in the specified labor rate.

Costs of Compliance

We estimate that this proposed AD affects 803 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection for part number.	1 work-hour × $85 per hour = $85 per inspection cycle.	None	$85 per inspection cycle.	$68,255 per inspection cycle.

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

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replacement	5 work-hours × $85 per hour = $425	$4,770	$5,195

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

Authority for this Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

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

(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.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2006–25001; Directorate Identifier 2006–NM–079–AD.

Comments Due Date

(a) We must receive comments by November 25, 2011.

Affected ADs

(b) None.

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) Joint Aircraft System Component (JASC)/Air Transport Association (ATA) of America Code 78: Engine exhaust.

Unsafe Condition

(e) This AD was prompted by a report that the top 3 inches of the aero/fire seals of the blocker doors on the thrust reverser torque boxes are not fireproof. We are issuing this AD to prevent a fire in the fan compartment (a fire zone) from migrating through the seal to a flammable fluid in the thrust reverser actuator compartment (a flammable fluid leakage zone), which could result in an uncontrolled fire.

Compliance

(f) Comply with this AD within the compliance times specified, unless already done.

Inspection to Determine Type of Aero/Fire Seals

(g) For airplanes having an original airworthiness certificate issued before the effective date of this AD, and for airplanes on which the date of issuance of the original export certificate of airworthiness is before the effective date of this AD: Within 60 months or 8,200 flight cycles, whichever occurs first, after the effective date of this AD, perform a one-time detailed inspection to determine the color of the aero/fire seals of the blocker doors on the thrust reverser torque boxes on the engines. For any aero/fire seal having a completely grey color (which is the color of seals with part number (P/N) 315A2245–1 or 315A2245–2), with no red at the upper end of the seal, do the actions specified in paragraph (h) of this AD. For any aero/fire seal having a red color at the upper end of the seal (which indicates installation of seals with P/N 315A2245–7 or 315A2245–8), no further action is required by this AD. A review of airplane maintenance records is acceptable in lieu of this inspection if from that review the part number of the correct aero/fire seals (P/N 315A2245–7 or –8) can be conclusively determined to be installed.

Note 1: 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 mirrors, magnifying lenses, etc., may be necessary. Surface cleaning and elaborate procedures may be required.''

Replacement of the Aero/Fire Seals

(h) For any aero/fire seal identified during the inspection/records check required by paragraph (g) of this AD to have a non-fireproof seal: Within six months after doing the actions required by paragraph (g) of this AD, replace the aero/fire seals of the blocker doors on the thrust reverser torque boxes on the engines with new, improved aero/fire seals, in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–78–1074, Revision 1, dated September 15, 2005. Replacing the aero/fire seals of the blocker doors on the thrust reverser torque boxes on the engines with new, improved aero/fire seals, in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–78–1074, Revision 1, dated September 15, 2005, is terminating action for the inspection required by paragraph (g) of this AD.

Parts Installation

(i) As of the effective date of this AD, no person may install a non-fireproof thrust reverser seal having P/N 315A2245–1 or P/N 315A2245–2 on any airplane.

Credit for Actions Accomplished in Accordance with Previous Service Information

(j) Replacements done before the effective date of this AD in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–78–1074, dated April 7, 2005, are acceptable for compliance with the requirements of paragraph (h) of this AD.

Alternative Methods of Compliance (AMOCs)

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

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

Related Information

(l) For more information about this AD, contact Chris Parker, Aerospace Engineer, Propulsion Branch, ANM–140S, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; *phone:* 425–917–6496; *fax:* 425–917–6590; *e-mail:* chris.r.parker@faa.gov.

(m) 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.

Issued in Renton, Washington, on September 30, 2011.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–26104 Filed 10–7–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–1060; Directorate Identifier 2011–NM–015–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A310 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for the products listed above that would supersede an existing AD. This proposed 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:

Within the scope of the Fuel System Safety Program (FSSP), analyses of the wire routing showed that the route 2S of the fuel electrical circuit in the Right Hand (RH) wing must be modified in order to ensure better segregation between fuel quantity indication wires and the 115 Volts Alternating Current (VAC) wires of route 2S.

This condition, if not corrected, could result in short circuits leading to arcing, and possible fuel tank explosion.

* * * * *

The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

DATES: We must receive comments on this proposed AD by November 25, 2011.

ADDRESSES: You may send comments by any of the following methods:

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

For service information identified in this proposed AD, contact Airbus SAS–EAW (Airworthiness Office), 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; e-mail: *account.airworth-eas@airbus.com;* Internet *http://www.airbus.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 Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–2125; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2011–1060; Directorate Identifier 2011–NM–015–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

On January 3, 2008, we issued AD 2008–01–05, Amendment 39–15330 (73 FR 2795, January 16, 2008). That AD required actions intended to address an unsafe condition on the products listed above.

Since we issued AD 2008–01–05, Amendment 39–15330 (73 FR 2795, January 16, 2008), we have determined

that the route 2S of the fuel electrical circuit in the right hand wing must be modified to ensure better segregation between fuel quantity indication wires and the 115 volts alternating current wires of route 2S. The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2011–0005, dated January 17, 2011 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

Within the scope of the Fuel System Safety Program (FSSP), analyses of the wire routing showed that the route 2S of the fuel electrical circuit in the Right Hand (RH) wing must be modified in order to ensure better segregation between fuel quantity indication wires and the 115 Volts Alternating Current (VAC) wires of route 2S.

This condition, if not corrected, could result in short circuits leading to arcing, and possible fuel tank explosion.

To address this unsafe condition, [Direction Générale de l'Aviation Civile] DGAC France issued AD 2002–578(B) [which corresponds to FAA AD 2004–15–16, Amendment 39–13750 (69 FR 45578, July 30, 2004)] to require improvements of the design as specified in Airbus Service Bulletin (SB) A310–28–2148 original issue or Revision 01. EASA AD 2007–0230 [which corresponds to FAA AD 2008–01–05 (73 FR 2795, January 16, 2008)], which superseded DGAC France AD 2002–578(B), required those same actions, plus additional work as defined in Airbus SB A310–28–2148 Revision 02.

Since EASA AD 2007–0230 was issued, an operator reported the possibility of chafing with the new routing of the wire bundle 2S in the RH wing pylon area to the generator wire bundle of engine 2. The modification of this zone was introduced by A310–28–2148 Revision 02 as additional work. Investigation showed that, to avoid the risk of chafing, the affected wiring harnesses must be installed at a higher position to provide sufficient clearance with the newly routed wire bundle 2S conduit.

Airbus published Revision 03 of SB A310–28–2148 to describe these changes, but a new interference has been found and requires updating SB A310–28–2148 to Revision 04 [or 05].

For the reasons described above, this new [EASA] AD retains the requirements of EASA AD 2007–0230, which is superseded, and requires the additional work as specified in Revision 04 [or 05] of Airbus SB A310–28–2148.

Required actions include modifying the wire routings and installing a modified bracket. You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Airbus has issued Mandatory Service Bulletin A310–28–2148, Revision 05, dated August 3, 2010. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

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 proposed different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a NOTE within the proposed AD.

Costs of Compliance

We estimate that this proposed AD would affect 61 airplanes of U.S. registry. The following table provides the estimated costs for U.S. operators to comply with this proposed AD.

TABLE—ESTIMATED COSTS

Action	Work hours	Average labor rate per hour	Parts	Cost per airplane	Number of U.S.-registered airplanes	Fleet cost
Modification (required by AD 2004–15–16, Amendment 39-13750 (69 FR 45578, July 30, 2004))	35	$85	$4,459	$7,434	68	$505,512
Modification (required by AD 2008–01–05, Amendment 39-15330 (73 FR 2795, January 16, 2008))	22	85	1,870	3,740	68	254,320
Modification (new proposed action)	62	85	2,210	7,480	61	456,280

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

For the reasons discussed above, I certify this proposed regulation:

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The FAA amends § 39.13 by removing Amendment 39–15330 (73 FR 2795, January 16, 2008) and adding the following new AD:

Airbus: Docket No. FAA–2011–1060; Directorate Identifier 2011–NM–015–AD.

Comments Due Date

(a) We must receive comments by November 25, 2011.

Affected ADs

(b) This AD supersedes AD 2008–01–05, Amendment 39–15330 (73 FR 2795, January 16, 2008).

Applicability

(c) This AD applies to Airbus Model A310–203, –204, –221, –222, –304, –322, –324, and –325 airplanes; certificated in any category; all serial numbers.

Subject

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

Reason

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

Within the scope of the Fuel System Safety Program (FSSP), analyses of the wire routing showed that the route 2S of the fuel electrical circuit in the Right Hand (RH) wing must be modified in order to ensure better segregation between fuel quantity indication wires and the 115 Volts Alternating Current (VAC) wires of route 2S.

This condition, if not corrected, could result in short circuits leading to arcing, and possible fuel tank explosion.

* * * * *

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 2004–15–16 Amendment 39–13750 (69 FR 45578, July 30, 2004), With New Service Information

Modification

(g) For all airplanes except airplanes on which Airbus Service Bulletin A310–28–2148, Revision 02, dated March 9, 2007, has been done (Airbus Modifications 12427 and 12435): Within 4,000 flight hours after September 3, 2004 (the effective date of AD 2004–15–16 (69 FR 45578, July 30, 2004)), modify the routing of wires in the RH wing by installing cable sleeves, per the Accomplishment Instructions of Airbus Service Bulletin A310–28–2148, Revision 01, dated October 29, 2002; Revision 02, dated March 9, 2007; or Revision 05, dated August 3, 2010. As of February 20, 2008 (the effective date of AD 2008–01–05, Amendment 39–15330 (73 FR 2795, January 16, 2008)), Revision 02 must be used. As of the effective date of this AD, Revision 05 must be used.

Actions Accomplished Previously

(h) Modification of the routing of wires accomplished before September 3, 2004, per Airbus Service Bulletin A310–28–2148, dated January 23, 2002, is acceptable for compliance with the corresponding requirements of paragraph (g) of this AD.

Restatement of Requirements of AD 2008–01–05, Amendment 39–15330 (73 FR 2795, January 16, 2008), With New Service Information

Modification (Additional Work)

(i) For airplanes on which the actions specified in Airbus Service Bulletin A310–28–2148, dated January 23, 2002; or Airbus Service Bulletin A310–28–2148, Revision 01, dated October 29, 2002; have been done before February 20, 2008, except for airplanes on which Airbus Service Bulletin A310–28–2148, Revision 02, dated March 9, 2007, has been done (Airbus Modifications 12427 and 12435): Within 6,000 flight hours or 30 months after February 20, 2008, whichever occurs first, perform further modification by installing additional protection sleeves in the outer wing area near the cadensicon sensor and segregating wire route 2S in the RH pylon area, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A310–28–2148, Revision 02, dated March 9, 2007; or Revision 05, dated August 3, 2010. As of the effective date of this AD, Revision 05 must be used.

New Requirements of This AD

Additional Modification/Installation for Certain Airplanes

(j) For airplanes on which the actions specified in Airbus Service Bulletin A310–28–2148, Revision 02, dated March 9, 2007, have been accomplished, and do not have production modification 07633 and on which Airbus Service Bulletin A310–36–2015 has not been done: Within 6,000 flight hours or 30 months after the effective date of this AD, whichever occurs first, modify the wire routings, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A310–28–2148, Revision 05, dated August 3, 2010.

(k) For airplanes on which the actions specified in Airbus Service Bulletin A310–28–2148, Revision 02, dated March 9, 2007, have been accomplished, and have production modification 07633 or on which Airbus Service Bulletin A310–36–2015 has been done: Within 1,000 flight hours after the effective date of this AD, install a modified bracket, in accordance with paragraph 3.B.(7) ''Additional Work 2'' of the Accomplishment Instructions of Airbus Service Bulletin A310–28–2148, Revision 05, dated August 3, 2010.

(l) For airplanes on which the actions specified in Airbus Service Bulletin A310–28–2148, Revision 03, dated June 2, 2009, have been accomplished; and have modification 07633 done in production or on which the actions specified in Airbus Service Bulletin A310–36–2015 have been done; no further action is required by this AD.

Credit for Actions Accomplished in Accordance With Previous Service Information

(m) Modifications done in accordance with Airbus Service Bulletin A310–28–2148, Revision 04, dated April 14, 2010, before the effective date of this AD are acceptable for compliance with the corresponding modification required by paragraph (g), (i), (j), and (k) of this AD.

FAA AD Differences

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

Other FAA AD Provisions

(n) 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: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–2125; 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. AMOCs approved previously in accordance with AD 2008–01–05, Amendment 39–15330 (73 FR 2795, January 16, 2008), are approved as AMOCs for the corresponding provisions of 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

(o) Refer to MCAI European Aviation Safety Agency (EASA) Airworthiness Directive 2011–0005, dated January 17, 2011; and Airbus Service Bulletin A310–28–2148, Revision 05, dated August 3, 2010; for related information.

Issued in Renton, Washington, on September 28, 2011.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–26106 Filed 10–7–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–1062; Directorate Identifier 2011–NM–038–AD]

RIN 2120–AA64

Airworthiness Directives; Saab AB, Saab Aerosystems Model 340A (SAAB/SF340A) and SAAB 340B Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for the products listed above that would supersede an existing AD. This proposed 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:

In 2003, a number of reports had been received concerning broken wires and corroded connectors in the SAAB 340 main landing gear (MLG) emergency release system. The investigation results showed that these were due to improper repairs and installations, not conforming to the approved type design.

This condition, if not corrected, could inhibit the functioning of the separation bolt, preventing proper release of the MLG during an emergency situation, possibly resulting in damage to aeroplane during landing and injury to the occupants.

* * * * *

The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

DATES: We must receive comments on this proposed AD by November 25, 2011.

ADDRESSES: You may send comments by any of the following methods:

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

For service information identified in this proposed AD, contact Saab AB, Saab Aerosystems, SE–581 88, Linköping, Sweden; telephone +46 13 18 5591; fax +46 13 18 4874; e-mail *saab2000.techsupport@saabgroup.com;* Internet *http://www.saabgroup.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 Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Shahram Daneshmandi, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1112; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2011–1062; Directorate Identifier 2011–NM–038–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

On May 28, 2004, we issued AD 2004–12–03, Amendment 39–13662 (69 FR 35235, June 24, 2004). That AD required actions intended to address an unsafe condition on the products listed above.

Since we issued AD 2004–12–03, Amendment 39–13662 (69 FR 35235, June 24, 2004), we have received reports that the previous modification does not fully meet the expected results; therefore, an improved separation bolt harness having part number (P/N) 7292520–691 has been designed to replace the current separation bolt harness having P/N 7292520–678. The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2011–0003, dated January 17, 2011 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

In 2003, a number of reports had been received concerning broken wires and corroded connectors in the SAAB 340 main landing gear (MLG) emergency release system. The investigation results showed that these were due to improper repairs and installations, not conforming to the approved type design.

This condition, if not corrected, could inhibit the functioning of the separation bolt, preventing proper release of the MLG during an emergency situation, possibly resulting in damage to aeroplane during landing and injury to the occupants.

To address that unsafe condition, Swedish AD (SAD) 1–186 was issued to require an inspection and, depending on findings, corrective action, in accordance with SAAB Service Bulletin (SB) 340–32–127.

Subsequently, Saab introduced a modification to ensure correct functioning of the MLG emergency release system. Accomplishment of that modification (SAAB SB 340–32–128) was made mandatory by SAD 1–189 [which corresponds to FAA AD 2004–12–03 (69 FR 35235, June 24, 2004)].

Since that [SAD] AD was issued, service experience has shown that this modification does not fully meet the expected results.

Prompted by these findings, SAAB has developed an improved separation bolt harness with a new routing.

For the reasons described above, this AD requires replacement of the current

separation bolt harness Part Number (P/N) 7292520–678 with the improved unit, P/N 7292520–691.

You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Saab has issued Service Bulletin 340–32–139, Revision 01, dated November 1, 2010. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

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 proposed different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a NOTE within the proposed AD.

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 111 products of U.S. registry. We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

For certain model—	Action—	Number of affected air-planes—	Work hours—	Parts cost—	Total cost—
SAAB SF340A and SAAB 340B series airplanes (retained actions from existing AD 2004–12–03 (69 FR 35235, June 24, 2004).	Inspection and modification of harnesses.	111	6 work-hours × $85 per hour = $510.	$1,475	$168,280, or $1,985 per airplane.
SAAB SF340A and SF340B series airplanes (new proposed action).	Replace separation bolt harnesses.	111	10 work-hours × $85 per hour = $850.	1,790	$96,140, or $2,640 per airplane.

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

For the reasons discussed above, I certify this proposed regulation:

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The FAA amends § 39.13 by removing Amendment 39–13662 (69 FR 35235, June 24, 2004) and adding the following new AD:

Saab AB, Saab Aerosystems: Docket No. FAA–2011–1062; Directorate Identifier 2011–NM–038–AD.

Comments Due Date

(a) We must receive comments by November 25, 2011.

Affected ADs

(b) This AD supersedes AD 2004–12–03, Amendment 39–13662 (69 FR 35235, June 24, 2004).

Applicability

(c) This AD applies to Saab AB, Saab Aerosystems Model 340A (SAAB/SF340A) and SAAB 340B airplanes, all serial numbers, certificated in any category.

Subject

(d) Air Transport Association (ATA) of America Code 32: Landing gear.

Reason

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

In 2003, a number of reports had been received concerning broken wires and corroded connectors in the SAAB 340 main landing gear (MLG) emergency release system. The investigation results showed that these were due to improper repairs and installations, not conforming to the approved type design.

This condition, if not corrected, could inhibit the functioning of the separation bolt, preventing proper release of the MLG during an emergency situation, possibly resulting in damage to aeroplane during landing and injury to the occupants.

* * * * *

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 2004–12–03, Amendment 39–13662 (69 FR 35235, June 24, 2004), With Changes

Inspection

(g) Within 3 months after July 29, 2004 (the effective date of AD 2004–12–03, Amendment 39–13662 (69 FR 35235, June 24, 2004)), perform an inspection of the MLG's separation bolt harness for broken wires and corroded connectors, and any applicable corrective actions by doing all of the actions, in accordance with the Accomplishment Instructions of Saab Service Bulletin 340–32–127, dated December 18, 2002; or Revision 01, dated January 23, 2003. Perform the inspection/corrective actions in accordance with Saab Service Bulletin 340–32–127, dated December 18, 2002; or Revision 01, dated January 23, 2003. Perform any applicable corrective actions before further flight.

Concurrent Service Bulletins

(h) For Model SAAB SF340A series airplanes: Within 12 months after July 29, 2004, do the actions specified in table 1 of this AD, as applicable.

TABLE 1—PRIOR/CONCURRENT ACTIONS

For airplanes with serial Nos.—	Accomplish all actions associated with—	According to the accomplishment instructions of—
004 through 108 inclusive	Modifying the MLG separation bolt's electrical harness.	Saab Service Bulletin 340-32-041, Revision 01, dated October 9, 1987.
004 through 078 inclusive	Modifying the MLG separation bolt's electrical harness.	Saab Service Bulletin 340-32-028, Revision 01, dated November 25, 1986.

New Requirements of This AD

(i) Within 12 months after the effective date of this AD: Replace the separation bolt harnesses having part number (P/N) 7292520–678 with separation bolt harnesses having P/N 7292520–691, in accordance with the Accomplishment Instructions of Saab Service Bulletin 340–32–139, Revision 01, dated November 1, 2010.

Parts Installation

(j) As of the effective date of this AD, no person may install a separation bolt harness having P/N 7292520–678, on any airplane.

Credit for Actions Accomplished in Accordance With Previous Service Information

(k) Actions done before the effective date of this AD in accordance with Saab Service Bulletin 340–32–139, dated January 12, 2010, are acceptable for compliance with the requirements of paragraph (i) of this AD.

FAA AD Differences

Note 1: This AD differs from the MCAI and/or service information as follows: Although the MCAI states not to install a separation bolt having P/N 7292520–678 on any airplane after modification of the airplane, this AD states not to install a separation bolt having P/N 7292520–678 on any airplane as of the effective date of this AD.

Other FAA AD Provisions

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

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Shahram Daneshmandi, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1112; fax (425) 227–1149. Information may be e-mailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

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

Related Information

(m) Refer to MCAI EASA Airworthiness Directive 2011–0003, dated January 17, 2011; and the service information specified in paragraphs (m)(1) through (m)(5) of this AD, as applicable; for related information.

(1) Saab Service Bulletin 340–32–139, Revision 01, dated November 1, 2010.

(2) Saab Service Bulletin 340–32–127, dated December 18, 2002.

(3) Saab Service Bulletin 340–32–127, Revision 01, dated January 23, 2003.

(4) Saab Service Bulletin 340–32–041, Revision 01, dated October 9, 1987.

(5) Saab Service Bulletin 340–32–028, Revision 01, dated November 25, 1986.

Issued in Renton, Washington, on September 28, 2011.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–26110 Filed 10–7–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–1067; Directorate Identifier 2011–NM–034–AD]

RIN 2120–AA64

Airworthiness Directives; Fokker Services B.V. Model F.27 Mark 050 and F.28 Mark 0070 and 0100 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for the products listed above. This proposed 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:

As required by current certification standards, each transport aeroplane has passenger compartment exit signs and emergency lighting strips installed to locate the emergency exits. A number of these strips

and signs are not electrically powered, but are self illuminated by means of a hydrogen isotope, known as Tritium. As this isotope decays over time, these signs will [lose] their brightness.

To remain compliant with regulations, Tritium exit signs and lighting strips should be replaced when their brightness has deteriorated below accepted levels. Currently, the Maintenance Review Board (MRB) Maintenance Planning Document does not include an inspection task for signs and strips containing Tritium.

This condition, if not detected and corrected, could result in insufficiently bright exit signs and lighting strips, preventing safe evacuation during an emergency, possibly resulting in injury to occupants.

* * * * *

The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

DATES: We must receive comments on this proposed AD by November 25, 2011.

ADDRESSES: You may send comments by any of the following methods:

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

For service information identified in this proposed AD, contact Fokker Services B.V., Technical Services Dept., P.O. Box 231, 2150 AE Nieuw-Vennep, the Netherlands; telephone +31 (0)252–627–350; fax +31 (0)252–627–211; e-mail *technicalservices.fokkerservices @stork.com;* Internet *http://www.my fokkerfleet.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 Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

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

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2011–1067; Directorate Identifier 2011–NM–034–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2010–0261, dated December 9, 2010 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

As required by current certification standards, each transport aeroplane has passenger compartment exit signs and emergency lighting strips installed to locate the emergency exits. A number of these strips and signs are not electrically powered, but are self illuminated by means of a hydrogen isotope, known as Tritium. As this isotope decays over time, these signs will [lose] their brightness.

To remain compliant with regulations, Tritium exit signs and lighting strips should be replaced when their brightness has deteriorated below accepted levels. Currently, the Maintenance Review Board (MRB) Maintenance Planning Document does not include an inspection task for signs and strips containing Tritium.

This condition, if not detected and corrected, could result in insufficiently bright exit signs and lighting strips, preventing safe evacuation during an emergency, possibly resulting in injury to occupants.

To correct this unsafe condition, EASA issued AD 2010–0200, which required [a detailed visual] inspection of the brightness of all Tritium exit signs and strips and, depending on findings, replacement of insufficiently bright signs and lighting strips.

Following the issuance of [EASA] AD 2010–0200, Fokker Services discovered that one Service Bulletin (SB), SBF100–33–023, contained errors in the two groups of aeroplane serial numbers and, consequently, in the related instructions for those aeroplanes in that SB.

For the reasons described above, this new [EASA] AD retains the requirements of EASA AD 2010–0200, which is superseded, amends the Applicability and refers to Revision 1 of SBF100–33–023 for the accomplishment instructions.

Note: The MRB document will be updated before July 2011 to include an appropriate maintenance task to ensure that the Tritium exit signs and lighting strips meet the minimum brightness requirements.

You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Fokker Services B.V. has issued Service Bulletins SBF50–33–038, dated July 5, 2010; and SBF100–33–023, Revision 1, dated November 4, 2010. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

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 proposed different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a NOTE within the proposed AD.

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 4 products of U.S. registry. We also estimate that it would take about 1 work-hour per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $340, or $85 per product.

In addition, we estimate that any necessary follow-on actions would take about 2 work-hours and require parts costing $833, for a cost of $1,003 per product. We have no way of determining the number of products that may need these actions.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Fokker Services B.V.: Docket No. FAA–2011–1067; Directorate Identifier 2011–NM–034–AD.

Comments Due Date

(a) We must receive comments by November 25, 2011.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Fokker Services B.V. Model airplanes identified in paragraphs (c)(1), (c)(2), and (c)(3) of this AD, certificated in any category.

(1) F.27 Mark 050 airplanes having serial numbers (S/N)s: 20104, 20105, 20121 through 20123 inclusive, 20130 through 20135 inclusive, 20141 through 20145 inclusive, 20150, 20156 through 20176 inclusive, 20178 through 20180 inclusive, 20182 through 20199 inclusive, 20202, 20204 through 20207 inclusive, 20210, 20211, 20213 through 20252 inclusive, 20254 through 20266 inclusive, 20270 through 20279 inclusive, 20281, 20283 through 20288 inclusive, 20296 through 20303 inclusive, 20306, 20307, 20312, 20313, 20316, 20317, 20328, 20331, 20333, and 20335.

(2) F.28 Mark 0070 and 0100 airplanes having S/Ns: 11257, 11258, 11262, 11264 through 11266 inclusive, 11287, 11301, 11317, 11340, 11342, 11352 through 11356 inclusive, 11360, 11368 through 11370 inclusive, 11376, 11377, 11385, 11395, 11402, 11403, 11405 through 11408 inclusive, 11411 through 11419 inclusive, 11425 through 11428 inclusive, 11434 through 11437 inclusive, 11447 through 11449 inclusive, 11457 through 11459 inclusive, 11467, 11469, 11478, 11479, 11481, 11482, 11487, 11492 through 11495 inclusive, 11497, 11498, 11501, 11503, 11506, 11507, 11509, 11514, 11521, 11528, 11529, 11532, 11536 through 11541 inclusive, 11543, 11545, 11547, 11549, 11551, 11553 through 11583 inclusive, and 11585.

(3) F.28 Mark 0100 airplanes, if in a post-Fokker Service Bulletin SBF100–52–060 configuration, having S/Ns: 11244 through 11256 inclusive, 11259 through 11261 inclusive, 11263, 11267 through 11286 inclusive, 11288 through 11300 inclusive, 11302 through 11316 inclusive, 11318 through 11339 inclusive, 11341, 11343 through 11351 inclusive, 11357 through 11367 inclusive, 11371 through 11375 inclusive, 11378 through 11384 inclusive, 11386 through 11394 inclusive, 11396 through 11401 inclusive, 11404, 11409, 11410, 11420 through 11424 inclusive, 11429 through 11433 inclusive, 11438 through 11446 inclusive, 11450 through 11456 inclusive, 11460 through 11466 inclusive, 11468, 11470 through 11477 inclusive, 11480, 11483 through 11486 inclusive, 11488 through 11491 inclusive, 11496, 11499, 11500, 11502, 11504, 11505, 11508, 11510 through 11513 inclusive, 11515 through 11520 inclusive, 11522, 11523, and 11527.

Subject

(d) Air Transport Association (ATA) of America Code 33: Lights.

Reason

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

As required by current certification standards, each transport aeroplane has passenger compartment exit signs and emergency lighting strips installed to locate the emergency exits. A number of these strips and signs are not electrically powered, but are self illuminated by means of a hydrogen isotope, known as Tritium. As this isotope decays over time, these signs will [lose] their brightness.

To remain compliant with regulations, Tritium exit signs and lighting strips should be replaced when their brightness has deteriorated below accepted levels. Currently, the Maintenance Review Board (MRB) Maintenance Planning Document does not include an inspection task for signs and strips containing Tritium.

This condition, if not detected and corrected, could result in insufficiently bright exit signs and lighting strips, preventing safe evacuation during an emergency, possibly resulting in injury to occupants.

* * * * *

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 six months after the effective date of this AD, do a detailed visual inspection of the tritium exit signs and emergency lighting strips for required brightness, in accordance with the Accomplishment Instructions of Fokker Service Bulletin SBF50–33–038, dated July 5, 2010; or SBF100–33–023, Revision 1, dated November 4, 2010; as applicable. If any exit signs or emergency lighting strips are insufficiently bright, before further flight, replace the exit signs or emergency lighting strips, in accordance with the

Accomplishment Instructions of Fokker Service Bulletin SBF50–33–038, dated July 5, 2010; or SBF100–33–023, Revision 1, dated November 4, 2010; as applicable. A review of airplane maintenance records is acceptable in lieu of the inspection in this paragraph if the tritium exit signs and emergency lighting strips can be conclusively determined to have been manufactured in 2003 or earlier, from that review; however, the replacement in this paragraph must be accomplished before further flight after doing the review.

Parts Installation

(h) As of the effective date of this AD, no person may install any tritium exit signs or emergency lighting strips if the manufacturing date is seven years or more before the intended installation date, or if the manufacturing date cannot be determined; unless the tritium exit sign or emergency lighting strip has been inspected in accordance with paragraph (g) of this AD, and does not need replacement.

Credit for Actions Accomplished in Accordance With Previous Service Information

(i) Inspecting and replacing the tritium exit sign or emergency lighting strip in accordance with Fokker Service Bulletin SBF100–33–023, dated July 5, 2010, before the effective date of this AD is acceptable for compliance with the corresponding inspection and replacement required by paragraph (g) of this AD.

FAA AD Differences

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

Other FAA AD Provisions

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

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1137; fax (425) 227–1149. Information may be e-mailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

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

Related Information

(k) Refer to MCAI European Aviation Safety Agency Airworthiness Directive 2010–0261, dated December 9, 2010; Fokker Service Bulletin SBF50–33–038, dated July 5, 2010; and Fokker Service Bulletin SBF100–33–023, Revision 1, dated November 4, 2010; for related information.

Issued in Renton, Washington, on September 30, 2011.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–26108 Filed 10–7–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–1063; Directorate Identifier 2011–NM–080–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Model 767–200 and –300 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Model 767–200 and 767–300 series airplanes. This proposed AD would require installing cargo bulkhead supports, ceiling supports, secondary dam support, drainage tubing, and ceiling panels to the forward lower lobe in the forward cargo compartment. This proposed AD was prompted by reports of water accumulation in the forward lower lobe of the forward cargo compartment. We are proposing this AD to prevent water from accumulating in the forward lower lobe of the forward cargo compartment and entering the adjacent electronic equipment bay, which could result in an electrical short and the potential loss of several functions essential for safe flight.

DATES: We must receive comments on this proposed AD by November 25, 2011.

ADDRESSES: You may send comments by any of the following methods:

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

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P. O. Box 3707, MC 2H–65, Seattle, Washington 98124–2207; *phone:* 206–544–5000, extension 1; *fax:* 206–766–5680; *e-mail: me.boecom@boeing.com; Internet: https://www.myboeingfleet.com.* 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 proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (*phone:* 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Francis Smith, Aerospace Engineer, Cabin Safety & Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, WA 98057–3356; *phone:* 425–917–6596; *fax:* 425–917–6590; *e-mail: Francis.Smith@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2011–1063; Directorate Identifier 2011–NM–080–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any

personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We received reports of high levels of water accumulation in the forward lower lobe of the forward cargo compartment and the potential for water to enter into the electronic equipment bay adjacent to it. Water coming through the floor panels can accumulate up to 12 gallons at this location and typical aircraft movement may not remove all the water. This condition, if not corrected, could result in water accumulating in the forward lower lobe of the forward cargo compartment and entering the adjacent electronic equipment bay, which could result in an electrical short and the potential loss of several functions essential for safe flight.

Relevant Service Information

We reviewed Boeing Alert Service Bulletin 767–25A0505, Original Issue, dated January 14, 2011. The service information describes procedures for the installing cargo bulkhead supports, right-side ceiling supports, left-side ceiling supports, secondary dam support, drainage tubing, and ceiling panels in the forward lobe of the forward cargo compartment.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of these same type designs.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in the service information described previously.

Costs of Compliance

We estimate that this proposed AD affects 1 airplane of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Installation	16 work-hours × $85 per hour = $1,360 per installation	Up to $27,077	Up to $28,437	Up to $28,437.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

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

(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.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2011–1063; Directorate Identifier 2011–NM–080–AD.

Comments Due Date

(a) We must receive comments by November 25, 2011.

Affected ADs

(b) None.

Applicability

(c) This AD applies to The Boeing Company Model 767–200 and 767–300 series airplanes, certificated in any category, as identified in Boeing Alert Service Bulletin 767–25A0505, Original Issue, dated January 14, 2011.

Subject

(d) Joint Aircraft System Component (JASC)/Air Transport Association (ATA) of America Code 25: Equipment and Furnishings.

Unsafe Condition

(e) This AD was prompted by reports of water accumulation in the forward lower lobe of the forward cargo compartment. We are issuing this AD to prevent water from accumulating in the forward lower lobe of the forward cargo compartment and entering the adjacent electronic equipment bay, which could result in an electrical short and the potential loss of several functions essential for safe flight.

Compliance

(f) Comply with this AD within the compliance times specified, unless already done.

Retrofit Installation of Drains, Dam, and Support Structure

(g) Within 24 months after the effective date of this AD: Install cargo bulkhead

supports, right-side ceiling supports, left-side ceiling supports, secondary dam support, drainage tubing, and ceiling panels, in accordance with Boeing Alert Service Bulletin 767–25A0505, Original Issue, dated January 14, 2011.

Alternative Methods of Compliance (AMOCs)

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

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

Related Information

(i) For more information about this AD, contact Francis Smith, Aerospace Engineer, Cabin Safety & Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, WA 98057–3356; *phone:* 425–917–6596; *fax:* 425–917–6590; *e-mail: Francis.Smith@faa.gov.*

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

Issued in Renton, Washington, on September 28, 2011.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–26109 Filed 10–7–11; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2010–0277; Directorate Identifier 2009–NM–217–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Model 767 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking (NPRM); reopening of comment period.

SUMMARY: We are revising an earlier proposed airworthiness directive (AD) for all Model 767 airplanes. That NPRM proposed repetitive inspections to detect fatigue cracking in the wing skin, and corrective actions if necessary. That NPRM was prompted by reports of cracking in the upper wing skin at the fastener holes common to the inboard and outboard pitch load fittings of the front spar which could result in the loss of the strut-to-wing upper link load path and possible separation of a strut and engine from the airplane during flight. This action revises that NPRM by reducing compliance times. We are proposing this supplemental NPRM to correct the unsafe condition on these products. Since these actions impose an additional burden over that proposed in the NPRM, we are reopening the comment period to allow the public the chance to comment on these proposed changes.

DATES: We must receive comments on this supplemental NPRM by November 25, 2011.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

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

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 proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Berhane Alazar, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue, SW., Renton, Washington 98057–3356; phone: 425–917–6577; fax: 425–917–6590; e-mail: *berhane.alazar@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2010–0277; Directorate Identifier 2009–NM–217–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We issued an NPRM to amend 14 CFR part 39 to include an AD that would apply to Model 767–200, –300, –300F, and –400ER series airplanes. That NPRM was published in the **Federal Register** on March 29, 2010 (75 FR 15357). That NPRM proposed to require repetitive inspections to detect fatigue cracking in the upper wing skin at the fastener holes common to the inboard and outboard pitch load fittings of the front spar, and corrective actions if necessary.

Actions Since Previous NPRM (75 FR 15357, March 29, 2010) Was Issued

Since we issued the previous NPRM (75 FR 15357, March 29, 2010), one

operator reported finding a fastener hole with significant crack sizes of 0.53 and 0.31 inch on either side of the hole on an airplane having accumulated 18,900 total flight cycles and 89,500 total flight hours at the time of the inspection. These cracks were found sooner than expected; therefore, certain initial inspection compliance times (grace periods) have been reduced.

Relevant Service Information

Boeing has issued Alert Service Bulletin 767–57A0117, Revision 1, dated March 2, 2011, to reduce certain initial inspection compliance times (grace periods) from 4,000 flight cycles or 12,000 flight hours, to 2,000 flight cycles or 6,000 flight hours (whichever occurs first), respectively. The procedures in Revision 1 of this service bulletin are essentially the same as those in Boeing Alert Service Bulletin 767–57A0117, Original Issue, dated October 1, 2009, which was referenced in the NPRM (75 FR 15357, March 29, 2010) as the appropriate source of service information for accomplishing the proposed requirements.

We have revised this supplemental NPRM to refer to Boeing Alert Service Bulletin 767–57A0117, Revision 1, dated March 2, 2011, given credit for Boeing Alert Service Bulletin 767–57A0117, Original Issue, dated October 1, 2009, and re-identified subsequent paragraphs.

Comments

We gave the public the opportunity to comment on the previous NPRM (75 FR 15357, March 29, 2010). The following presents the comments received on the NPRM and the FAA's response to each comment.

Request for Clarification of Inspection Locations

Continental Airlines requested that we clarify the locations on which the inspections are done because the Accomplishment Instructions of Boeing Alert Service Bulletin 767–57A0117, Original Issue, dated October 1, 2009, specify doing detailed and ultrasonic inspections of the upper wing skin surface, but also mention certain instructions that specify doing the inspections on the lower surface of the upper wing skin.

We agree that clarification is needed. The upper surface of the upper wing skin is the location for the inspection. Boeing Alert Service Bulletin 767–57A0117, Revision 1, dated March 2, 2011 (described previously), specifies that the inspections be done on the ''upper wing skin surface.'' To clarify the location of the inspections, we have changed the wording of that phrase in the Summary and paragraphs (e) and (g) of this supplemental NPRM to ''upper surface of the upper wing skin.''

Request for Clarification of Certain Repair Conditions

All Nippon Airways (ANA) requested that we add the reference ''Condition 2D'' to paragraph (i) of the NPRM (75 FR 15357, March 29, 2010), which is reidentified as paragraph (h) of this supplemental NPRM, to clarify that only Condition 2D of Table 1, paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 767–57A0117, Original Issue, dated October 1, 2009, requires contacting Boeing for appropriate action. ANA added that ''Condition 2D'' specifies to ''contact Boeing for additional instructions and do the repair,'' but paragraph (i) of the NPRM refers to contacting Boeing for appropriate action. The commenter requested clarification.

We agree to provide clarification. We disagree with adding a reference to Condition 2D in paragraph (h) of this supplemental NPRM. Condition 2D of the Accomplishment Instructions of Boeing Alert Service Bulletin 767–57A0117, Revision 1, dated March 2, 2011 (this revised service bulletin is referenced in this supplemental NPRM as the appropriate source of service information), is the only condition that requires contacting Boeing for additional instructions and doing the repair. However, we have revised the language in paragraph (h) of this supplemental NPRM to match the language in Boeing Alert Service Bulletin 767–57A0117, Revision 1, dated March 2, 2011.

Request for Clarification of Repair Limits of Figures 5 and 6 of Boeing Alert Service Bulletin 767–57A0117, Original Issue, Dated October 1, 2009

Boeing and ANA requested we clarify that any cracks found can be repaired using Figures 5 and 6 of Boeing Alert Service Bulletin 767–57A0117, Original Issue, dated October 1, 2009, provided such cracks are within the repair limits described in those figures. Boeing stated that while Figures 5 and 6 provide repairs for cracks removed up to a final hole diameter of 0.540 inch from the starting hole size of 0.375 inch, the NPRM (75 FR 15357, March 29, 2010) would require that all repairs be submitted for FAA approval. Boeing requested that we change paragraph (i) of the NPRM (paragraph (h) of this supplemental NPRM) to further limit the repair conditions that require FAA approval to include cracks that exceed the repair limits contained in Figures 5 and 6 of Boeing Alert Service Bulletin 767–57A–0117, Original Issue, dated October 1, 2009.

We disagree. Paragraph (h) of this supplemental NPRM does not require all cracks to be repaired in accordance with paragraph (j) of this supplemental NPRM. Only those cracks beyond the documented limits in Boeing Alert Service Bulletin 767–57A0117, Revision 1, dated March 2, 2011, for which that service bulletin states to ''contact Boeing'' are required to be repaired in accordance with paragraph (j) of this supplemental NPRM. Paragraph (h) of this supplemental NPRM refers to conditions specified in that service bulletin, which include the limitation noted by the commenter. No change has been made to this supplemental NPRM in this regard.

Request for Definition of Condition 2D of Boeing Alert Service Bulletin 767–57A0117, Original Issue, Dated October 1, 2009

Continental Airlines requested changing the definition of Condition 2D of Boeing Alert Service Bulletin 767–57A0117, Original Issue, dated October 1, 2009. Continental Airlines stated that the definition is, ''Any crack found in one or more of the affected fastener hole locations that can not be removed with a final hole diameter of less than or equal to 0.540 inches.'' Continental Airlines noted that the condition of ''less than or equal to 0.540 inches'' is already covered under Condition 2C and suggested changing the wording to ''Any crack found in one or more of the affected fastener hole locations that can not be removed with a final hole diameter of 0.540 inches.''

We disagree with changing the definition of Condition 2D. Condition 2C specifies cracks that can be removed with a repaired hole diameter greater than 0.453 inch and less than or equal to 0.540 inch. Condition 2D specifies cracks that cannot be removed with a repaired hole diameter of less than or equal to 0.540 inch. No change has been made to this supplemental NPRM in this regard.

Request To Retain the Compliance Time Specified in Boeing Alert Service Bulletin 767–57A0117, Original Issue, Dated October 1, 2009

ANA requested that the compliance time specified in Boeing Alert Service Bulletin 767–57A0117, Original Issue, dated October 1, 2009, be retained as proposed in the NPRM (75 FR 15357, March 29, 2010) instead of reduced as specified in Boeing Alert Service Bulletin 767–57A0117, Revision 1, dated March 2, 2011. ANA stated that

they changed their ''C'' check maintenance schedule, which aligns better with the compliance times specified in Boeing Alert Service Bulletin 767–57A0117, Original Issue, Dated October 1, 2009.

We do not agree with the commenter's request to extend the compliance times. The intent of this supplemental NPRM, as stated in the preamble section, ''Actions Since Previous NPRM Was Issued,'' is to reduce the initial proposed compliance times based on failures found on airplanes below the proposed compliance times. In developing an appropriate compliance time for this action, we considered the safety implications, parts availability, and normal maintenance schedules for the timely accomplishment of the inspection. In consideration of these items, as well as the reports of cracking, we have determined that the revised compliance times specified in Boeing Alert Service Bulletin 767–57A0117, Revision 1, dated March 2, 2011, will ensure an acceptable level of safety.

Since maintenance schedules vary widely among operators, we tried to accommodate most affected operators by allowing the inspections to be done during scheduled maintenance intervals. However, under the provisions of paragraph (j) of this supplemental NPRM, we will consider requests for approval of an extension of the compliance time if sufficient data are submitted to substantiate that the extension would provide an acceptable level of safety.

Request To Change Wording in Figure 5 of Boeing Alert Service Bulletin 767–57A0117, Original Issue, Dated October 1, 2009

Continental Airlines stated that the ''More Data'' column of Step 2, Figure 5, of Boeing Alert Service Bulletin 767–57A0117, Original Issue, dated October 1, 2009, references ''Table 1 or Table 2 below.'' Continental noted that there are no tables ''below'' on that particular page, but are on the following page.

We infer that the commenter is requesting that we revise this supplemental NPRM to clarify the location of the tables. We disagree. Although those tables are not physically ''below'' on the same page, those tables can be easily located and can still be considered ''below'' as they follow the discussion items. No change has been made to this supplemental NPRM in this regard.

Request for Clarification of Step 4, Figure 5, of Boeing Alert Service Bulletin 767–57A0117, Original Issue, Dated October 1, 2009

Continental Airlines requested clarification of the wording in the ''More Data'' column of Step 4, Figure 5, of Boeing Alert Service Bulletin 767–57A0117, Original Issue, dated October 1, 2009. The commenter stated that the reference to ''SRM 51–40–09,'' in the ''More Data'' section of this service bulletin is for aluminum structure. Continental believed the intent is to cold work the skin hole only for airplanes with titanium pitch load fittings. Continental requested that we clarify this definition.

We agree that the cold working was meant for the wing skin holes for airplanes having titanium pitch load fittings. However, we have determined that the titanium fitting maintains an adequate level of safety if the cold working process is carried out through the entire stack-up. The other option would be to cold work only the aluminum skin, but that would be cost prohibitive and impractical to remove the titanium fitting, cold work the aluminum skin, and re-install the titanium fitting on the airplane. No change has been made to the supplemental NPRM in this regard.

Request To Change Location of Appendix A Reference of Boeing Alert Service Bulletin 767–57A0117, Original Issue, Dated October 1, 2009

Continental Airlines stated that it may be beneficial to reference Appendix A in Figure 6 of Boeing Alert Service Bulletin 767–57A0117, Original Issue, dated October 1, 2009.

We partially agree. Although it could be beneficial to reference Appendix A in Figure 6, Appendix A already is referenced in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 767–57A0117, Revision 1, dated March 2, 2011 (this revised service bulletin is referenced in this supplemental NPRM). No change has been made to the supplemental NPRM in this regard.

FAA's Determination

We are proposing this supplemental NPRM because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of these same type designs. Certain changes described above expand the scope of the original NPRM (75 FR 15357, March 29, 2010). As a result, we have determined that it is necessary to reopen the comment period to provide additional opportunity for the public to comment on this supplemental NPRM.

Proposed Requirements of the Supplemental NPRM

This supplemental NPRM would require accomplishing the actions specified in the service information described previously, except as discussed under ''Differences Between the Supplemental NPRM and the Service Information.''

Differences Between the Supplemental NPRM and the Service Information

Boeing Alert Service Bulletin 767–57A0117, Revision 1, dated March 2, 2011, specifies to contact the manufacturer for instructions on how to repair certain conditions, but this proposed AD would require repairing those conditions in one of the following ways:

- Using a method that we approve; or
- Using data that meet the certification basis of the airplane, and that have been approved by the Boeing Commercial Airplanes Organization Designation Authorization that we have authorized to make those findings.

Costs of Compliance

We estimate that this proposed AD affects 417 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	10 work-hours × $85 per hour = $850 per inspection cycle	$28,836	$29,686	$12,379,062

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

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Hole repair	1 work-hour per hole × maximum 48 holes per airplane × $85 per hour = up to $4,080 per airplane.	$0	Up to $4,080.
Fastener replacement	1 work-hour per hole × maximum 48 holes per airplane × $85 per hour = up to $4,080 per airplane.	0	Up to $4,080.
Freeze plug repair	1 work-hour per hole × maximum 48 holes per airplane × $85 per hour = up to $4,080 per airplane.	0	Up to $4,080.

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

For the reasons discussed above, I certify this proposed regulation:

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

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

(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.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2010–0277; Directorate Identifier 2009–NM–217–AD.

(a) Comments Due Date

We must receive comments by November 25, 2011.

(b) Affected ADs

None

(c) Applicability

This AD applies to The Boeing Company Model 767–200, –300, –300F, and –400ER series airplanes; certificated in any category; as identified in Boeing Alert Service Bulletin 767–57A0117, Revision 1, dated March 2, 2011.

(d) Subject

Joint Aircraft System Component (JASC)/Air Transport Association (ATA) of America Code 57, Wings.

(e) Unsafe Condition

This AD was prompted by reports of cracking in the upper wing skin at the fastener holes common to the inboard and outboard front spar pitch load fittings. We are issuing this AD to detect and correct fatigue cracking in the upper surface of the upper wing skin at the fastener holes common to the inboard and outboard pitch load fittings of the front spar, which could result in the loss of the strut-to-wing upper link load path and possible separation of a strut and engine from the airplane during flight.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Initial and Repetitive Inspection

Except as provided by paragraph (i) of this AD, at the applicable time specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 767–57A0117, Revision 1, dated March 2, 2011: Do detailed and ultrasonic inspections, or do an open-hole high-frequency eddy current inspection, to detect cracking in the upper surface of the upper wing skin at the fastener holes common to the inboard and outboard pitch load fittings of the front spar; and do all applicable corrective actions; in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 767–57A0117, Revision 1, dated March 2, 2011, except as required by paragraph (h) of this AD. Do all applicable corrective actions before further flight. Repeat the applicable inspections thereafter at intervals not to exceed the applicable time specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 767–57A0117, Revision 1, dated March 2, 2011.

(h) Exceptions to the Service Bulletin

(1) If any cracking is found during any inspection required by this AD, and Boeing Alert Service Bulletin 767–57A0117, Revision 1, dated March 2, 2011, specifies to contact Boeing for additional instructions: Before further flight, repair the cracking using a method approved in accordance with the procedures specified in paragraph (j) of this AD.

(2) Where Boeing Alert Service Bulletin 767–57A0117, Revision 1, dated March 2, 2011, specifies a compliance time after the date on Boeing Alert Service Bulletin 767–57A0117, Original Issue, dated October 1, 2009, this AD requires compliance within the specified compliance time after the effective date of this AD.

(i) Credit for Actions Accomplished in Accordance With Previous Service Information

Actions done before the effective date of this AD in accordance with Boeing Alert Service Bulletin 767–57A0117, dated October 1, 2009, are acceptable for compliance with the corresponding requirements of paragraph (g) of this AD.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as

appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in the Related Information section of this AD. Information may be e-mailed to: *9–ANM–Seattle–ACO–AMOC–Requests@faa.gov.*

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

(k) Related Information

(1) For more information about this AD, contact Berhane Alazar, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue, SW., Renton, Washington 98057–3356; phone: 425–917–6577; fax: 425–917–6590; e-mail: *berhane.alazar@faa.gov.* Or, e-mail information to *9–ANM–Seattle–ACO–AMOC–Requests@faa.gov.*

(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.* 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.

Issued in Renton, Washington, on September 28, 2011.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–26107 Filed 10–7–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–1065; Directorate Identifier 2011–NM–007–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Boeing Model 747–400 series airplanes. This proposed AD was prompted by reports of water leaking into electrical and electronic equipment in the main equipment center, which could result in an electrical short and potential loss of several functions essential for safe flight. This proposed AD would require modifying the floor panels, removing drains; installing floor supports, floor drain trough doublers, drain troughs, and drains; and sealing and taping the floor panels. We are proposing this AD to correct the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by November 25, 2011.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

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

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, *Attention:* Data & Services Management, P. O. Box 3707, MC 2H–65, Seattle, Washington 98124–2207; phone: 206–544–5000, extension 1; fax: 206–766–5680; e-mail: *me.boecom@boeing.com; Internet*: *https://www.myboeingfleet.com.* 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 proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Francis Smith, Aerospace Engineer, Cabin Safety & Environmental Systems Branch, ANM–150S, Seattle Aircraft Certification Office (ACO), FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; *phone:* 425–917–6596; *fax:* 425–917–6590; *e-mail: Francis.Smith@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2011–1065; Directorate Identifier 2011–NM–007–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We have received reports of water leaking into electrical and electronic equipment in the main equipment center on Model 747–400 Boeing Converted Freighter (BCF) airplanes. The water leaked through the main deck floor panels, fasteners, and floor fittings. The source of the water includes rain and snow coming in through the main deck doors, as well as wet cargo. This condition, if not corrected, could result in an electrical short and potential loss of several functions essential for safe flight.

Relevant Service Information

We reviewed Boeing Special Attention Service Bulletin 747–25–3586, dated November 12, 2010. This service information describes procedures for the following actions at stations 210 and 530.

- Modifying by removing and reworking floor panels
- Removing drains
- Installing new floor supports
- Installing floor drain trough doublers, and drain troughs
- Installing new drains

Additionally, in certain areas between stations 140 and 640, this service information describes installing sealant and tape.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in the service information described previously.

Costs of Compliance

We estimate that this proposed AD affects 12 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Floor panel reworking and sealing; installing drains, drain trough doublers, and drain troughs.	Up to 644 work-hours × $85 per hour = $54,740.	$64,033	Up to $118,773	Up to $1,425,276.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

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

(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.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2011–1065;
Directorate Identifier 2011–NM–007–AD.

(a) Comments Due Date

We must receive comments by November 25, 2011.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 747–400 series airplanes, certificated in any category, as identified in Boeing Special Attention Service Bulletin 747–25–3586, dated November 12, 2010.

(d) Subject

Joint Aircraft System Component (JASC)/Air Transport Association (ATA) of America Code 25, Equipment and Furnishings.

(e) Unsafe Condition

This AD was prompted by reports of water leaking into electrical and electronic equipment in the main equipment center. We are issuing this AD to prevent water from entering the main equipment center, which could result in an electrical short and potential loss of several functions essential for safe flight.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Floor Panel Sealing

Within 24 months after the effective date of this AD: Modify the floor panels; remove drains; install floor supports, floor drain trough doublers, drain troughs, and drains; and seal and tape the floor panels; at the applicable locations; in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–25–3586, dated November 12, 2010.

(h) Alternative Methods of Compliance (AMOCs)

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

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

(i) Related Information

(1) For more information about this AD, contact Francis Smith, Aerospace Engineer, Cabin Safety & Environmental Systems Branch, ANM–150S, Seattle Aircraft Certification Office (ACO), FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; *phone:* 425–917–6596; *fax:* 425–917–6590; *e-mail: Francis.Smith@faa.gov*.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, *Attention:* Data & Services Management, P. O. Box 3707, MC 2H–65, Seattle, Washington 98124–2207; *phone:* 206–544–5000, extension 1; *fax:* 206–766–

5680; *e-mail: me.boecom@boeing.com; Internet: https://www.myboeingfleet.com.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.

Issued in Renton, Washington, on September 30, 2011.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–26105 Filed 10–7–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–1064; Directorate Identifier 2011–NM–075–AD]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc. Model BD–100–1A10 (Challenger 300) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for the products listed above. This proposed 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:

It was discovered that the Horizontal Stabilizer Trim Actuator (HSTA) No Back and the Number 1 Motor Brake Assembly (MBA) can both fail dormant. A failure of the HSTA No Back and the Brake System along with additional component failure could result in an uncontrollable horizontal stabilizer surface runaway without the ability to retrim. This condition, if not corrected, could lead to the loss of the aeroplane.

* * * * *

The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

DATES: We must receive comments on this proposed AD by November 25, 2011.

ADDRESSES: You may send comments by any of the following methods:

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

For service information identified in this proposed AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; e-mail *thd.crj@aero.bombardier.com;* Internet *http://www.bombardier.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 Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Cesar Gomez, Aerospace Engineer, Airframe and Mechanical Systems Branch, ANE–171, FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone (516) 228–7318; fax (516) 794–5531.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2011–1064; Directorate Identifier 2011–NM–075–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian Airworthiness Directive CF–2011–05, dated March 24, 2011 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

It was discovered that the Horizontal Stabilizer Trim Actuator (HSTA) No Back and the Number 1 Motor Brake Assembly (MBA) can both fail dormant. A failure of the HSTA No Back and the Brake System along with additional component failure could result in an uncontrollable horizontal stabilizer surface runaway without the ability to retrim. This condition, if not corrected, could lead to the loss of the aeroplane.

As a result, new Airworthiness Limitation Tasks, consisting of a functional test of the HSTA No Back and a functional test of the HSTA Brake System, have been introduced to ensure that a dormant failure of either component is detected and corrected.

This [TCCA] directive mandates the revision of the approved maintenance schedule to include these new tasks, including phase-in schedules.

You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Bombardier, Inc. has issued Temporary Revision 5–2–59, dated November 25, 2010, to Section 5–10–40, ''Certification Maintenance Requirements,'' of Part 2, ''Airworthiness Limitations,'' of the Bombardier Challenger 300 BD–100 Time Limits/Maintenance Checks Manual. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

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 proposed different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a NOTE within the proposed AD.

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 76 products of U.S. registry. We also estimate that it would take about 1 work-hour per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $6,460, or $85 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 proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Bombardier, Inc.: Docket No. FAA–2011–1064; Directorate Identifier 2011–NM–075–AD.

Comments Due Date

(a) We must receive comments by November 25, 2011.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all Bombardier, Inc. Model BD–100–1A10 (Challenger 300) airplanes, certificated in any category.

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

Subject

(d) Air Transport Association (ATA) of America Code 55: Stabilizers.

Reason

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

It was discovered that the Horizontal Stabilizer Trim Actuator (HSTA) No Back and the Number 1 Motor Brake Assembly (MBA) can both fail dormant. A failure of the HSTA No Back and the Brake System along with additional component failure could result in an uncontrollable horizontal stabilizer surface runaway without the ability to retrim. This condition, if not corrected, could lead to the loss of the aeroplane.

* * * * *

Compliance

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

Actions

(g) Within 30 days the effective date of this AD: Revise the maintenance program by incorporating Task 27–40–00–107, ''Horizontal Stabilizer Trim Actuator (HSTA) No Back,'' in accordance with Bombardier Temporary Revision 5–2–59, dated November 25, 2010, to Section 5–10–40, ''Certification Maintenance Requirements,'' of Part 2, ''Airworthiness Limitations,'' of the Bombardier Challenger 300 BD–100 Time Limits/Maintenance Checks Manual. For this task, the initial compliance time starts at the applicable time specified in paragraph (g)(1) or (g)(2) of this AD.

(1) For HSTAs with 2,600 or fewer total flight hours on the HSTA as of the effective date of this AD: Prior to the accumulation of 3,000 total flight hours on the HSTA.

(2) For HSTAs with more than 2,600 total flight hours on the HSTA as of the effective date of this AD: Within 400 flight hours or 6 months after the effective date of this AD, whichever occurs first.

(h) Within 30 days after the effective date of this AD, whichever occurs later: Revise the maintenance program by incorporating Task 27–41–05–105, ''Functional Test of the Horizontal Stabilizer Trim Actuator (HSTA) Brake System,'' in accordance with Bombardier Temporary Revision 5–2–59, dated November 25, 2010, to Section 5–10–40, ''Certification Maintenance Requirements,'' of Part 2, ''Airworthiness Limitations,'' of the Bombardier Challenger 300 BD–100 Time Limits/Maintenance Checks Manual. For this task, the initial compliance time starts at the applicable time specified in paragraph (h)(1) or (h)(2) of this AD.

(1) For airplanes with 400 or fewer total flight hours as of the effective date of this AD: Prior to the accumulation of 800 total flight hours.

(2) For airplanes with more than 400 total flight hours as of the effective date of this AD: Within 400 flight hours or 12 months after the effective date of this AD, whichever occurs first.

Note 2: The maintenance program revision required by paragraphs (g) and (h) of this AD may be done by inserting a copy of Bombardier TR 5–2–59, dated November 25, 2010, into Section 5–10–40, ''Certification Maintenance Requirements,'' of Part 2,

''Airworthiness Limitations,'' of the Bombardier Challenger 300 BD–100 Time Limits/Maintenance Checks Manual. When this TR has been included in the general revisions of Section 5–10–40, ''Certification Maintenance Requirements,'' of Part 2, ''Airworthiness Limitations,'' of the Bombardier Challenger 300 BD–100 Time Limits/Maintenance Checks Manual, the general revisions may be inserted in Section 5–10–40, ''Certification Maintenance Requirements,'' of Part 2, ''Airworthiness Limitations,'' of the Bombardier Challenger 300 BD–100 Time Limits/Maintenance Checks Manual, provided that the relevant information in the general revision is identical to that in Bombardier TR 5–2–59, dated November 25, 2010, to Section 5–10–40, ''Certification Maintenance Requirements,'' of Part 2, ''Airworthiness Limitations,'' of the Bombardier Challenger 300 BD–100 Time Limits/Maintenance Checks Manual.

No Alternative Actions or Intervals

(i) After accomplishing the revision required by paragraphs (g) and (h) of this AD, no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions or intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (j)(1) of this AD.

FAA AD Differences

Note 3: This AD differs from the MCAI and/or service information as follows:

No differences.

Other FAA AD Provisions

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

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York Aircraft Certification Office (ACO), ANE–170, 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 ACO, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone 516–228–7300; fax 516–794–5531. 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

(k) Refer to MCAI Transport Canada Civil Aviation (TCCA) Airworthiness Directive CF–2011–05, dated March 24, 2011; and Bombardier Temporary Revision 5–2–59, dated November 25, 2010, to Section 5–10–40, ''Certification Maintenance Requirements,'' of Part 2, ''Airworthiness Limitations,'' of the Bombardier Challenger 300 BD–100 Time Limits/Maintenance Checks Manual; for related information.

Issued in Renton, Washington, on September 30, 2011.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–26111 Filed 10–7–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–1061; Directorate Identifier 2011–NM–053–AD]

RIN 2120–AA64

Airworthiness Directives; Dassault Aviation Model FALCON 7X Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

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

The manufacturer of the Transformer Rectifier Unit (TRU) part of the Ram Air Turbine (RAT) system has identified an incorrect design of the part.

* * * * *

This condition, if not corrected, and if occurring while the RAT is deployed, could result in a degraded direct current power which is distributed to essential aeroplane systems and therefore aeroplane operations might be impaired.

* * * * *

The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

DATES: We must receive comments on this proposed AD by November 25, 2011.

ADDRESSES: You may send comments by any of the following methods:

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

For service information identified in this proposed AD, contact Dassault Falcon Jet, P.O. Box 2000, South Hackensack, New Jersey 07606; telephone 201–440–6700; Internet *http://www.dassaultfalcon.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 Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

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

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2011–1061; Directorate Identifier 2011–NM–053–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov*, including any

personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2011–0008, dated January 18, 2011 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

The manufacturer of the Transformer Rectifier Unit (TRU) part of the Ram Air Turbine (RAT) system has identified an incorrect design of the part.

The internal wiring that conducts the high voltage alternative current from the RAT generator may become loose due to insufficient crimping of the wire and contacts.

This condition, if not corrected, and if occurring while the RAT is deployed, could result in a degraded direct current power which is distributed to essential aeroplane systems and therefore aeroplane operations might be impaired.

To address this unsafe condition, the manufacturer of the RAT TRU has developed an improved RAT TRU with a new Part Number (P/N).

This [EASA] AD requires replacement of the affected RAT TRU by a modified RAT TRU.

You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Dassault Aviation has issued Mandatory Service Bulletin 7X–163, dated December 1, 2010. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

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 proposed different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a NOTE within the proposed AD.

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 27 products of U.S. registry. We also estimate that it would take about 13 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Required parts would cost about $16,310 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 the proposed AD on U.S. operators to be $470,205, or $17,415 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 proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Dassault Aviation: Docket No. FAA–2011–1061; Directorate Identifier 2011–NM–053–AD.

Comments Due Date

(a) We must receive comments by November 25, 2011.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Dassault Aviation Model FALCON 7X airplanes, all serial numbers, certificated in any category; equipped with any Ram Air Turbine (RAT) Transformer Rectifier Unit (TRU) having part number (P/N) 5913703.

Subject

(d) Air Transport Association (ATA) of America Code 24: Electrical Power.

Reason

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

The manufacturer of the Transformer Rectifier Unit (TRU) part of the Ram Air Turbine (RAT) system has identified an incorrect design of the part.

* * * * *

This condition, if not corrected, and if occurring while the RAT is deployed, could result in a degraded direct current power which is distributed to essential aeroplane systems and therefore aeroplane operations might be impaired.

* * * * *

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 28 months after the effective date of this AD, replace any RAT TRU having P/N 5913703 with a RAT TRU having P/N 5915825, in accordance with the Accomplishment Instructions of Dassault Mandatory Service Bulletin 7X–163, dated December 1, 2010.

Parts Installation

(h) As of the effective date of this AD, no person may install any RAT TRU having P/N 5913703, on any airplane.

FAA AD Differences

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

Other FAA AD Provisions

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

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to *Attn:* Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1137; fax (425) 227–1149: Information may be e-mailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

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

Related Information

(j) Refer to MCAI European Aviation Safety Agency Airworthiness Directive 2011–0008, dated January 18, 2011; and Dassault Mandatory Service Bulletin 7X–163, dated December 1, 2010; for related information.

Issued in Renton, Washington, on September 28, 2011.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–26112 Filed 10–7–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–1066; Directorate Identifier 2011–NM–050–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD), for certain Airbus Model A300 B2–1C, B2K–3C, B2–203, B4–2C, B4–103, and B4–203 airplanes and Model A300 B4–601, B4–603, B4–620, B4–622, B4–605R, B4–622R, and F4–605R airplanes, that would supersede an existing AD. This proposed 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:

Following the occurrence of cracks on the MLG [main landing gear] Rib 5 RH [right-hand] and LH [left-hand] attachment fitting lower flanges, DGAC [Direction Générale de l'Aviation Civile] France AD 2003–318(B) was issued to require repetitive inspections and, as terminating action * * * [.]

Subsequently, new cases of cracks were discovered during scheduled maintenance checks by operators of A300B4 and A300–600 type aeroplanes on which the terminating action * * * [was] embodied. This condition, if not corrected, could affect the structural integrity of those aeroplanes.

* * * * *

The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

DATES: We must receive comments on this proposed AD by November 25, 2011.

ADDRESSES: You may send comments by any of the following methods:

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

For service information identified in this proposed AD, contact Airbus SAS—EAW (Airworthiness Office), 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; e-mail *account.airworth-eas@airbus.com*; Internet *http://www.airbus.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 Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–2125; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2011–1066; Directorate Identifier 2011–NM–050–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any

personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

On November 3, 2010, we issued AD 2010–23–26, Amendment 39–16516 (75 FR 74610, December 1, 2010). That AD required actions intended to address an unsafe condition on the products listed above.

Since we issued AD 2010–23–26, Amendment 39–16516 (75 FR 74610, December 1, 2010), we have determined that it is necessary to mandate the optional spot-facing modification specified in paragraph (q) of the existing AD: The European Aviation Safety Agency (EASA), which is the aviation authority for the Member States of the European Community, has issued EASA Airworthiness Directive 2011–0029, dated February 24, 2011 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

Following the occurrence of cracks on the MLG [main landing gear] Rib 5 RH [right-hand] and LH [left-hand] attachment fitting lower flanges, DGAC [Direction Générale de l'Aviation Civile] France AD 2003–318(B) was issued to require repetitive inspections and, as terminating action, the embodiment of Airbus Service Bulletins (SB) A300–57–0235 and A300–57–6088 * * *.

Subsequently, new cases of cracks were discovered during scheduled maintenance checks by operators of A300B4 and A300–600 type aeroplanes on which the terminating action SB's were embodied. This condition, if not corrected, could affect the structural integrity of those aeroplanes.

To address and correct this condition, Airbus developed an inspection programme for aeroplanes modified in accordance with SB A300–57–0235 or A300–57–6088. This inspection programme was required to be implemented by DGAC France AD F–2005–113, original issue and later revision 1 [parallel to part of FAA AD 2006–12–13, Amendment 39–14639 (71 FR 33994, June 13, 2006)].

A new EASA [European Aviation Safety Agency] AD 2008–0111, superseding DGAC France AD F–2005–113R1, was issued to reduce the applicability. For aeroplanes already compliant with DGAC France AD F–2005–113R1, no further action was required.

Since EASA AD 2008–0111 issuance, Airbus reviewed the inspection programmes of SB A300–57A0246 and SB A300–57A6101 to introduce repetitive inspections including a new inspection technique for holes 47 and 54 and to reduce inspections threshold and intervals from 700 Flight Cycles (FC) to 400 FC until a revised terminating action is made available.

For the reasons stated above, EASA AD 2009–0081 superseded EASA AD 2008–0111 and required operators to comply with the new inspection programme introduced in Revisions 3 of Airbus SB A300–57A0246 and Airbus SB A300–57A6101.

EASA AD 2009–0081 R1 [which corresponds to FAA AD 2010–23–26, Amendment 39–16516 (75 FR 74610, December 1, 2010)] has been published to introduce an optional terminating action which consisted of spot-facing the sensitive holes of the MLG Rib 5 (LH and RH) bottom flanges.

Later discussions with Airbus have demonstrated the necessity to require the spot-facing modification as a final solution (no longer optional). This new [EASA] AD retains the inspection requirements of EASA AD 2009–0081 R1, which is superseded, and requires the spot-facing of sensitive holes of the MLG Rib 5 (LH and RH) bottom flanges as terminating action.

Required actions include repairing discrepancies (*e.g.,* cracking or a 2nd oversize or greater fastener hole). You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Airbus has issued Mandatory Service Bulletins A300–57–0254, Revision 01, including Appendix 1, dated June 14, 2011; and A300–57–6110, Revision 01, including Appendix 1, dated June 6, 2011. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

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 proposed different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a NOTE within the proposed AD.

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 155 products of U.S. registry.

The actions that are required by AD 2010–23–26, Amendment 39–16516 (75 FR 74610, December 1, 2010), and retained in this AD take about 79 work-hours per product, at an average labor rate of $85 per work hour. Required parts cost about $10,270 per product. Based on these figures, the estimated cost of the currently required actions is $16,985 per product.

We estimate that it would take about 100 work-hours per product to comply with the new basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $1,317,500, or $8,500 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 proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The FAA amends § 39.13 by removing Amendment 39–16516 (75 FR 74610, December 1, 2010) and adding the following new AD:

Airbus: Docket No. FAA–2011–1066; Directorate Identifier 2011–NM–050–AD.

Comments Due Date

(a) We must receive comments by November 25, 2011.

Affected ADs

(b) This AD supersedes AD 2010–23–26, Amendment 39–16516 (75 FR 74610, December 1, 2010).

Applicability

(c) This AD applies to the airplanes, certificated in any category, identified in paragraphs (c)(1) and (c)(2) of this AD; except airplanes on which Airbus Modification 11912 or 11932 has been installed.

(1) Airbus Model A300 B2–1C, B2K–3C, B2–203, B4–2C, B4–103, and B4–203 airplanes.

(2) Airbus Model A300 B4–601, B4–603, B4–620, B4–622, B4–605R, B4–622R, and F4–605R airplanes.

Subject

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

Reason

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

Following the occurrence of cracks on the MLG [main landing gear] Rib 5 RH [right-hand] and LH [left-hand] attachment fitting lower flanges, DGAC [Direction Générale de l'Aviation Civile] France AD 2003–318(B) was issued to require repetitive inspections and, as terminating action, the embodiment of Airbus Service Bulletins (SB) A300–57–0235 and A300–57–6088 * * *.

Subsequently, new cases of cracks were discovered during scheduled maintenance checks by operators of A300B4 and A300–600 type aeroplanes on which the terminating action SB's were embodied. This condition, if not corrected, could affect the structural integrity of those aeroplanes.

* * * * *

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 2000–05–07, Amendment 39–11616 (65 FR 12077, March 8, 2000):

Repetitive Inspections

(g) Perform a detailed inspection and a high-frequency eddy current (HFEC) inspection to detect cracks in Gear Rib 5 of the main landing gear (MLG) attachment fittings at the lower flange, in accordance with the Accomplishment Instructions of any applicable service bulletin listed in Table 1 and Table 2 of this AD, at the time specified in paragraph (g)(1) or (g)(2) of this AD. After April 12, 2000 (the effective date of AD 2000–05–07, Amendment 39–11616 (65 FR 12077, March 8, 2000)), only the service bulletins listed in Table 2 of this AD may be used. Repeat the inspections thereafter at intervals not to exceed 1,500 flight cycles, until the actions specified in paragraph (i), (j), or (l) of this AD are accomplished.

TABLE 1—REVISION 01 OF SERVICE BULLETINS

Model—	Airbus service bulletin—	Revision—	Dated—
A300 B4–601, B4–603, B4–620, B4–622, B4–605R, B4–622R and F4–605R airplanes.	A300–57–6087	01	March 11, 1998.
A300 B2–1C, B2K–3C, B2–203, B4–2C, B4–103, and B4–203 airplanes.	A300–57–0234	01	March 11, 1998.

TABLE 2—OTHER REVISIONS OF SERVICE BULLETINS

Model—	Airbus service bulletin—	Revision—	Dated—
A300 B4–601, B4–603, B4–620, B4–622, B4–605R, B4–622R, and F4–605R airplanes.	A300–57A6087	02, including Appendix 01	June 24, 1999.
		03, including Appendix 01	May 19, 2000.
		04, including Appendix 01	February 19, 2002.
		05, including Appendix 01	March 10, 2008.
A300 B2–1C, B2K–3C, B2–203, B4–2C, B4–103, and B4–203 airplanes.	A300–57A0234	02	June 24, 1999.
		03, including Appendix 01	September 2, 1999.
		04, including Appendix 01	May 19, 2000.
		05, including Appendix 01	February 19, 2002.

(1) For airplanes that have accumulated 20,000 or more total flight cycles as of March 9, 1998 (the effective date of AD 98–03–06, Amendment 39–10298 (63 FR 5224, February 2, 1998)): Inspect within 500 flight cycles after March 9, 1998.

(2) For airplanes that have accumulated less than 20,000 total flight cycles as of March 9, 1998: Inspect prior to the accumulation of 18,000 total flight cycles, or within 1,500 flight cycles after March 9, 1998, whichever occurs later.

Note 1: For the purposes of this AD, a detailed inspection is defined as: ''An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good

lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required.''

Note 2: Accomplishment of the initial detailed and HFEC inspections prior to April 12, 2000, in accordance with Airbus Service Bulletin A300–57A0234 or A300–57A6087, both dated August 5, 1997, as applicable, is considered acceptable for compliance with the initial inspections required by paragraph (g) of this AD.

Repair for Any Crack Found During Inspections Required by Paragraph (g) of This AD

(h) If any crack is detected during any inspection required by paragraph (g) of this AD, prior to further flight, accomplish the requirements of paragraph (h)(1) or (h)(2) of this AD, as applicable.

(1) If a crack is detected at one hole only, and the crack does not extend out of the spotface of the hole, repair in accordance with the Accomplishment Instructions of the applicable service bulletin in Table 2 of this AD.

(2) If a crack is detected at more than one hole, or if any crack at any hole extends out of the spotface of the hole, repair in accordance with a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, or the European Aviation Safety Agency (EASA) (or its delegated agent).

Terminating Modification for Repetitive Inspections Required by Paragraphs (g) and (j) of This AD

(i) Except as required by paragraph (l) of this AD, prior to the accumulation of 21,000 total flight cycles, or within 2 years after October 20, 1999 (the effective date of AD 99–19–26, Amendment 39–11313 (64 FR 49966, September 15, 1999)), whichever occurs later: Modify Gear Rib 5 of the MLG attachment fittings at the lower flange in accordance with the Accomplishment Instructions of the applicable service bulletin in Table 3 of this AD. After July 18, 2006 (the effective date of AD 2006–12–13, Amendment 39–14639 (71 FR 33994, June 13, 2006)), only Revision 04 of Airbus Service Bulletin A300–57–6088, and Revisions 04 and 05 of Airbus Service Bulletin A300–57–0235 may be used. Accomplishment of this modification constitutes terminating action for the repetitive inspection requirements of paragraphs (g) and (j) of this AD.

TABLE 3—SERVICE BULLETINS FOR TERMINATING MODIFICATION

Model—	Airbus service bulletin—	Revision—	Dated—
A300 B4–601, B4–603, B4–620, B4–622, B4–605R, B4–622R, and F4–605R airplanes.	A300–57–6088	01, including Appendix 01	February 1, 1999.
		02	September 5, 2002.
		04	December 3, 2003.
A300 B2–1C, B2K–3C, B2–203, B4–2C, B4–103, and B4–203 airplanes.	A300–57–0235	01, including Appendix 01	February 1, 1999.
		03	September 5, 2002.
		04	March 13, 2003.
		05	December 3, 2003.

Note 3: Accomplishment of the modification required by paragraph (i) of this AD prior to April 12, 2000, in accordance with Airbus Service Bulletin A300–57–6088 or A300–57–0235, both dated August 5, 1998; as applicable; is acceptable for compliance with the requirements of that paragraph.

Restatement of Requirements of AD 2006–12–13, Amendment 39–14639 (71 FR 33994, June 13, 2006):

Additional Repetitive Inspections

(j) For airplanes on which the modification specified in paragraph (i) or (l) of this AD has not been done before July 18, 2006 (the effective date of AD 2006–12–13, Amendment 39–14639 (69 FR 54063, September 7, 2004)), perform a detailed and an HFEC inspection to detect cracks of the lower flange of Gear Rib 5 of the MLG at holes 43, 47, 48, 49, 50, 52, and 54, in accordance with the applicable service bulletin listed in Table 4 of this AD. Perform the inspections at the applicable time specified in paragraph (j)(1), (j)(2), (j)(3), or (j)(4) of this AD. Repeat the inspections thereafter at intervals not to exceed 700 flight cycles until the terminating modification required by paragraph (l) of this AD is accomplished. Accomplishment of the inspections per paragraph (j) of this AD terminates the inspection requirements of paragraph (g) of this AD.

TABLE 4—SERVICE BULLETINS FOR REPETITIVE INSPECTIONS

Model—	Airbus service bulletin—	Revision—	Dated—
A300 B4–601, B4–603, B4–620, B4–622, B4–605R, B4–622R, and F4–605R airplanes.	A300–57A6087	04, including Appendix 01	February 19, 2002.
		05, including Appendix 01	March 10, 2008.
A300 B2–1C, B2K–3C, B2–203, B4–2C, B4–103, and B4–203 airplanes.	A300–57A0234	05, including Appendix 01	February 19, 2002.

(1) For Model A300 B2–1C, B2K–3C, B2–203, B4–2C, B4–103, and B4–203 airplanes; and Model A300 B4–601, B4–603, B4–620, B4–622, B4–605R, B4–622R, and F4–605R airplanes that have accumulated 18,000 or more total flight cycles as of July 18, 2006: Within 700 flight cycles after July 18, 2006.

(2) For Model A300 B2–1C, B2K–3C, and B2–203 airplanes that have accumulated less than 18,000 total flight cycles as of July 18, 2006: Prior to the accumulation of 18,000 total flight cycles, or within 700 flight cycles after July 18, 2006, whichever occurs later.

(3) For Model A300 B4–2C, B4–103, and B4–203 airplanes that have accumulated less than 18,000 total flight cycles as of July 18, 2006: Prior to the accumulation of 14,500 total flight cycles, or within 700 flight cycles after July 18, 2006, whichever occurs later.

(4) For Model A300 B4–601, B4–603, B4–620, B4–622, B4–605R, B4–622R, and F4–605R airplanes that have accumulated less than 18,000 total flight cycles as of July 18, 2006: Prior to the accumulation of 11,600 total flight cycles, or within 700 flight cycles after July 18, 2006, whichever occurs later.

Crack Repair

(k) If any crack is detected during any inspection required by paragraph (j) of this AD, prior to further flight, accomplish the requirements of paragraphs (k)(1) and (k)(2) of this AD, as applicable.

(1) If a crack is detected at only one hole, and the crack does not extend out of the spotface of the hole, repair in accordance with Airbus Service Bulletin A300–57A0234, Revision 05, including Appendix 01, dated February 19, 2002 (for Model A300 B2–1C, B2K–3C, B2–203, B4–2C, B4–103, and B4–203 airplanes); or A300–57A6087, Revision 04, including Appendix 01, dated February 19, 2002; or A300–57A6087, Revision 05, dated March 10, 2008 (for Model A300 B4–601, B4–603, B4–620, B4–622, B4–605R, B4–622R, and F4–605R airplanes); as applicable.

(2) If a crack is detected at more than one hole, or if any crack at any hole extends out of the spotface of the hole, repair in accordance with a method approved by the Manager, International Branch, ANM–116, or the EASA (or its delegated agent).

Terminating Modification for Repetitive Inspections Required by Paragraphs (g) and (j) of This AD for Certain Airplanes

(l) For airplanes on which the terminating modification in paragraph (i) of this AD has not been accomplished before July 18, 2006: At the earlier of the times specified in paragraphs (l)(1) and (l)(2) of this AD, modify Gear Rib 5 of the MLG attachment fittings at the lower flange. Except as provided by paragraph (m) of this AD, do the modification in accordance with the applicable service bulletin in Table 5 of this AD. This action terminates the repetitive inspections requirements of paragraphs (g) and (j) of this AD.

(1) Prior to the accumulation of 21,000 total flight cycles, or within 2 years after October 20, 1999, whichever is later.

(2) Within 16 months after July 18, 2006.

TABLE 5—SERVICE BULLETINS FOR TERMINATING MODIFICATION

Model—	Airbus service bulletin—	Revision—	Dated—
A300 B4–601, B4–603, B4–620, B4–622, B4–605R, B4–622R and F4–605R airplanes.	A300–57–6088	04	December 3, 2003.
A300 B2–1C, B2K–3C, B2–203, B4–2C, B4–103, and B4–203 airplanes.	A300–57–0235	04	March 13, 2003.
		05	December 3, 2003.

(m) Where the applicable service bulletin specified in paragraph (l) of this AD specifies to contact Airbus for modification instructions; or if there is a previously installed repair at any of the affected fastener holes; or if a crack is found when accomplishing the modification: Prior to further flight, modify in accordance with a method approved by the Manager, International Branch, ANM–116, or the EASA (or its delegated agent).

Actions Accomplished per Previous Issues of Service Bulletins

(n) Actions accomplished before July 18, 2006, in accordance with the service bulletins listed in Table 6 of this AD, are considered acceptable for compliance with the corresponding action specified in paragraphs (g) through (m) of this AD.

TABLE 6—PREVIOUS ISSUES OF SERVICE BULLETINS

Airbus service bulletin—	Revision—	Dated—
A300–57–0235	02, including Appendix 01	September 27, 1999.
	03	September 5, 2002.
A300–57–6088	02	September 5, 2000.
	03	March 13, 2003.

No Reporting

(o) Although the service bulletins identified in Tables 1, 2, 3, 4, 5, and 6 of this AD specify to submit certain information to the manufacturer, this AD does not include such a requirement.

Restatement of Requirements of AD 2010–23–26, Amendment 39–16516 (75 FR 74610, December 1, 2010), with Certain Service Information Required after the Effective Date of This AD:

Actions and Compliance

(p) Unless already done, do the following actions.

(1) At the applicable time specified in paragraph (p)(2) of this AD, perform a detailed inspection for cracking at the locations specified in paragraphs (p)(1)(i), (p)(1)(ii), and (p)(1)(iii) of this AD, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A300–57A0246, Revision 03, dated March 11, 2009, or Revision 04, dated September 9, 2009; or Airbus Mandatory Service Bulletin A300–57A6101, Revision 03, dated March 11, 2009, or Revision 04, dated September 9, 2009; as applicable. As of the effective date of this AD only Revision 04 of these service bulletins may be used.

(i) The bottom flange and vertical web in the area between the wing rear spar/gear Rib 5 attachment and the forward reaction-rod pick-up lug.

(ii) On the inboard side, around the fastener holes at locations 43, 47 to 50, 52, and 54.

(iii) On the outboard side, the lower flange, the vertical web and around the fastener holes at locations 43, 47 to 50, 52 and 54.

(2) Do the inspection required by paragraph (p)(1) of this AD at the later of the times in paragraphs (p)(2)(i) and (p)(2)(ii) of this AD.

(i) Within 400 flight cycles after the accomplishment of the actions required by paragraph (i) or (l) of this AD, as applicable.

(ii) Within 400 flight cycles or 4 months after January 5, 2011 (the effective date of AD 2010–23–26, Amendment 39–16516 (75 FR 74610, December 1, 2010)), whichever occurs first.

(3) If no cracking is detected during the inspection required by paragraph (p)(1) of this AD, before further flight, perform a fluorescent penetrant inspection (FPI) at holes location 47 and 54, in the right-hand and left-hand MLG Rib 5 attachment fitting lower flange, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A300–57A0246, Revision 03, dated March 11, 2009, or Revision 04, dated September 9, 2009; or Airbus Mandatory Service Bulletin A300–57A6101, Revision 03, dated March 11, 2009, or Revision 04, dated September 9, 2009; as applicable. As of the effective date of this AD, only Revision 04 of these service bulletins may be used.

(4) Thereafter, at intervals not to exceed 400 flight cycles, repeat the detailed and FPI inspections, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A300–57A0246, Revision 03, dated March 11, 2009, or Revision 04, dated September 9, 2009; or Airbus Mandatory Service Bulletin A300–57A6101, Revision 03, dated March 11, 2009, or Revision 04, dated September 9, 2009; as applicable; until the terminating action required by paragraph (q) of this AD has been

accomplished. As of the effective date of this AD, only Revision 04 of these service bulletins may be used.

(5) If any crack is detected during any of the inspections required by paragraphs (p)(1), (p)(3), and (p)(4) of this AD, and Airbus Mandatory Service Bulletin A300–57A0246, Revision 03, dated March 11, 2009, or Revision 04, dated September 9, 2009; or Airbus Mandatory Service Bulletin A300–57A6101, Revision 03, dated March 11, 2009, or Revision 04, dated September 9, 2009; recommends contacting Airbus for appropriate action: Before further flight, contact Airbus for a repair solution, and do the repair; or repair the cracking using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, or EASA or its delegated agent. As of the effective date of this AD, only Revision 04 of these service bulletins may be used.

New Requirements of This AD:

Terminating Action

(q) Within 30 months after the effective date of this AD: Modify the spot-faces around all the fastener holes at locations 43, 47 to 50, 52, and 54 (except for spot-faces of holes which have been previously repaired) on the bottom flange MLG ribs, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A300–57–0254, Revision 01, including Appendix 1, dated June 14, 2011; or Airbus Mandatory Service Bulletin A300–57–6110, Revision 01, including Appendix 1, dated June 6, 2011; as applicable. Accomplishing this modification terminates the repetitive inspection requirements of paragraph (p)(4) of this AD.

Credit for Actions Accomplished in Accordance With Previous Service Information

(r) Modifying the spot-faces before the effective date of this AD, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A300–57–0254, dated June 4, 2010; or Airbus Mandatory Service Bulletin A300–57–6110, dated June 7, 2010; as applicable; is considered acceptable for compliance with the requirements of paragraph (q) of this AD.

FAA AD Differences

Note 4: This AD differs from the MCAI and/or service information as follows: No differences.

Other FAA AD Provisions

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

(1) *Alternative Methods of Compliance (AMOCs):* Manager, International Branch, ANM–116, 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: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–2125; 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. AMOCs approved previously in accordance with AD 2000–05–07, Amendment 39–11616 (65 FR 12077, March 8, 2000); AD 2006–12–13, Amendment 39–14639 (69 FR 54063, September 7, 2004); and AD 2010–23–26, Amendment 39–16516 (75 FR 74610, December 1, 2010), are approved as AMOCs for the corresponding provisions of 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

(t) Refer to MCAI EASA Airworthiness Directive 2011–0029, dated February 24, 2011; and the service information specified in Table 7 of this AD, for related information.

TABLE 7—RELATED SERVICE INFORMATION

Airbus—	Revision—	Dated—
Mandatory Service Bulletin A300–57A0246	04, including Appendices 1 and 2	September 9, 2009.
Mandatory Service Bulletin A300–57–0254	01	June 14, 2011.
Mandatory Service Bulletin A300–57A6101	04, including Appendices 1 and 2	September 9, 2009.
Mandatory Service Bulletin A300–57–6110	01	June 6, 2011.
Service Bulletin A300–57A0234	02	June 24, 1999.
	03, including Appendix 01	September 2, 1999.
	04, including Appendix 01	May 19, 2000.
	05, including Appendix 01	February 19, 2002.
Service Bulletin A300–57A6087	02, including Appendix 01	June 24, 1999.
	03, including Appendix 01	May 19, 2000.
	04, including Appendix 01	February 19, 2002.
	05, including Appendix 01	March 10, 2008.
Service Bulletin A300–57–0235	04	March 13, 2003.
	05	December 3, 2003.
Service Bulletin A300–57–6088	04	December 3, 2003.

Issued in Renton, Washington, on September 30, 2011.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–26113 Filed 10–7–11; 8:45 am]

BILLING CODE 4910–13–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Chapter II

[Docket No. CPSC–2011–0074]

Table Saw Blade Contact Injuries; Advance Notice of Proposed Rulemaking; Request for Comments and Information

AGENCY: Consumer Product Safety Commission.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Consumer Product Safety Commission (''CPSC'' or ''Commission'' or ''we'') is considering whether a new performance safety standard is needed to address an unreasonable risk of injury associated with table saws. We are conducting this proceeding under the authority of the Consumer Product Safety Act (''CPSA''), 15 U.S.C. 2051–2084. This advance notice of proposed rulemaking (''ANPR'') invites written comments from interested persons

concerning the risk of injury associated with table saw blade contact, the regulatory alternatives discussed in this notice, other possible means to address this risk, and the economic impacts of the various alternatives. We also invite interested persons to submit an existing standard, or a statement of intent to modify or develop a voluntary standard, to address the risks of injury described in this ANPR.[1]

DATES: Written comments and submissions in response to this notice must be received by December 12, 2011.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2011–0074, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

To ensure timely processing of comments, the Commission is no longer accepting comments submitted by electronic mail (e-mail) except through *www.regulations.gov.*

Written Submissions

Submit written submissions in the following way:

Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions), preferably in five copies, to: Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to *http://www.regulations.gov.* Do not submit confidential business information, trade secret information, or other sensitive or protected information electronically. Such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Caroleene Paul, Directorate for Engineering Sciences, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, Maryland 20850; telephone (301) 987–2225; fax (301) 869–0294; e-mail *cpaul@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

On April 15, 2003, Stephen Gass, David Fanning, and James Fulmer, *et al.* (''petitioners'') requested that we require performance standards for a system to reduce or prevent injuries from contact with the blade of a table saw. The petitioners cited estimates of 30,000 annual injuries involving table saws, with approximately 90 percent of the injuries occurring to the fingers and hands, and 10 percent of the injuries resulting in amputation. The petitioners alleged that current table saws pose an unacceptable risk of severe injury because they are inherently dangerous and lack an adequate safety system to protect the user from accidental contact with the blade.

In the **Federal Register** of July 9, 2003 (68 FR 40912) and September 5, 2003 (68 FR 52753), we invited comments on the issues raised by the petition (Petition No. CP03–2). We received 69 comments. CPSC staff's initial briefing package regarding the petition is available on the CPSC Web site at *http://www.cpsc.gov/library/foia/foia06/brief/tablesaw.pdf.* On July 11, 2006, the Commission voted (2–1) to grant the petition and directed CPSC staff to draft an ANPR. On July 15, 2006, the Commission lost its quorum and was unable to move forward with publication of an ANPR at that time. However, CPSC staff continued to evaluate table saws and initiated a special study from January 2007 to December 2008, to gather more accurate estimates on table saw injuries and hazard patterns related to table saw injuries. Based on CPSC staff's updated information on blade contact injuries associated with table saw use, and CPSC staff's evaluation of current technologies on table saws, we believe it is appropriate to issue an ANPR on table saw blade contact injuries at this time. CPSC staff's updated briefing package, which supplements the initial briefing package, is available on the CPSC Web site at *http://www.cpsc.gov/library/foia/foia11/brief/tablesaw.pdf.*

B. Statutory Authority

We are conducting this proceeding under authority of the Consumer Product Safety Act (''CPSA''). 15 U.S.C. 2051–2084. The Commission believes it has the statutory authority to move forward with this ANPR because table saws that are used by consumers present risks that may not be eliminated or reduced to a sufficient extent by actions undertaken under the Occupational Safety and Health Act. 15 U.S.C. § 2080(a).

Before adopting a CPSA standard, the Commission may issue an ANPR, as provided in section 9(a) of the CPSA. 15 U.S.C. 2058(a). If the Commission decides to continue the rulemaking proceeding after considering responses to the ANPR, the Commission must then publish the text of the proposed rule, along with a preliminary regulatory analysis, in accordance with section 9(c) of the CPSA. 15 U.S.C. 2058(c). If the Commission thereafter moves forward to issue a final rule, in addition to the text of the final rule, it must publish a final regulatory analysis that includes: (1) A description of the potential benefits and costs of the rule; (2) a summary of any alternatives that were considered, their potential costs and benefits, and the reasons for their rejection; and (3) a summary and assessment of any significant issues raised on the preliminary regulatory analysis that accompanied the proposed rule. 15 U.S.C. 2058(f)(2). In addition, the Commission, among other things, must make findings that an existing or proposed voluntary standard would not be adequate, that the benefits of the rule bear a reasonable relationship to its costs, and that the rule is the least burdensome requirement that prevents or adequately reduces the risk of injury. 15 U.S.C. 2058(f)(3).

C. The Product

Table saws are stationary power tools used for the straight sawing of various materials—but primarily wood. In essence, a table saw consists of a table that sits on a base and through which a spinning blade protrudes. To make a cut, the table saw operator places the workpiece on the table, and, typically guided by a rip fence or miter gauge, slides the workpiece into the blade.

There are three basic table saw categories that comprise the population of table saws used for both consumer and professional use: bench saws, contractor saws, and cabinet saws. Generally, the range of quality and accuracy of a table saw is commensurate with its size, motor horsepower, weight, and, indirectly, price.

Bench saws are lightweight, inexpensive saws, designed to be moved around easily and placed temporarily on a work bench or stand. Prices for bench saws range from $100 to $600. Contractor saws are characterized by a set of light-duty legs and a bigger table and motor than a bench saw. Prices for a contractor saw range from about $500 to $1,800, or more. These saws are generally quieter, more accurate, and able to cut materials up to 2 inches

[1] The Commission voted 5–0 to publish this ANPR in the **Federal Register**. Chairman Inez M. Tenenbaum and Commissioner Robert Adler issued statements. The Web address for Commissioners' statements is: *http://www.cpsc.gov/pr/statements.html.*

thick. Cabinet saws are heavier than contractor saws because the higher powered motor is enclosed in a solid base. Prices for cabinet saws range from $1,000 to $3,000. These saws are designed for heavy use, and the greater weight reduces vibration so that cuts are smooth and more accurate. These saws are typically the highest grade saw found in the home woodworking shop.

Standard safety devices on table saws are designed to prevent the saw blade from making contact with the operator and to prevent the saw blade from imparting its kinetic energy to the workpiece and throwing the workpiece back toward the operator, a phenomenon known as kickback. The configuration and specific design of safety devices vary from manufacturer to manufacturer, but the safety devices generally fall into two basic categories: blade guards and kickback prevention devices.

Traditionally, table saws sold in the United States have employed a blade guard system that combines a hood-type blade guard, splitter (also known as spreader), and anti-kickback pawls as a single unit that is bolted to the saw's carriage assembly. The hood is a single, rectangular piece of transparent plastic that surrounds the exposed blade with a sloped front to allow the guard to rise and ride over the workpiece as the piece is fed toward the blade during a cut. The splitter generally serves as the main support and connection point for the blade guard and the anti-kickback pawls. Thus, removing the splitter for any reason, necessarily removes the rest of the blade guard system and the protections those devices might offer.

Splitters, riving knives, and anti-kickback pawls are the primary safety devices on table saws that are intended to prevent kickback of the workpiece. Splitters ride within the cut, or kerf, to prevent the workpiece from closing up and pinching the blade, which can cause the workpiece to be thrown back toward the operator. Because the height of the splitter is often taller than the blade, splitters must be removed when making non-through cuts because the top portion of the blade must be exposed to cut into the workpiece. If other safety devices are attached to the splitter, removal of the splitter removes these safety devices as well.

Riving knives are curved steel plates that are similar to, and perform the same function as, splitters, but sit very close to the blade and rise no higher than the top of the saw blade. The riving knife attaches to the arbor assembly so that it moves up and down with the blade. These characteristics allow riving knives to be used while making non-through cuts because the top of the blade is exposed. A properly installed riving knife may be the most effective way to prevent kickback because it limits workpiece access to the rear teeth of the saw blade. Anti-kickback pawls consist of two hinged and barbed pieces of metal that allow passage of the workpiece but will dig into the workpiece if it begins to move back toward the operator.

CPSC staff has identified several characteristics of traditional blade guard systems that are likely to hinder table saw use and motivate consumers to remove them to make performing a cut simpler or easier. These characteristics include:

(1) Potential jamming of the workpiece on the guard: Some blade guards may jam on the leading edge of the workpiece, requiring the consumer to push the workpiece forcefully or to raise the guard manually;

(2) Poor visibility caused by the guard: Hood guards can limit visibility when lining up cuts and during a cut, especially with sawdust accumulation in the guard;

(3) Poor splitter alignment with the blade: A splitter can bend over time with use of the table saw. A blade guard system with a splitter that is not aligned properly with the blade can make feeding the workpiece through the blade increasingly difficult and can actually increase the likelihood of kickback; and

(4) Mandatory removal of the blade guard for certain cuts: The splitter and blade guard must be removed for certain oversized cuts, very narrow cuts, and any type of non-through cut. To switch back to typical through cuts, the splitter and guard must be reinstalled in keeping with manufacturers' recommendations that blade guard systems be used whenever performing a through cut.

D. The Market

CPSC staff has identified at least 15 manufacturers and importers of table saws. According to the Power Tool Institute (''PTI''), its members account for approximately 85 percent of all table saws sold in the United States. Most manufacturers are large, diversified, international corporations with billions of dollars in sales, of which table saws generally make up a relatively small part of their revenue. Several other U.S. corporations manufacture or import smaller numbers of table saws for the U.S. market. According to PTI, estimated annual shipments of table saws have fluctuated widely in recent years. In 2006 and 2007, estimated shipments were 800,000 to 850,000 units. However, estimated shipments declined to 650,000 in 2008, 589,000 in 2009, and 429,000 in 2010.

CPSC staff also obtained information from PTI regarding the expected useful life estimates for different categories of table saws, ranging from 6 years for an inexpensive bench saw, to 17 years for a contractor saw, to 24 years for an expensive cabinet saw. Based on these expected product lives and sales data for the different types of saws, PTI estimated the number of table saws in use at 8.0 million in 2001/2002, and 9.5 million in 2007/2008. CPSC staff believes that this estimate is generally consistent with independent estimates of table saws in use, based upon product population estimates using the CPSC's Product Population Model (''PPM''). The PPM is used by CPSC staff to estimate the number of products in use, given sales estimates and information on expected product life. Assuming an average retail price of $500 per table saw, and average annual shipments of about 700,000 units, CPSC staff believes that annual retail sales may be in the range of $300 to $400 million.

CPSC staff also reviewed tariff and trade data from the U.S. Department of Commerce and the U.S. International Trade Commission, which showed that China and Taiwan together account for more than $150 million dollars in annual imports. Allowing for markups of table saws at the manufacturer/private labeler level and the retail level, CPSC staff found that imports may account for a majority of the estimated $300 million to $400 million in shipments estimated. According to CPSC staff, exports from the United States appear to be minimal, less than $1 million annually.

E. Incident Data

CPSC staff first reviewed the National Electric Injury Surveillance System (''NEISS'') data in 2001 and 2002. The data indicated that there were 38,000 total emergency room-treated injuries associated with table saws in 2001, and 38,980 injuries in 2002. In 2001, CPSC staff conducted follow-up investigations on stationary saw-related injuries for NEISS cases treated between October 1, 2001 and December 31, 2001. As a result of the investigations, CPSC staff was able to identify injuries that resulted from previously unspecified saw categories, resulting in more precise injury estimates for 2001 and 2002. Of the 28,300 emergency room-treated injuries in 2001 and 2002 involving table saw operator blade contact, most of the injuries were sustained to the finger(s), and the majority of the injuries were lacerations. Fewer injuries resulted in amputations. The remaining injuries

included fractures, avulsions (the forcible separation or tearing away of a part of the body), and crushings.

Since its initial review of table saw blade contact injuries, based on data from NEISS, CPSC staff found that the estimated number of emergency department-treated injuries associated with table saws averaged 36,400 per year from 2001 to 2008. The trend analysis conducted by CPSC staff of the annual estimates for 2001 to 2008, indicated that the number of all saw-related injuries (including table saws, band and radial saws, handheld saws, and saws not specified) was steady during this time.

CPSC staff conducted a follow-up special study on stationary saw-related injuries between January 2007 to December 2008, to gather more accurate estimates on table saw injuries and hazard patterns related to table saw injuries. The special study conducted follow-up interviews on emergency room-treated table saw incidents that were reported through NEISS. The special study allowed more precise table saw injury estimates to be computed for 2007 (38,300 injuries), and 2008 (41,200 injuries). Of the 79,500 total emergency department-treated injuries associated with table saws in 2007 and 2008, an estimated 76,100 injuries were sustained by operators of the table saws. Of the injuries to table saw operators, an estimated 66,900 injuries (88%) involved blade contact, which is the pattern of addressable hazards that this ANPR seeks to address.

CPSC staff estimates that there were approximately 66,900 emergency room-treated injuries involving table saw operator blade contact in 2007 and 2008. Of the 66,900 emergency room-treated injuries involving table saw operator blade contact in 2007 and 2008, the majority (68.5%) of the victims were between the ages of 15 to 64 years old, and 31 percent were 65 years old or older. Among the operator blade contact injuries, laceration was the most frequent (65.9%) form of injury, followed by fractures (12.4%), amputation (12.0%), and avulsion (8.5%). The rate of hospitalization was 7.1 percent, compared to an average 4 percent rate of hospitalization for all consumer products reported through the NEISS system. Because CPSC staff determined that the injury trend associated with all saws has been relatively stable from 2001 and 2008, and they concluded that the results of the special study represented the most accurate estimates available, CPSC staff relied on the data from the special study for 2007 and 2008 to summarize blade contact injuries and their associated hazard patterns.

Of the 66,900 emergency room-treated injuries involving table saw operator blade contact in 2007 and 2008, approximately 20,700 (30.9%) of the injuries occurred on table saws where a blade guard was in use. Approximately 44,500 (66.5%) of the injuries occurred on table saws that did not have a blade guard attached. The most common reason for absence of the blade guard was removal by the consumer (75.0%). An estimated 23,800 injuries (35.5%) occurred as a result of kickback of the material, including scenarios where kickback of the material caused the operator's hand to be pulled into the blade, resulting in a laceration injury or amputation. Of the 23,800 blade contact injuries that occurred as a result of kickback, lacerations were the most frequent (61.2%) form of injury followed by amputations (15.6%), fractures (14.2%), and avulsions (6.5%). The rate of hospitalization was 9.0 percent.

Of the 66,900 emergency room-treated injuries involving table saw operator blade contact in 2007 and 2008, an estimated 39,600 injuries (59.2%) did not occur as a result of kickback of the material. Non-kickback injury scenarios included situations caused by a lapse in attention of the operator, such as reaching over the blade to retrieve a cut piece or otherwise not being aware of the blade during a cut. Of the 39,600 blade contact injuries that did not occur as a result of kickback, lacerations were the most frequent (69.4%) form of injury, followed by fractures (11.0%), amputations (9.5%), and avulsions (9.5%). The rate of hospitalization was 5.0 percent. CPSC staff did not find sufficient information regarding whether kickback caused operator contact with the blade in approximately 3,500 of the 66,900 operator blade contact injuries.

F. Economic Considerations

The Commission's Injury Cost Model (''ICM'') uses empirically derived relationships between emergency department injuries estimated through NEISS and injuries treated in other settings (*e.g.,* doctor's offices, clinics) to estimate the number of injuries treated outside hospital emergency departments. Based on CPSC's 2007–2008 special study, staff estimated that approximately 33,450 emergency department-treated blade contact injuries occurred annually over the 2-year period 2007–2008. From these 33,450 annual injuries, the ICM projects an annual total of 67,300 medically treated blade contact injuries with an associated injury cost of approximately $2.36 billion per year. CPSC staff determined that deaths resulting from blade contact during table saw use are rare and appear to be the result of secondary effects of the injuries (*e.g.,* heart attack) rather than the injuries themselves. Accordingly, economic costs from deaths have been excluded.

CPSC staff's preliminary review showed that societal costs per blade contact injury amount to approximately $35,000. This includes costs for medical treatment, lost time from work, product liability litigation, and pain and suffering. The relatively high societal costs, compared to the $22,000 average cost for all medically treated consumer product related injuries, reflect the high costs associated with amputations and the relatively high hospitalization rate associated with these injuries.

CPSC staff's preliminary review also showed that the expected present value of the societal costs of blade contact injuries over the life of a table saw is substantial. Therefore, an effective performance-based table saw standard potentially could result in significant reductions in the injury costs associated with blade contact. However, current systems designed to address blade contact injuries on table saws appear to be costly and could substantially increase the retail cost of table saws, especially among the least expensive bench saws.

G. Existing Standards

The current U.S. voluntary consensus standard for table saws is the seventh edition of UL 987, *Stationary and Fixed Electric Tools.* Underwriters Laboratories Inc. (''UL'') published this standard in 1971, and has revised it several times. The original requirement for table saw guarding specified a complete guard that consisted of a hood, a spreader, and some type of anti-kickback device. The requirement further specified that the guard hood completely enclose the sides and top portion of the saw blade above the table and that the guard automatically adjust to the thickness of the workpiece. A blade guard that met this requirement was typically a hinged, rectangular piece of clear plastic.

The sixth edition of UL 987, published in January 2005, added design and performance requirements for a riving knife and performance requirements for anti-kickback devices. This revision essentially required new table saws to employ a permanent riving knife that was adjustable for all table saw operations. The requirement also allowed for riving knife/spreader combination units, where the riving

knife could be used as the attachment point for a blade guard during through cuts. The effective date for the riving knife requirement is January 31, 2014, for currently listed products, and January 31, 2008, for new products submitted for listing to the UL standard.

The current edition, the seventh edition of UL 987, published in November 2007, expanded the table saw guarding requirements to include descriptions of a new modular blade guard design developed by a joint venture of the leading table saw manufacturers. The revised standard specified that the blade guard shall consist not of a hood, but of a top-barrier guarding element and two side-barrier guarding elements. The new modular guard design was intended to be an improvement over traditional hood guard designs by providing better visibility, being easier to remove and install, and incorporating a permanent riving knife design. The revised standard also specified detailed design and performance requirements for the modular blade guard, riving knife, and anti-kickback device(s). The effective date for the new requirements was January 31, 2010.

The Occupational Safety and Health Administration (''OSHA'') currently has regulations on table saws used in the workplace, which are codified at 29 CFR 1910.213, Woodworking Machinery Requirements. The OSHA regulations require that table saws in the workplace include a blade guard, a spreader, and an anti-kickback device. 29 CFR 1910.213(c)(1)–(3). The OSHA regulations require the saw be guarded by a hood with certain performance standards including, among other things, requirements that the hood be strong enough to withstand certain pressures, be adjustable to the thickness of the material being cut, and be constructed in a way to protect the operator from flying splinters and broken saw teeth. 29 CFR 1910.213(c)(1). The OSHA regulations also require inspection and maintenance of woodworking machinery. For example, unsafe saws must be removed from service immediately, push sticks or push blocks must be provided at the workplace for guiding or pushing material past the blade, and emphasis must be placed on the cleanliness around woodworking machinery and, in particular, the effective functioning of guards and prevention of fire hazards. 29 CFR 1910.213(s).

CPSC staff found that the primary differences between consumer and professional users of table saws are environment and training/experience. In many work production environments where a specific cut is performed continuously, guards and safety cut-off switches are custom designed for that set up. The area is specifically designed to be as safe as possible and safety is a continuous focus through warning/instruction signs and posters that are often displayed throughout the work area. The workplace is also subject to spontaneous inspection by OSHA inspectors; therefore, the prospect of being fined for safety violations increases the likelihood that workers or supervisors will help ensure safety codes are followed. In addition, professional woodworkers are in an industrial setting where employees often receive training on safety practices and in the proper use of the tool. Professional woodworkers are more likely to have had training and to be experienced in performing any special or complex operations with the saw and are more likely to recognize situations and set-ups that may be dangerous or require extra care and caution.

Amateur woodworkers generally have little or no safety training, nor training in the proper use of the table saw. They may take woodworking classes or watch a training video, but the home users typically have far less experience than professional woodworkers and may discover dangerous or difficult operations only by actually experiencing near accidents or problems. The home woodworker also does not have the same OSHA-regulated protections in the home-based woodshop. The focus on a safe environment in a consumer setting is dependent upon the knowledge and initiative of the home woodworker, but there is no oversight to educate and motivate the consumer to prepare as safe an environment as possible.

CPSC staff also reviewed the 2007–2008 special study of table saw-related injury estimates to assess whether they were work-related. Narratives and responses in the 862 cases in the table saw study were reviewed to identify cases that might be work-related. Four of the cases appeared to be work-related, and another 12 cases appeared to be potentially work-related. Combined, these cases comprised less than 2 percent of the sample data and less than 2 percent of the estimated 79,500 total table or bench saw injuries over the two years 2007–2008. The remaining 846 cases in the special study represented an estimated 78,000 non-work-related injuries.

We believe that OSHA regulations may not adequately reduce the risk of operator blade contact injuries to consumers because these regulations are primarily intended to ensure a safer work environment in the professional workplace setting, rather than the home woodworking environment. OSHA regulations rely on a comprehensive approach to promote safe practices in the workplace. These strategies include training and outreach, as well as mandatory safety standards and enforcement. This approach would not be available to consumers operating table saws in a home woodworking environment. CPSC staff's review showed that less than 2 percent of the estimated 79,500 total table or bench saw injuries over the 2007–2008 period appear to be work-related. Moreover, we note that the OSHA regulations for guarding are essentially identical to the requirements in the now superseded fifth edition of the voluntary standard for table saws, UL 987, *Standard for Stationary and Fixed Electric Tools.* Accordingly, the existing OSHA regulations for table saws do not reflect the latest revisions to UL 987, which require riving knives and the new modular blade guard design developed by the table saw industry. However, even if OSHA incorporates the new UL requirements in its regulations, we believe that current safety devices still may not adequately address the operator blade contact injuries associated with table saw use by consumers.

H. Regulatory Alternatives

One or more of the following alternatives could be used to reduce the identified risks associated with table saw blade contact injuries:

1. Voluntary Standard. If the industry developed, adopted, and substantially conformed to an adequate voluntary standard, we could defer to the voluntary standard, instead of issuing a mandatory rule. The current voluntary standard for table saws includes requirements for a splitter/spreader, blade guard, and anti-kickback device to address the hazard posed by contact with the saw blade. The voluntary standards body only recently has begun to review requirements for a riving knife that may reduce certain kickback conditions that can result in unexpected blade contact. However, a riving knife would not address the blade contact injuries that were not caused by kickback of the material, an estimated 39,600 injuries in 2007 and 2008.

CPSC staff evaluated two new technologies that have been introduced to the table saw market since 2007 to address blade contact injury. Technologies that address blade contact injuries on table saws can be categorized by their main purpose: (1) Prevention of the event, and (2) mitigation of the event.

In 2007, a joint venture of the leading table saw manufacturers introduced a new modular blade guard design to the market. The new modular guard, like traditional blade guard systems, is aimed at preventing the event of blade contact. In general, traditional blade guards and the new modular blade guards can effectively prevent most physical side, rear, and downward contact with the table saw blade but will primarily act as a tactile warning for front approach contact with the blade. The new modular blade guard system appears to be a significant improvement over most traditional blade guard systems because it uses a permanent, adjustable riving knife, rather than a removable splitter, as the primary kickback prevention device and support for the guard. However, the new blade guard system still would not prevent blade contact injuries resulting from the hand approaching the front, or leading portion, of the blade. Furthermore, the new blade guard system still can hinder certain table saw tasks, thereby encouraging its removal, and it can prevent certain sawing tasks from being performed unless it is removed. CPSC staff's review showed that removing the blade guard system is easy but installation can be tricky and, if the process is repeated, it can also be time-consuming and burdensome. These characteristics may motivate some consumers—especially experienced or expert woodworkers—not to bother reinstalling the system once it is removed.

In 2008, the petitioners developed a contractor saw with a blade contact detection and reaction system that was introduced to the table saw market as the SawStop system. Blade contact detection and reaction systems function as a secondary safety system to mitigate the event of blade contact. The system is not intended to prevent table saw blade contact incidents, but rather, to lessen the consequences of blade contact when it occurs. The SawStop system includes two components: An electronic detection unit, and a brake. The system induces a small electrical signal onto the saw blade that is partially absorbed by the human body if contact is made. When this reduction in signal is detected, the system applies a brake to the blade that stops and retracts the blade below the table surface within milliseconds. In principle, the only injury likely to be sustained by direct contact with the saw blade when the system functions as intended is a small cut.

The SawStop system reviewed by CPSC staff did not seem to interfere with most sawing operations, and, once installed, the system is essentially invisible to the consumer until it is needed. If the system is activated or the standard 10-inch blade needs to be replaced with a smaller dado blade (a type of saw blade used to cut grooves), the brake cartridge underneath the table surface must be replaced. Removing and reinstalling the brake cartridge when switching to and from dado sets, or once the system has been activated, can be difficult. However, in all likelihood, system activation would occur only after contact with the skin, a situation in which the consumer might have sustained serious injury had the system not been in place.

We are concerned that the requirements in the voluntary standard for table saws, UL 987, Stationary and Fixed Electric Tools, which mandate a permanent riving knife and the new modular blade guard system, may not adequately address the operator blade contact injuries associated with table saw use. While we support the recent progress UL has made in improving the voluntary standard to address blade contact injuries by focusing solely on prevention of skin-to-blade contact, the standard requirements do not appear to address adequately the number or severity of blade contact injuries that occur on table saws, nor do they address the associated societal costs. In addition, while we believe that the new modular guard design is a significant improvement over the old guard design, the effectiveness of any blade guard system depends upon an operator's willingness to use it. Safety equipment that hinders the ability to operate the product likely will result in consumers bypassing, avoiding, or discarding the safety equipment. In addition, of the 66,900 table saw operator blade contact injuries in 2007 and 2008, approximately 20,700 (30.9%) of the injuries occurred on table saws where the blade guard was in use. The current voluntary standard for table saws does not appear to address those types of injuries. Accordingly, we are particularly interested in obtaining information regarding current or developing voluntary standards that would address table saw blade contact injuries.

2. Mandatory rule. We could issue a rule mandating performance requirements on table saws that would address blade contact injuries.

3. Labeling rule. We could issue a rule requiring specified warnings and instructions to address table saw blade contact injuries.

I. Request for Information and Comments

This ANPR is the first step in a proceeding that could result in a mandatory safety standard for table saws to address the risk of injury associated with blade contact from table saws. We invite interested persons to submit their comments on any aspect of the alternatives discussed above in part H of this document. In particular, we request the following additional information:

1. Written comments with respect to the risk of injury identified by the Commission, the regulatory alternatives being considered, and other possible alternatives for addressing the risk;
2. Any existing standard or portion of a standard that could be issued as a proposed regulation;
3. A statement of intention to modify or develop a voluntary standard to address the risk of injury discussed in this notice, along with a description of a plan (including a schedule) to do so;
4. Studies, tests, or surveys that have been performed to analyze table saw blade contact injuries, severity of injuries, and costs associated with the injuries;
5. Studies, tests, or surveys that analyze table saw use in relation to approach/feed rates, kickback, and blade guard use and effectiveness;
6. Studies, tests, or descriptions of new technologies, or new applications of existing technologies that can address blade contact injuries, and estimates of costs associated with incorporation of new technologies or applications;
7. Estimated manufacturing cost, per table saw, of new technologies or applications that can address blade contact injuries;
8. Expected impact of technologies that can address blade contact injuries on wholesale and retail prices of table saws;
9. Expected impact of technologies that can address blade contact injuries on utility and convenience of use;
10. Information on effectiveness or user acceptance of new blade guard designs;
11. Information on manufacturing costs of new blade guard designs;
12. Information on usage rates of new blade guard designs;
13. Information on U.S shipments of table saws prior to 2002, and between 2003 and 2005;
14. Information on differences between portable bench saws, contractor saws, and cabinet saws in frequency and duration of use;
15. Information on differences between saws used by consumers, saws

used by schools, and saws used commercially in frequency and duration of use;

16. Studies, research, or data on entry information of materials being cut at blade contact (*i.e.,* approach angle, approach speed, and approach force);

17. Information that supports or disputes preliminary economic analyses on the cost of employing technologies that reduce blade contact injuries on table saws;

18. Studies, research, or data on appropriate indicators of performance for blade-to-skin requirements that mitigate injury;

19. Studies, research, or data that validates human finger proxies for skin-to-blade tests;

20. Studies, research, or data on detection/reaction systems that have been employed to mitigate blade contact injuries;

21. Studies, research, or data on the technical challenges associated with developing new systems that could be employed to mitigate blade contact injuries;

22. Studies, research, or data on guarding systems that have been employed to prevent or mitigate blade contact injuries;

23. Studies, research, or data on kickback of a workpiece during table saw use;

24. The costs and benefits of mandating a labeling or instructions requirement; and

25. Other relevant information regarding the addressability of blade contact injuries.

Comments and other submissions should be identified by identified by Docket No. CPSC–2011–0074 and submitted in accordance with the instructions provided above. All comments and other submissions must be received by December 12, 2011.

Dated: October 5, 2011.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2011–26171 Filed 10–7–11; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Part 514

RIN 3141–AA40

Fees

AGENCY: National Indian Gaming Commission, Interior.

ACTION: Proposed rule.

SUMMARY: The National Indian Gaming Commission (NIGC) proposes to amend its fee regulations by requiring tribes to submit their fees and fee statements on a quarterly basis, basing the fee calculation on the gaming operation's fiscal year, establishing an assessment for fees submitted one to 90 days late, and establishing a fingerprinting fee payment process.

DATES: The agency must receive comments on or before December 12, 2011.

ADDRESSES: You may submit comments by any one of the following methods, however, please note that comments sent by electronic mail are strongly encouraged.

- *E-mail comments to: reg.review@nigc.gov.*
- *Mail comments to:* National Indian Gaming Commission, 1441 L Street, NW., Suite 9100, Washington, DC 20005.
- *Hand deliver comments to:* 1441 L Street, NW., Suite 9100, Washington, DC 20005.
- *Fax comments to:* National Indian Gaming Commission at 202–632–0045.

FOR FURTHER INFORMATION CONTACT: National Indian Gaming Commission, 1441 L Street, NW., Suite 9100 Washington, DC 20005. Telephone: 202–632–7009; e-mail: *reg.review@nigc.gov.*

SUPPLEMENTARY INFORMATION:

I. Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal.

II. Background

The Indian Gaming Regulatory Act (IGRA or Act), Public Law 100–497, 25 U.S.C. 2701 *et seq.,* was signed into law on October 17, 1988. The Act establishes the National Indian Gaming Commission (''Commission'') and sets out a comprehensive framework for the regulation of gaming on Indian lands. The purposes of IGRA include providing a statutory basis for the operation of gaming by Indian Tribes as a means of promoting tribal economic development, self-sufficiency, and strong tribal governments; ensuring that the Indian tribe is the primary beneficiary of the gaming operation; and declaring that the establishment of independent federal regulatory authority for gaming on Indian lands, the establishment of federal standards for gaming on Indian lands, and the establishment of a National Indian Gaming Commission are necessary to meet congressional concerns regarding gaming and to protect such gaming as a means of generating tribal revenue. 25 U.S.C. 2702.

The IGRA established an agency funding framework whereby gaming operations licensed by tribes pay a fee to the Commission for each gaming operation that conducts Class II or Class III gaming activity that is regulated by IGRA. 25 U.S.C. 2717(a)(1). These fees are used to fund the Commission in carrying out its regulatory authority. Fees are based on the gaming operation's gross revenues which are defined as the annual total amount of money wagered, less any amounts paid out as prizes or paid for prizes awarded and less allowance for amortization of capital expenditures for structures. 25 U.S.C. 2717(a)(6). The rate of fees is established annually by the Commission and shall be payable on a quarterly basis. 25 U.S.C. 2717(a)(3). IGRA limits the total amount of fees imposed during any fiscal year to .08 percent of the gross gaming revenues of all gaming operations subject to regulation under IGRA. Failure of a gaming operation to pay the fees imposed by the Commission's fee schedule can be grounds for a civil enforcement action. 25 U.S.C. 2713(a)(1). The purpose of Part 514 is to establish how the NIGC sets and collects those fees, to establish a basic formula for tribes to utilize in calculating the amount of fees to pay, and to advise of the consequences for failure to pay the fees.

On November 18, 2010, the National Indian Gaming Commission (NIGC) issued a Notice of Inquiry and Notice of Consultation advising the public that the NIGC was conducting a comprehensive review of its regulations and requesting public comment on which of its regulations were most in need of revision, in what order the Commission should review its regulations, and the process NIGC should utilize to make revisions. 75 FR 70680. On April 4, 2011, after holding eight consultations and reviewing all comments, NIGC published a Notice of Regulatory Review Schedule (NRR) setting out a consultation schedule and process for review. 76 FR 18457. Part 514 was included in the first regulatory group reviewed pursuant to the NRR.

III. Development of the Proposed Rule

The Commission conducted a total of 11 tribal consultations as part of its review of Part 514. Tribal consultations were held in every region of the country

and were attended by over 189 tribes and 535 tribal leaders or their representatives. In addition to tribal consultations, on May 10, 2011, the Commission requested public comment on a Preliminary Draft of amendments to Part 514. 76 FR 26967. After considering the comments received from the public and through tribal consultations, the Commission proposes five amendments to Part 514: changing the fee calculation from a calendar year to a fiscal year basis; changing the payment schedule to a quarterly payment system; ensuring language is consistent with industry standards; creating a ticketing system for payments submitted late; and formalizing the fingerprinting fee system. The Commission does not propose any amendments to the definition of gross gaming revenue.

A. Change the Fee Calculation to a Calculation Based on a Gaming Operation's Fiscal Year

Currently, each gaming operation regulated by IGRA must submit fee statements showing the calculation of assessable gross revenues for the previous calendar year. The Preliminary Draft of amendments to Part 514 proposed changing the timeframe of the fee calculation from the calendar year to the gaming operation's fiscal year. It is important to note that fees set by the Commission continue to be based on the gross gaming revenues of tribes, subject to the .08 percent limit established by 25 U.S.C. 2717. Comments received on the Preliminary Draft of Part 514 generally supported basing annual fees on a gaming operation's fiscal year rather than a calendar year. One commenter objected to the use of a fiscal year for calculating annual fees. The commenter expressed concern created by a conversion from a calendar year to a fiscal year and the inevitable overlap period that conversion would create.

In this proposed rule, Section 514.7 addresses the overlap period by requiring the tribe to notify the Commission of the ''stub period'' and submit the financial statements and fees for that period within 90 days of the tribe's request. Further, this proposed rule does not mandate a tribe change their fiscal year. While many tribes utilize a fiscal year that is not based on the calendar year, other tribes do utilize a fiscal year based on a calendar year. The Commission believes that the use of a fiscal year for calculating annual fees and completing fee statements will result in fewer inaccuracies in the calculation. The Commission notes that errors in calculating the fees have occurred as a result of a gaming operation's fiscal year being different than the calendar year. This proposed amendment changes the annual timeframe for calculating the fees; the formula contained in the regulation for calculating the assessable gross gaming revenue remains the same. The Commission believes that this proposed amendment will result in greater efficiencies for both NIGC and tribes by reducing the likelihood of errors in the fee calculation.

B. Require Submission of Quarterly Fee Statements and Payments

Part 514 currently requires each gaming operation regulated by IGRA to submit bi-annual fee statements showing its assessable gross revenues and to submit fee payment with those statements. The statements must show the amounts derived from each class of game, the amounts deducted for prizes, and amounts deducted for amortization of structures. The statements must also include the computation of the fees payable, showing all the amounts used in the calculation. The statements are due on or before June 30th and December 31st of each year.

The Preliminary Draft of Part 514 proposed changing from a bi-annual submission requirement to a quarterly submission requirement. Comments support this proposed amendment, noting however, that there should be no prohibition on pre-paying the fees for an entire year. The Commission is not proposing a revision that would prohibit pre-payment. However, quarterly fee statements are still required, even if the fee has been prepaid. Based on a review of the comments received, the Commission proposes to amend Part 514 to require the submission of quarterly fee statements and payments.

C. Ensure Regulation Language is Consistent With Industry Standards

The discussion draft Part 514 proposed amendments which would utilize standard industry language. The discussion draft proposed changing ''admission fees'' to ''entry fees''. ''Entry fee'' is a term commonly used in the gaming industry and the Commission believes the clarification will eliminate concern that an ''admission fee'' includes admission to concerts or other non-gaming activity. The Commission did not receive any comments on the Preliminary Draft that opposed the changes. Accordingly, the Commission proposes amending Part 514 to incorporate these revisions.

D. Revise the Late Payment Fee System

IGRA and NIGC regulations provide that a failure to pay fees may result in closure or revocation of approval of any license, ordinance, or resolution required under IGRA. The NIGC has issued Notices of Violation (NOV) and civil fine assessments to tribes submitting their fees late. The Commission notes that because the NIGC does not receive federal appropriations to fund its operations, it is vital that fees are submitted in a timely manner to ensure the continued funding of NIGC operations. Tribes have commented that a NOV for the late payment of fees can be an unnecessarily punitive response. In response to this concern, the Commission circulated in the Preliminary Draft a fine system that would address fees paid less than and upto 90 days after they are due.

Comments received on the Preliminary Draft supported the development of a system that addresses a late payment in a tiered approach. Comments acknowledged the need for submission of fees in a timely manner, but also noted that the circumstances of minor delays should be considered before issuance of a NOV and civil fine assessment.

The Commission proposes amending Part 514 to add a ''ticket'' system which assesses a fine for a late fee payment. The proposed Rule distinguishes between ''late payments'' and ''failure to pay annual fees.'' A payment received between 1 and 90 days late is a ''late payment'' and would be subject to an increasing percentage based late payment fine. A payment received after 90 days constitutes a ''failure to pay annual fees'' and subjects the tribe to a potential NOV and civil fine assessment. The proposed rule also includes a mechanism whereby the Chair may consider any mitigating circumstances surrounding the late payments and reduce the fine due. Per federal law, any fines are payable to U.S. Treasury, not the NIGC.

E. Formalize the Fingerprinting Fee Process

The NOI asked whether the Part should include a section on fingerprint processing fees. Comments received in response to the NOI supported this revision.

The Commission included in the Preliminary Draft provisions for the collection of fees for processing fingerprints. The section requires the Commission to adopt preliminary rates for processing fingerprints at the same time as the annual fee schedule is set and modified (March 1 and June 1 of each year). If a tribe fails to pay its bill for fingerprint fees, the Chair may suspend further fingerprint card processing for that tribe.

Comments received supported this revision. Some comments expressed concern about fluctuating costs and the need to adjust costs as needed. In order to address this issue, the proposed rule provides for the Commission to review the fee rate annually and establish a preliminary rate in March and adopt a final rate in July of each year. Another comment recommended the fingerprinting fees being included in the calculation of net revenues as a statutorily required operating expense. The proposed draft does not include this language as *net revenues* is a statutorily defined term.

The proposed amendment includes the provisions circulated in the Preliminary Draft. The Commission believes formalizing the procedures for assessing fingerprint card processing fees in a regulation provides transparency and clarity.

F. Definition of Gross Gaming Revenue

In the Notice of Inquiry, the Commission asked whether the definition of *gross gaming revenue* should be revised to include the GAAP definition. The discussion draft however, did not include this revision. Comments noted that the GAAP definition, while providing a standard definition, may be inconsistent with the definition contained in the Act. The Commission agrees and therefore does not propose any change to the definition of *gross gaming revenue.*

Regulatory Matters

Regulatory Flexibility Act

The proposed rule will not have a significant impact on a substantial number of small entities as defined under the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* Moreover, Indian Tribes are not considered to be small entities for the purposes of the Regulatory Flexibility Act.

Small Business Regulatory Enforcement Fairness Act

The proposed rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. The rule does not have an effect on the economy of $100 million or more. The rule will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, local government agencies or geographic regions. Nor will the proposed rule have a significant adverse effect on competition, employment, investment, productivity, innovation, or the ability of the enterprises, to compete with foreign based enterprises.

Unfunded Mandate Reform Act

The Commission, as an independent regulatory agency, is exempt from compliance with the Unfunded Mandates Reform Act, 2 U.S.C. 1502(1); 2 U.S.C. 658(1).

Takings

In accordance with Executive Order 12630, the Commission has determined that the proposed rule does not have significant takings implications. A takings implication assessment is not required.

Civil Justice Reform

In accordance with Executive Order 12988, the Commission has determined that the rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order.

National Environmental Policy Act

The Commission has determined that the rule does not constitute a major federal action significantly affecting the quality of the human environment and that no detailed statement is required pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4321, *et seq.*

Paperwork Reduction Act

The information collection requirements contained in this rule were previously approved by the Office of Management and Budget (OMB) as required by 44 U.S.C. 3501 *et seq.* and assigned OMB Control Number 3141–0007, which expired in August of 2011. The NIGC is in the process of reinstating that Control Number.

Authority: 25 U.S.C. 2706(b)(10); E.O. 13175.

Dated: October 3, 2011, Washington, DC.

Text of the Proposed Rules

For the reasons discussed in the Preamble, the Commission proposes to revise 25 CFR part 514 to read as follows:

PART 514—FEES

Sec.

514.1 What is the purpose of this part?
514.2 When will the annual rates be published?
514.3 What is the maximum fee rate?
514.4 What are ''assessable gross revenues'' and how does a tribe calculate the amount of the annual fees it owes?
514.5 When must a tribe pay its annual fees?
514.6 What are the quarterly statements that must be submitted with the fee payments?
514.7 What should a tribe do if it changes its fiscal year?
514.8 Where should fees, quarterly statements, and other communications about fees be sent?
514.9 What happens if a tribe submits its fee payment or quarterly statement late?
514.10 When does a late payment or quarterly statement submission become a failure to pay?
514.11 Can a tribe or gaming operation appeal a proposed late fee?
514.12 When does a notice of late submission and/or a proposed late fee become a final order of the Commission and final agency action?
514.13 How are late submission fees paid, and can interest be assessed?
514.14 What happens if a tribe overpays its fees or if the Commission does not expend the full amount of fees collected in a fiscal year?
514.15 May tribes submit fingerprint cards to the NIGC for processing?
514.16 How does the Commission adopt the fingerprint processing fee?
514.17 How are fingerprint processing fees collected by the Commission?

Authority: 25 U.S.C. 2706, 2710, 2710, 2717, 2717a

§ 514.1 What is the purpose of this part?

Each gaming operation under the jurisdiction of the Commission, including a tribe with a certificate of self-regulation, shall pay to the Commission annual fees as established by the Commission. The Commission, by a vote of not less than two of its members, shall adopt the rates of fees to be paid.

§ 514.2 When will the annual rates be published?

(a) The Commission shall adopt preliminary rates for each calendar year no later than March 1st of each year, and, if considered necessary, shall modify those rates no later than June 1st of that year.

(b) The Commission shall publish the rates of fees in a notice in the **Federal Register**.

§ 514.3 What is the maximum fee rate?

(a) The rates of fees imposed shall be—

(1) No more than 2.5 percent of the first $1,500,000 (1st tier), and

(2) No more than 5 percent of amounts in excess of the first $1,500,000 (2nd tier) of the assessable gross revenues from each gaming operation subject to the jurisdiction of the Commission.

(b) If a tribe has a certificate of self-regulation, the rate of fees imposed shall be no more than .25 percent of assessable gross revenues from self-regulated class II gaming operations.

§ 514.4 What are "assessable gross revenues" and how does a tribe calculate the amount of the annual fee it owes?

(a) For purposes of computing fees, assessable gross revenues for each gaming operation are the annual total amount of money wagered on class II and III games, entry fees (including table or card fees), less any amounts paid out as prizes or paid for prizes awarded, and less an allowance for amortization of capital expenditures for structures as reflected in the gaming operation's audited financial statements.

(b) Each gaming operation subject to these regulations shall calculate the annual fee based on the gaming operation's fiscal year.

(c) Unless otherwise provided by the regulations, generally accepted accounting principles shall be used.

(d) The allowance for amortization of capital expenditures for structures shall be either:

(1) An amount not to exceed 5% of the cost of structures in use throughout the year and 2.5% (two and one-half percent) of the cost of structures in use during only a part of the year; or

(2) An amount not to exceed 10% of the total amount of depreciation expenses for the year.

(e) Examples of computations follow:

(1) For paragraph (d)(1) of this section:

Gross gaming revenues:		
Money wagered	$1,000,000	.....
Entry fees	5,000	.....
		$1,005,000
Less:		
Prizes paid in cash	500,000	
Cost of other prizes awarded	10,000	510,000
Gross gaming profit	495,000	
Less allowance for amortization of capital expenditures for structures:		
Capital expenditures for structures made in—		
Prior years	750,000	.....
Current year	50,000	.....
Maximum allowance:		
$750,000 × .05 =	37,500	.....
50,000 × .025 =	1,250	38,750
Assessable gross revenues	.....	456,250

(2) For paragraph (d)(2) of this section:

Gross gaming revenues:		
Money wagered		$1,000,000
Entry fees	$5,000	1,005,000
Less:		
Prizes paid in cash	500,000	
Cost of other prizes awarded	10,000	510,000
Gross gaming profit	495,000	
Less allowance for amortization of capital expenditures for structures:		
Total amount of depreciation per books	400,000	
Maximum allowance:		
$400,000 × .10 =		40,000
Gross gaming revenues	455,000	
Assessable gross revenues	455,000	

(f) All class II and III revenues from gaming operations are to be included.

§ 514.5 When must a tribe pay its annual fees?

Each gaming operation shall calculate the amount of fees to be paid and remit them with the quarterly statement required in § 514.6. The fees payable shall be computed using:

(a) The most recent rates of fees adopted by the Commission pursuant to paragraph (a) of § 514.1,

(b) The assessable gross revenues for the previous fiscal year as calculated using § 514.4, and

(c) The amounts paid and credits received during the fiscal year, if applicable.

§ 514.6 What are the quarterly statements that must be submitted with the fee payments?

(a) Each gaming operation subject to the jurisdiction of the Commission shall file with the Commission quarterly statements showing its assessable gross revenues for the previous fiscal year.

(b) These statements shall show the amounts derived from each type of game, the amounts deducted for prizes, and the amounts deducted for the amortization of structures.

(c) The quarterly statements shall be sent to the Commission within three (3) months, six (6) months, nine (9) months, and twelve (12) months of the end of the gaming operation's fiscal year.

(d) The quarterly statements shall identify an individual or individuals to be contacted should the Commission need to communicate further with the gaming operation. The telephone numbers of the individual(s) shall be included.

(e) Each quarterly statement shall include the computation of the fees payable, showing all amounts used in the calculations. The required calculations are as follows:

(1) Multiply the 1st tier assessable gross revenues, as calculated using § 514.4, by the rate for those revenues adopted by the Commission.

(2) Multiply the 2nd tier assessable gross revenues, as calculated using § 514.4, by the rate for those revenues adopted by the Commission.

(3) Add (total) the results (products) obtained in paragraphs (e)(1) and (2) of this section.

(4) Multiply the total obtained in paragraph (e)(3) of this section by ¼.

(5) The amount computed in paragraph (e)(4) of this section is the amount to be remitted.

(f) Examples of fee computations follow:

(1) Where a filing is made for the first quarter of the fiscal year, the previous year's assessable gross revenues as calculated using section 514.4 of this Part are $2,000,000, the fee rates adopted by the Commission are 0.0% on the first $1,500,000 and .08% on the remainder, the amounts to be used and the computations to be made are as follows:

1st tier revenues—$1,500,000 × 0.0% =	0
2nd tier revenues—500,000 × .08% =	$400
Annual fees	400
Multiply for fraction of year— ¼ or	.25
Fees for first payment	100
Amount to be remitted	100

(2) [Reserved]

(g) As required by part 571 of this chapter, quarterly statements must be reconciled with a tribe's audited or reviewed financial statements for each gaming location. These reconciliations must be made available upon the request of any authorized representative of the NIGC.

§ 514.7 What should a tribe do if it changes its fiscal year?

If a gaming operation changes its fiscal year, it shall notify the Commission of the change within thirty (30) days. The Commission may request that the tribe prepare and submit to the Commission the fees and statements required by this subsection for the stub period from the end of the previous fiscal year to the beginning of the new fiscal year. The submission must be sent to the Commission within ninety (90) days of its request.

§ 514.8 Where should fees, quarterly statements, and other communications about fees be sent?

The statements, remittances and communications about fees shall be transmitted to the Commission at the following address: Comptroller, National Indian Gaming Commission, 1441 L Street, NW., Suite 9100, Washington, DC 20005. Checks should be made payable to the National Indian Gaming Commission (do not remit cash).

§ 514.9 What happens if a tribe submits its fee payment or quarterly statement late?

(a) In the event that a gaming operation fails to submit a fee payment or quarterly statement in a timely manner, the Chair of the Commission may issue a notice specifying:

(1) The date the statement and/or payment was due;

(2) The number of calendar days late the statement and/or payment was submitted;

(3) A citation to the federal or tribal requirement that has been or is being violated;

(4) The action being considered by the Chair; and

(5) Notice of rights of appeal pursuant to part 577 of this chapter.

(b) Within fifteen (15) days of service of the notice, a respondent may submit written information about the notice to the Chair. The Chair shall consider any information submitted by the respondent as well as the respondent's history of untimely submissions or failure to file statements and/or fee payments over the preceding five (5) years in determining the amount of the late fee, if any.

(c) When practicable, within thirty (30) days of issuing the notice described in paragraph (a) of this section to a respondent, the Chair of the Commission may assess a proposed late fee against a respondent for each failure to file a timely quarterly statement and/or fee payment:

(1) For statements and/or fee payments one (1) to thirty (30) calendar days late, the Chair may propose a late fee of up to, but not more than ten percent (10%) of the fee amount for that quarter, as calculated in § 514.6(e);

(2) For statements and/or fee payments thirty-one (31) to sixty (60) calendar days late, the Chair may propose a late fee of up to, but not more than fifteen percent (15%) of the fee amount for that quarter, as calculated in § 514.6(e);

(3) For statements and/or fee payments sixty-one (61) to ninety (90) calendar days late, the Chair may propose a late fee of up to, but not more than twenty percent (20%) of the fee amount for that quarter, as calculated in § 514.6(e).

§ 514.10 When does a late payment or quarterly statement submission become a failure to pay?

(a) Statements and/or fee payments over ninety (90) calendar days late constitute a failure to pay the annual fee, as set forth in IGRA, 25 U.S.C. 2717(a)(3), and NIGC regulations, 25 CFR 573.6(a)(2). In accordance with 25 U.S.C. 2717(a)(3), failure to pay fees shall be grounds for revocation of the approval of the Chair of any license, ordinance or resolution required under IGRA for the operation of gaming.

(b) In accordance with § 573.6(a)(2) of this chapter, if a tribe, management contractor, or individually owned gaming operation fails to pay the annual fee, the Chair may issue a notice of violation and, simultaneously with or subsequently to the notice of violation, a temporary closure order.

§ 514.11 Can a tribe or gaming operation appeal a proposed late fee?

(a) Proposed late fees assessed by the Chair may be appealed under part 577 of this chapter.

(b) At any time prior to the filing of a notice of appeal under part 577 of this chapter, the Chair and the respondent may agree to settle the notice of late submission, including the amount of the proposed late fee. In the event a settlement is reached, a settlement agreement shall be prepared and executed by the Chair and the respondent. If a settlement agreement is executed, the respondent shall be deemed to have waived all rights to further review of the notice or late fee in question, except as otherwise provided expressly in the settlement agreement. In the absence of a settlement of the issues under this paragraph, the respondent may contest the proposed late fee before the Commission in accordance with part 577 of this chapter.

§ 514.12 When does a notice of late submission and/or a proposed late fee become a final order of the Commission and final agency action?

If the respondent fails to appeal under part 577 of this chapter, the notice and the proposed late fee shall become a final order of the Commission and final agency action.

§ 514.13 How are late submission fees paid, and can interest be assessed?

(a) Late fees assessed under this part shall be paid by the person or entity assessed and shall not be treated as an operating expense of the operation.

(b) The Commission shall transfer the late fee paid under this subchapter to the U.S. Treasury.

(c) Interest shall be assessed at rates established from time to time by the Secretary of the Treasury on amounts remaining unpaid after their due date.

§ 514.14 What happens if a tribe overpays its fees or if the Commission does not expend the full amount of fees collected in a fiscal year?

(a) The total amount of all fees imposed during any fiscal year shall not exceed the statutory maximum imposed by Congress. The Commission shall credit pro-rata any fees collected in excess of this amount against amounts otherwise due according to § 514.4.

(b) To the extent that revenue derived from fees imposed under the schedule

established under this paragraph are not expended or committed at the close of any fiscal year, such funds shall remain available until expended to defray the costs of operations of the Commission.

§ 514.15 May tribes submit fingerprint cards to the NIGC for processing?

Tribes may submit fingerprint cards to the Commission for processing by the Federal Bureau of Investigation (FBI) and the Commission may charge a fee to process fingerprint cards on behalf of the tribes.

§ 514.16 How does the Commission adopt the fingerprint processing fee?

(a) The Commission shall review annually the costs involved in processing fingerprint cards and, by a vote of not less than two of its members, shall adopt preliminary rates for each calendar year no later than March 1st of that year, and, if considered necessary, shall modify those rates no later than June 1st of that year.

(b) The fingerprint fee charge shall be based on fees charged by the Federal Bureau of Investigation and costs incurred by the Commission. Commission costs include Commission personnel, supplies, equipment costs, and postage to submit the results to the requesting tribe.

§ 514.17 How are fingerprint processing fees collected by the Commission?

(a) Fees for processing fingerprint cards will be billed monthly to each Tribe for cards processed during the prior month. Tribes shall pay the amount billed within forty-five (45) days of the date of the bill.

(b) The Chair may suspend fingerprint card processing for a tribe that has a bill remaining unpaid for more than forty-five (45) days.

(c) Fingerprint fees shall be sent to the following address: Comptroller, National Indian Gaming Commission, 1441 L Street, NW., Suite 9100, Washington, DC 20005. Checks should be made payable to the National Indian Gaming Commission (do not remit cash).

Dated: October 3, 2011, Washington, DC.

Tracie L. Stevens,

Chairwoman.

Steffani A. Cochran,

Vice-Chairwoman.

Daniel J. Little,

Associate Commissioner.

[FR Doc. 2011–25955 Filed 10–7–11; 8:45 am]

BILLING CODE 7565–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–140280–09]

RIN 1545–BK16

Tax Return Preparer Penalties Under Section 6695

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations that would modify existing regulations related to the tax return preparer penalties under section 6695 of the Internal Revenue Code (Code). These proposed regulations are necessary to monitor and to improve compliance with the tax return preparer due diligence requirements of section 6695(g). The proposed regulations affect tax return preparers. This document also provides notice of a public hearing on these proposed regulations.

DATES: Written or electronic comments must be received by November 10, 2011. Outlines of topics to be discussed at the public hearing scheduled for November 7, 2011, must be received by November 1, 2011.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–140280–09), room 5205, Internal Revenue Service, PO Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–140280–09), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC, or sent electronically via the Federal eRulemaking Portal at *http://www.regulations.gov/Regs* (IRS REG–140280–09). The public hearing will be held in the IRS Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Spence Hanemann, (202) 622–4940; concerning submissions of comments, the hearing, or to be placed on the building access list to attend the hearing, Richard Hurst, (202) 622–7180 (not toll-free numbers) or *richard.a.hurst@irscounsel.treas.gov.*

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in these proposed regulations was previously reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) under control number 1545–1570. Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, SE:W:CAR:MP:T:T:SP, Washington, DC 20224. Comments on the collection of information should be received by November 10, 2011. Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the IRS, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proper collection of information;

How the quality, utility, and clarity of the information to be collected may be enhanced; and

How the burden of complying with the proposed collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology.

The collection of information is in § 1.6695–2(b)(1) and (b)(4) of these proposed regulations, and is an increase in the total annual burden from the burden in the current regulations. The collection of this information will improve the IRS' ability to enforce compliance with the due diligence requirements under section 6695(g) with respect to determining eligibility for, or the amount of, the earned income credit (EIC) under section 32.

Currently, the IRS estimates that there are 550,000 persons who are tax return preparers with respect to determining the eligibility for, or the amount of, EIC.

This collection of information is mandatory. The likely respondents are individuals and businesses.

Estimated total annual recordkeeping and reporting burden is 3,025,000 hours.

Estimated annual burden per tax return preparer varies from 30 minutes to 10 hours, depending on individual circumstances, with an estimated average of 5 hours and 30 minutes.

Estimated number of affected practitioners is 550,000.

Estimated annual frequency of responses is one time per tax return or claim for refund on which EIC is reported.

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 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.

Background

This document contains proposed amendments to the Income Tax Regulations (26 CFR part 1) under section 6695 of the Code.

The Treasury Department and the IRS published final regulations in the **Federal Register** on December 22, 2008, as TD 9436, 73 FR 78430 (the December 2008 final regulations). The December 2008 final regulations were a product of a comprehensive review and overhaul of the regulations related to tax return preparer penalties, including those under section 6695. These proposed regulations introduce additional measures intended to improve compliance with the tax return preparer EIC due diligence requirements of section 6695(g).

Explanation of Provisions

The following is a summary of the proposed changes to the existing regulations affecting tax return preparers.

Tax Return Preparers Subject to Due Diligence Requirements

Section 301.7701–15(a) of the Procedure and Administration regulations defines a ''tax return preparer'' as ''any person who prepares for compensation, or who employs one or more persons to prepare for compensation, all or a substantial portion of any return of tax or any claim for refund of tax * * *.'' Proposed § 1.6695–2(a) changes ''signing tax return preparer'' to ''tax return preparer.'' Consequently, under the proposed regulations, all tax return preparers (whether an individual or firm) who determine eligibility for, or amount of, EIC under section 32 of the Code and who fail to satisfy the due diligence requirements of paragraph (b) of these proposed regulations are subject to the penalty under section 6695(g). Under the proposed regulations, a firm that employs a person to prepare for compensation a tax return or claim for refund may be subject to the penalty for its employee's failure to comply with the due diligence requirements.

Because a firm might not have direct knowledge of an employee's failure to comply with the due diligence requirements, however, proposed § 1.6695–2(c) provides additional requirements that must be met before the penalty will be imposed on a firm. Proposed § 1.6695–2(c)(1) provides that a firm will be subject to the penalty if a member of its principal management or the principal management of a branch office participated in or knew of the failure to comply with the due diligence requirements. Proposed § 1.6695–2(c)(2) also provides that a firm will be subject to the penalty if it failed to establish reasonable and appropriate procedures to ensure compliance with the due diligence requirements. Finally, proposed § 1.6695–2(c)(2) provides that, even if a firm has established reasonable and appropriate compliance procedures, it will be subject to the penalty if it disregarded its compliance procedures through willfulness, recklessness, or gross indifference in the preparation of the tax return or claim for refund for which the penalty is imposed. A firm has demonstrated gross indifference if it ignores facts that would lead a person of reasonable prudence and competence to investigate or ascertain whether an employee is complying with the due diligence requirements.

Submission of Form 8867

Current § 1.6695–2(b)(1) requires a tax return preparer to complete Form 8867, ''Paid Preparer's Earned Income Credit Checklist,'' or otherwise record the information required by Form 8867 in the tax return preparer's files. In response to concerns over improper payments of EIC determined by tax return preparers, the Department of the Treasury and the IRS are proposing to require tax return preparers to submit the Form 8867 with the tax return or claim for refund claiming the EIC.

Proposed § 1.6695–2(b)(1)(i), therefore, requires that the Form 8867 be submitted to the IRS in the manner required by forms, instructions, or other appropriate guidance. Comments are specifically requested regarding the best way for the Department of Treasury and the IRS to implement this submission requirement. Comments are also requested regarding how Form 8867 and Schedule EIC might be revised to reduce payments of improper EIC claims and to improve the IRS' ability to detect these claims.

A tax return preparer has satisfied the due diligence requirements of current § 1.6695–2(b)(1) if the tax return preparer records, in paper or electronic files, the information necessary to complete Form 8867. Under proposed § 1.6695–2(b)(1), the due diligence requirements of paragraph (b)(1) can only be satisfied by completion and submission of the Form 8867 (or its successor form) and, therefore, cannot be satisfied by submission of any other form or document.

Computation of Credit

The amendments in proposed § 1.6695–2(b)(2) are not substantive. The term ''tax return preparer'' has been substituted for the term ''preparer.'' Under the proposed regulations, tax return preparers would continue to complete the EIC Worksheet in the Form 1040 Instructions or any other form prescribed by the IRS, or otherwise record in paper or electronic files their EIC computation, including the method and information used to make the computation. To improve clarity, however, the defined terms ''Computation Worksheet'' and ''Alternative Computation Record'' have been replaced throughout the proposed regulation with descriptive language.

Retention of Records

Under proposed § 1.6695–2(b)(4)(i)(C), tax return preparers must still retain a record of how and when the information used to complete Form 8867 and the EIC Worksheet (or other record of the tax return preparer's EIC computation permitted under § 1.6695–2(b)(2)(i)(B)) was obtained. Additionally, a tax return preparer must also retain a copy of any document that was provided by the taxpayer and on which the tax return preparer relied to complete Form 8867 or the EIC Worksheet (or other record of the tax return preparer's EIC computation permitted under § 1.6695–2(b)(2)(i)(B)).

Proposed § 1.6695–2(b)(4)(ii) makes two changes. It substitutes ''paragraph (b)(4)(i)'' for ''paragraph (b)(4)'' in order to account for prior restructuring of paragraph (b)(4). It also changes the date through which tax return preparers must retain the records required by this section. The current retention date is three years after the June 30th following the date the return or claim for refund was presented to the taxpayer for signature. The proposed retention date is three years from the later of the due date of the return (determined without regard to any extension of time for filing) or the date the return or claim for refund was filed. This revision to the retention date will simplify the determination of the retention date for both the IRS and tax return preparers.

Exception to the Penalty Under Section 6695(g)

Proposed § 1.6695–2(d) retains the existing exception to the penalty, but excludes from the exception a firm that is subject to the penalty under the

special rules for firms in proposed § 1.6695–2(c). Thus, in no case could a firm that is subject to the penalty under proposed § 1.6695–2(c) satisfy the facts and circumstances test provided in proposed § 1.6695–2(d).

Proposed Effective and Applicability Dates

Proposed § 1.6695–2(e) provides that the rules in this notice of proposed rulemaking will apply to tax returns and claims for refund for tax years ending on or after December 31, 2011 that are filed after the date the final regulations are published in the **Federal Register**.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations.

When an agency issues a rulemaking proposal, the Regulatory Flexibility Act (RFA) (5 U.S.C. chapter 6), requires the agency to ''prepare and make available for public comment an initial regulatory flexibility analysis'' that will ''describe the impact of the proposed rule on small entities.'' (5 U.S.C. 603(a)). Section 605 of the RFA provides an exception to this requirement if the agency certifies that the proposed rulemaking will not have a significant economic impact on a substantial number of small entities.

The proposed rules affect tax return preparers who determine the eligibility for, or the amount of, EIC. The NAICS code that relates to tax preparation services (NAICS code 541213) is the appropriate code for tax return preparers subject to this notice of proposed rulemaking. Entities identified as tax preparation services are considered small under the Small Business Administration size standards (13 CFR 121.201) if their annual revenue is less than $7 million. The IRS estimates that approximately 75 to 85 percent of the 550,000 persons who work at firms or are self-employed tax return preparers are operating as or employed by small entities. The IRS has determined that these proposed rules will have an impact on a substantial number of small entities.

The IRS has determined, however, that the impact on entities affected by the proposed rule will not be significant. The current regulations under section 6695(g) already require tax return preparers to complete the Form 8867 or otherwise record in their files the information necessary to complete the form. Tax return preparers also must currently maintain records of the checklists and EIC computations, as well as a record of how and when the information used to compute the EIC was obtained by the tax return preparer. The amount of time necessary to submit, record, and retain the additional information required in these proposed regulations, therefore, should be minimal for these tax return preparers.

Based on these facts, the IRS hereby certifies that the collection of information contained in this notice of proposed rulemaking will not have a significant economic impact on a substantial number of small entities. Accordingly, a Regulatory Flexibility Analysis is not required.

Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on the impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS. The Treasury Department and the IRS request comments on the clarity of the proposed regulations and how they can be made easier to understand. All comments will be available for public inspection and copying at *http://www.regulations.gov* or upon request.

A public hearing has been scheduled for November 7, 2011, at 10 a.m. in the IRS Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. Due to building security procedures, visitors must enter at the Constitution Avenue entrance. In addition, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 30 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing must submit written or electronic comments and an outline of the topics to be discussed and the time to be devoted to each topic (a signed original and eight (8) copies) by November 1, 2011. A period of 10 minutes will be allotted to each person for making comments. An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal author of these proposed regulations is Spence Hanemann, Office of the Associate Chief Counsel (Procedure and Administration).

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

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

Authority: 26 U.S.C. 7805 * * *
Section 1.6695–2 also issued under 26 U.S.C. 6695(g). * * *

Par. 2. In § 1.6695–2, paragraphs (a), (b)(1), (b)(2), (b)(4), (c), and (d) are revised and new paragraph (e) is added to read as follows:

§ 1.6695–2 Tax return preparer due diligence requirements for determining earned income credit eligibility.

(a) *Penalty for failure to meet due diligence requirements.* A person who is a tax return preparer of a tax return or claim for refund under the Internal Revenue Code with respect to determining the eligibility for, or the amount of, the earned income credit (EIC) under section 32 and who fails to satisfy the due diligence requirements of paragraph (b) of this section will be subject to a penalty of $100 for each such failure.

(b) * * *

(1) *Completion and submission of Form 8867*—(i) The tax return preparer must complete Form 8867, ''Paid Preparer's Earned Income Credit Checklist,'' or such other form and such other information as may be prescribed by the Internal Revenue Service (IRS), and submit it in the manner required by forms, instructions, or other appropriate guidance.

(ii) The tax return preparer's completion of Form 8867 (or successor form) must be based on information provided by the taxpayer to the tax return preparer or otherwise reasonably obtained by the tax return preparer.

(2) *Computation of credit*—(i) The tax return preparer must either—

(A) Complete the Earned Income Credit Worksheet in the Form 1040 instructions or such other form and such other information as may be prescribed by the IRS; or

(B) Otherwise record in one or more documents in the tax return preparer's paper or electronic files the tax return preparer's EIC computation, including the method and information used to make the computation.

(ii) The tax return preparer's completion of the Earned Income Credit Worksheet (or other record of the tax return preparer's EIC computation permitted under paragraph (b)(2)(i)(B) of this section) must be based on information provided by the taxpayer to the tax return preparer or otherwise reasonably obtained by the tax return preparer.

* * * * *

(4) *Retention of records*—(i) The tax return preparer must retain—

(A) A copy of the completed Form 8867 (or successor form);

(B) A copy of the completed Earned Income Credit Worksheet (or other record of the tax return preparer's EIC computation permitted under paragraph (b)(2)(i)(B) of this section); and

(C) A record of how and when the information used to complete Form 8867 (or successor form) and the Earned Income Credit Worksheet (or other record of the tax return preparer's EIC computation permitted under paragraph (b)(2)(i)(B) of this section) was obtained by the tax return preparer, including the identity of any person furnishing the information, as well as a copy of any document that was provided by the taxpayer and on which the tax return preparer relied to complete Form 8867 (or successor form) or the Earned Income Credit Worksheet (or other record of the tax return preparer's EIC computation permitted under paragraph (b)(2)(i)(B) of this section).

(ii) The items in paragraph (b)(4)(i) of this section must be retained for three years from the due date of the return (determined without regard to any extension of time for filing) or the date the return or claim for refund was filed, whichever date is later, and may be retained on paper or electronically in the manner prescribed in applicable regulations, revenue rulings, revenue procedures, or other appropriate guidance (see § 601.601(d)(2) of this chapter).

(c) *Special rule for firms.* A firm that employs a tax return preparer subject to a penalty under section 6695(g) is also subject to penalty if, and only if—

(1) One or more members of the principal management (or principal officers) of the firm or a branch office participated in or knew of the failure to comply with the due diligence requirements of this section;

(2) The firm failed to establish reasonable and appropriate procedures to ensure compliance with the due diligence requirements of this section; or

(3) The firm disregarded its reasonable and appropriate compliance procedures through willfulness, recklessness, or gross indifference (including ignoring facts that would lead a person of reasonable prudence and competence to investigate or ascertain) in the preparation of the tax return or claim for refund with respect to which the penalty is imposed.

(d) *Exception to penalty.* The section 6695(g) penalty will not be applied with respect to a particular tax return or claim for refund if the tax return preparer can demonstrate to the satisfaction of the Internal Revenue Service that, considering all the facts and circumstances, the tax return preparer's normal office procedures are reasonably designed and routinely followed to ensure compliance with the due diligence requirements of paragraph (b) of this section, and the failure to meet the due diligence requirements of paragraph (b) of this section with respect to the particular return or claim for refund was isolated and inadvertent. The preceding sentence does not apply to a firm that is subject to the penalty as a result of paragraph (c) of this section.

(e) *Effective/applicability date.* This section is effective for tax returns and claims for refund filed after the date that these regulations are published as final regulations in the **Federal Register**, and applies to tax returns and claims for refund for tax years ending on or after December 31, 2011.

Steven T. Miller,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2011–26247 Filed 10–6–11; 11:15 am]

BILLING CODE 4830–01–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Part 334

Atlantic Ocean off Wallops Island and Chincoteague Inlet, Virginia; Danger Zone

AGENCY: United States Army Corps of Engineers, Department of Defense.

ACTION: Notice of proposed rulemaking and request for comments.

SUMMARY: The Corps of Engineers is proposing to amend an existing permanent danger zone in the waters of the Atlantic Ocean off Wallops Island and Chincoteague Inlet, Virginia. The National Aeronautics and Space Administration, Goddard Space Flight Center, Wallops Flight Facility conducts rocket-launching operations. The proposed amendment is necessary to protect the public from hazards associated with the rocket-launching operations. The proposed amendment would increase the danger zone to a 30 nautical mile sector.

DATES: Written comments must be submitted on or before November 10, 2011.

ADDRESSES: You may submit comments, identified by docket number COE–2011–0019, by any of the following methods:

Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

E-mail: david.b.olson@usace.army.mil. Include the docket number, COE–2011–0019, in the subject line of the message.

Mail: U.S. Army Corps of Engineers, Attn: CECW–CO–R (David B. Olson), 441 G Street NW., Washington, DC 20314–1000.

Hand Delivery/Courier: Due to security requirements, we cannot receive comments by hand delivery or courier.

Instructions: Direct your comments to docket number COE–2011–0019. All comments received will be included in the public docket without change and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the commenter indicates that the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI, or otherwise protected, through regulations.gov or e-mail. The regulations.gov web site is an

anonymous access system, which means we will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail directly to the Corps without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, we recommend that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If we cannot read your comment because of technical difficulties and cannot contact you for clarification, we may not be able to consider your comment. Electronic comments should avoid the use of any special characters, any form of encryption, and be free of any defects or viruses.

Docket: For access to the docket to read background documents or comments received, go to *www.regulations.gov.* All documents in the docket are listed. Although listed in the index, some information is not publicly available, such as CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form.

FOR FURTHER INFORMATION CONTACT: Mr. David Olson, Headquarters, Operations and Regulatory Community of Practice, Washington, DC at 202–761–4922, or Nancy Hankins, Corps of Engineers, Norfolk District, Regulatory Branch, at 757–201–6048.

SUPPLEMENTARY INFORMATION: Pursuant to its authorities in Section 7 of the Rivers and Harbors Act of 1917 (40 Stat. 266; 33 U.S.C. 1) and Chapter XIX of the Army Appropriations Act of 1919 (40 Stat. 892; 33 U.S.C. 3), the Corps of Engineers is proposing amendments to regulations in 33 CFR Part 334 for a permanent danger zone in the waters of the Atlantic Ocean off Wallops Island and Chincoteague Inlet, Virginia. The proposed modification of the existing permanent danger zone is necessary to protect the public from hazards associated with rocket-launching operations. The proposed modification expands the danger zone to a 30 nautical mile sector.

Procedural Requirements

a. Review Under Executive Order 12866

This proposed rule is issued with respect to a military function of the Department of Defense and the provisions of Executive Order 12866 do not apply.

b. Review Under the Regulatory Flexibility Act

This proposed rule has been reviewed under the Regulatory Flexibility Act (Pub. L. 96–354) which requires the preparation of a regulatory flexibility analysis for any regulation that will have a significant economic impact on a substantial number of small entities (i.e., small businesses and small governments). Unless information is obtained to the contrary during the public notice comment period, the Corps expects that the amendment of this danger zone would have practically no economic impact on the public, no anticipated navigational hazard, or interference with existing waterway traffic. This proposed rule if adopted, will have no significant economic impact on small entities.

c. Review Under the National Environmental Policy Act

Due to the administrative nature of this action and because there is no intended change in the use of the area, the Corps expects that this regulation, if adopted, will not have a significant impact to the quality of the human environment and, therefore, preparation of an environmental impact statement will not be required. An environmental assessment will be prepared after the public notice period is closed and all comments have been received and considered. It may be reviewed at the District office listed at the end of **FOR FURTHER INFORMATION CONTACT**, above.

d. Unfunded Mandates Act

This proposed rule does not impose an enforceable duty among the private sector and, therefore, it is not a Federal private sector mandate and it is not subject to the requirements of either Section 202 or Section 205 of the Unfunded Mandates Act. We have also found under Section 203 of the Act, that small governments will not be significantly and uniquely affected by this rulemaking.

List of Subjects in 33 CFR Part 334

Danger zones, Marine safety, Navigation (water), Restricted areas, Waterways.

For the reasons set out in the preamble, the Corps proposes to amend 33 CFR part 334 as follows:

PART 334—DANGER ZONE AND RESTRICTED AREA REGULATIONS

1. The authority citation for 33 CFR part 334 continues to read as follows:

Authority: 40 Stat. 266 (33 U.S.C. 1) and 40 Stat. 892 (33 U.S.C. 3).

2. Revise § 334.130 to read as follows:

§ 334.130 Atlantic Ocean off Wallops Island and Chincoteague Inlet, Va.; danger zone.

(a) *The area.* An area immediately behind and directly offshore from Wallops Island defined by lines drawn as follows: Beginning at latitude 37°53′00″ N, longitude 75°29′48″ W; thence to latitude 37°53′03″ N, longitude 74°50′52″ W; thence to latitude 37°38′28″ N, longitude 74°51′48″ W; thence to latitude 37°22′00″ N, longitude 75°09′35″ W; thence to latitude 37°19′11″ N, longitude 75°30′00″ W; thence to latitude 37°47′57″ N, longitude 75°32′19″ W; and thence to latitude 37°53′00″ N, longitude 75°29′48″ W.

(b) *The regulations.* (1) Persons and vessels shall only be prohibited from entering the area when launch operations are being conducted.

(2) In advance of scheduled launch operations which, in the opinion of the enforcing agency, may be dangerous to persons and watercraft, appropriate warnings will be issued to navigation interests through official government and civilian channels or in such other manner as the District Engineer, U.S. Army Corps of Engineers, may direct. Such warnings will specify the location, time, and duration of operations, and give other pertinent information as may be required in the interest of safety. Announcement of area of closure will appear in the weekly ''Notice to Mariners.''

(3) The intent to conduct rocket-launching operations in the area shall also be indicated by visual signals consisting of a large orange-colored ''blimp-shaped'' balloon by day and a rotating alternately red and white beacon by night. The balloon shall be flown at latitude 37°50′38″ N, longitude 75°28′47″ W and the beacon shall be displayed about 200 feet above mean high water at latitude 37°50′16″ N, longitude 75°29′07″ W. The appropriate signals shall be displayed 30 minutes prior to rocket-launching time and shall remain displayed until the danger no longer exists.

(4) In addition to visual signals and prior to conducting launch operations, the area will be patrolled by aircraft or surface vessels and monitored by radars and cameras to ensure no persons or watercraft are within the danger zone or designated area of interest within the danger zone. Patrol aircraft and surface vessels are equipped with marine band radios and may attempt to hail watercraft and request that they leave

the designated area and remain clear of the area at a safe distance until launch operations are complete, and launch will not occur until the designated area is clear. Patrol aircraft may also employ the method of warning known as ''buzzing'' which consists of low flight by the airplane and repeated opening and closing of the throttle. Surveillance vessels may also come close to watercraft and employ flashing light to establish communications to indicate that the watercraft is entering the designated hazard area.

(5) Any watercraft being so warned shall immediately leave designated area until the conclusion of launch operations, and shall remain at a distance that it will be safe from falling debris.

(6) Nothing in this regulation shall be intended to prevent commercial fishing or the lawful use of approved waterfowl hunting blinds along the shorelines of the Wallops Flight Facility at Wallops Island, Virginia, provided that all necessary licenses and permits have been obtained from the Virginia Marine Resources Commission, Virginia Department of Game and Inland Fisheries, and U.S. Fish and Wildlife Service. Commercial fishermen and waterfowl hunters must observe all warnings and range clearances during hazardous range operations.

(c) *Enforcement.* The regulations in this section shall be enforced by the Director, National Aeronautics and Space Administration, Goddard Space Flight Center, Wallops Flight Facility Wallops Island, Va., or such agencies as he or she may designate.

Dated: September 30, 2011.

Michael G. Ensch,

Chief, Operations and Regulatory, Directorate of Civil Works.

[FR Doc. 2011–26198 Filed 10–7–11; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Parts 212, 214, 215, 218, 222, 228, 241, 251, 254, and 292

RIN 0596—AB45

Appeal of Decisions Relating to Occupancy or Use of National Forest System Lands and Resources

AGENCY: USDA, Forest Service.

ACTION: Proposed rule; request for comment.

SUMMARY: The Forest Service, United States Department of Agriculture (USDA), is proposing to update, rename, and relocate the administrative appeal regulations governing occupancy or use of National Forest System (NFS) lands and resources. The appeal process for decisions related to occupancy or use of NFS lands and resources has remained substantially unchanged since 1989. The proposed rule simplifies the appeal process, shortens the appeal period, and reduces the cost of appeal while still providing a fair and deliberate procedure by which eligible individuals and entities may obtain administrative review of certain types of Forest Service decisions affecting their occupancy or use of NFS lands or resources. The proposed rule also relocates the provision entitled ''Mediation of Term Grazing Permit Disputes'' to a more appropriate location in the range management regulations. Finally, conforming technical revisions to other parts of the Code of Federal Regulations (CFR) affected by this proposed rule are being made.

DATES: Comments must be received in writing by December 12, 2011.

ADDRESSES: Submit comments through the Web site *http://www.regulations.gov* or mail written comments to Director, Ecosystem Management Coordination, Mailstop 1104, Forest Service, USDA, 1400 Independence Ave, SW., Washington, D.C. 20250–1103. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. Persons wishing to inspect the comments are encouraged to call ahead 202–205–1323 to facilitate entry into the building.

Comments concerning the information collection requirements contained in this proposed rule should reference OMB No. 0596–New and the docket number, date, and page number of this issue of the **Federal Register**. Comments concerning the information collection requirements may be submitted as provided for comments on the proposed rule.

FOR FURTHER INFORMATION CONTACT: Deb Beighley, Assistant Director, Appeals and Litigation, Ecosystem Management Coordination staff, 202–205–1277, or Mike McGee, Appeals Specialist, Ecosystem Management Coordination staff, 202–205–1323.

SUPPLEMENTARY INFORMATION:

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1. Background and Need for the Proposed Rule
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3. Conforming Substantive Changes to Other Parts of Title 36 of the CFR
4. Conforming Technical Changes to Other Parts of Title 36 of the CFR
5. Regulatory Certifications

1. Background and Need for the Proposed Rule

On January 23, 1989, the Forest Service, USDA adopted a new administrative appeal rule at 36 CFR part 251, subpart C (54 FR 3362) (the 251 Appeal Rule). The 251 Appeal Rule set procedures for holders of or, in some cases, applicants for a written authorization to occupy and use NFS lands and resources to appeal certain Forest Service decisions with regard to the issuance, approval, or administration of the written instrument. The rule established who may appeal, the kinds of decisions that can and cannot be appealed, the responsibilities of parties to the appeal, and the various timeframes that govern the conduct of an appeal. The appeal procedures vary depending on whether the decision subject to appeal was made by a District Ranger, Forest or Grassland Supervisor, Regional Forester, or the Chief. Except for the addition of a section governing mediation of term grazing permit disputes in 1999, the 251 Appeal Rule has changed little since its adoption in 1989.

As a result of technological advances, communications improvements, and the Agency's experience administering the 251 Appeal Rule for the past 20 years, the Forest Service has identified several modifications that will simplify the appeal process, shorten the appeal time period, and achieve cost savings.

The proposed rule relocates the 251 Appeal Rule to a new part 214, entitled ''Appeal of Decisions Relating to Occupancy or Use of National Forest System Lands and Resources.'' Current provisions in the 251 Appeal Rule will be rewritten or replaced with new provisions, and part 251, subpart C, will be removed. The proposed rule also moves the provision governing mediation of term grazing permit disputes to a new subpart D under the range management regulations found at 36 CFR part 222, since mediation is unique to the range management program and is not part of the administrative review process under the 251 Appeal Rule.

The following table provides a crosswalk between the 251 Appeal Rule and the proposed rule.

Current 36 CFR part 251, subpart C	Proposed 36 CFR part 214
§ 251.80 Purpose and scope	§ 214.1 Purpose and scope.
§ 251.81 Definitions and terminology	§ 214.2 Definitions.
§ 251.82 Appealable decisions	§ 214.4 Decisions that are appealable.
§ 251.83 Decisions not appealable	§ 214.5 Decisions that are not appealable.
§ 251.84 Obtaining notice	§ 214.7 Notice of an appealable decision.
§ 251.85 Election of appeal process	§ 214.6 Election of appeal process.
§ 251.86 Parties	§ 214.3 Parties to an appeal.
§ 251.87 Levels of appeal	§ 214.8 Levels of review.
§ 251.88(a) Filing Procedures	§ 214.9 Appeal content.
§ 251.90 Content of notice of appeals;	
§ 251.88(b), (c) Filing Procedures	§ 214.14 (b), (c), (e), (f), (g) Conduct of an appeal.
§ 251.95 Authority of reviewing officer;	
No equivalent	§ 214.14(a) Method of filing.
No equivalent	§ 214.14(h) Service of documents.
No equivalent	§ 214.14(i) Posting of Final Decision.
No equivalent	§ 214.14(j) Expenses.
§ 251.89 Time extensions	§ 214.14(d) Extensions of time.
§ 251.91 Stays	§ 214.13 Stays.
§ 251.92 Dismissal	§ 214.10 Dismissal of an appeal.
§ 251.93 Resolution of issues	§ 214.15 Resolution of issues prior to an appeal decision.
§ 251.94 Responsive statement	§ 214.12 Responsive statement and reply.
§ 251.96 Intervention	§ 214.11 Intervention.
§ 251.97 Oral presentation	§ 214.16 Oral presentation.
§ 251.98 Appeal record	§ 214.17 Appeal record.
§ 251.99 Appeal decision	§ 214.18 Appeal decision.
§ 251.100 Discretionary review	§ 214.19 Procedures for discretionary review.
§ 251.101 Policy in event of judicial proceedings	§ 214.20 Exhaustion of administrative remedies.
No equivalent	§ 214.21 Information collection requirements.
§ 251.102 Applicability and effective date	§ 214.22 Applicability and effective date.
§ 251.103 Mediation of term grazing permit disputes	Moved to 36 CFR part 222, subpart D.

2. Section-by-Section Analysis of Proposed Rule Changes

Section 214.1 Purpose and scope. This section replaces § 251.80 and generally describes the objectives of the administrative review process outlined in the proposed rule and briefly discusses its key features.

Section 214.1(a) corresponds with § 251.80(b) and explains that the purpose of this regulation is to establish a fair and deliberate process by which certain individuals and entities may obtain administrative review of specific written decisions issued by Forest Service officers that affect written authorizations for the occupancy or use of NFS lands and resources.

Section 214.1(b) corresponds with § 251.80(a) and identifies who is eligible to appeal, the decisions that are appealable and not appealable, the responsibilities of the parties to an appeal, and the time periods and procedures that govern the conduct of appeals.

Section 214.2 Definitions. This section replaces § 251.81 and defines technical terms and individuals who have a specific role in the administrative review process.

The proposed rule removes the following seven terms from the definitions and terminology section in the 251 Appeal Rule because they are not used in the proposed rule: ''Deciding Officer,'' ''Decisions regarding a written instrument or authorization to occupy and use National Forest System lands,'' ''Forest Service line officer,'' ''Issuance of a written instrument or authorization,'' ''Notice of appeal,'' ''Parties to an appeal,'' and ''Reviewing Officer.''

The proposed rule adds the following 12 terms to the definitions section: ''Appeal Deciding Officer,'' ''Responsible Official,'' ''Cancellation,'' ''Discretionary Reviewing Officer,'' ''Holder,'' ''Modification,'' ''Operator,'' ''Prospectus,'' ''Revocation,'' ''Solicited applicant,'' ''Suspension,'' and ''Termination.''

''Deciding Officer'' and ''Reviewing Officer'' in the 251 Appeal Rule are replaced by ''Responsible Official'' and ''Appeal Deciding Officer,'' respectively, in the proposed rule. ''Responsible Official'' refers to the Forest Service employee (generally a line officer) who has issued an appealable decision under the proposed rule, and ''Appeal Deciding Officer'' refers to the Forest Service employee (also generally a line officer) one organizational level above the Responsible Official who issues the appeal decision. ''Responsible Official'' is used in Forest Service appeal regulations at 36 CFR part 215 for projects and activities implementing land and resource management plans and in Forest Service regulations at 36 CFR part 218, which provide a predecisional administrative review process for decisions or activities authorized under the Healthy Forests Restoration Act, to denote the individual authorized to issue a decision that is subject to the objection process. For consistency, the Agency is proposing to use the same definition for ''Responsible Official'' in parts 214, 215, and 218. ''Appeal Deciding Officer'' is used in Forest Service appeal regulations at 36 CFR part 215 to refer to the individual responsible for issuing an appeal decision. For consistency, the Agency is proposing to use the same definition for ''Appeal Deciding Officer'' in parts 214 and 215. Additionally, the Agency is proposing to use the same definitions for ''Appeal,'' ''Appeal record,'' and ''Appellant'' in parts 214 and 215.

Another term from the 251 Appeal Rule, ''Notice of appeal,'' is replaced by the term ''Appeal'' in the proposed rule and refers to the document filed by a holder, operator, or solicited applicant in which relief is sought from an appealable decision. This term minimizes the potential for confusion that parties to an appeal experienced with the term ''notice of appeal,'' which could be interpreted either as the Forest Service's notification that an appealable decision had been issued or the holder's request for an appeal of a Forest Service decision.

The term ''written instrument or authorization'' in the 251 Appeal Rule

is renamed ''written authorization,'' and the definition is modified in the proposed rule.

Several definitions are adopted from other Forest Service regulations, including ''cancellation'' from § 222.1; ''revocation'' from § 251.51, and ''termination'' from § 251.51.

Seven terms are retained from the 251 Appeal Rule, including ''Appeal,'' ''Appeal decision,'' ''Appeal record,'' ''Appellant,'' ''Intervenor,'' ''Oral presentation,'' and ''Responsive statement.'' The Agency has revised some of the definitions for these terms, but has retained their overall meaning in the proposed rule.

The following terms are defined in the proposed rule:

Appeal. A document filed with an Appeal Deciding Officer in which an individual or entity seeks review of a Forest Service decision under this proposed rule.

Appeal Deciding Officer. The Forest Service employee who is one organizational level above the Responsible Official and who is authorized to issue an appeal decision under the proposed rule. This term replaces ''Reviewing Officer'' in § 251.81 and is consistent with terminology in other Forest Service appeal regulations, such as 36 CFR part 215.

Appeal decision. The final written decision issued by an Appeal Deciding Officer on an appeal filed under the proposed rule which affirms or reverses the Responsible Official's appealable decision in whole or in part, explains the basis for the decision, and provides additional instructions to the parties as necessary. This change simplifies the corresponding definition found in the 251 Appeal Rule.

Appeal record. The documentation and other information filed with the Appeal Deciding Officer by the parties to the appeal within the relevant time period established in § 214.17 and upon which review of an appeal is conducted.

Appellant. An individual or entity that has filed an appeal under this proposed rule.

Cancellation. The invalidation, in whole or in part, of a term grazing permit or an instrument for the disposal of mineral materials, consistent with use of that term in other Forest Service regulations, such as 36 CFR part 222. This definition addresses a type of decision that is appealable under the proposed rule.

Discretionary Reviewing Officer. The USDA or Forest Service employee one organizational level above the Appeal Deciding Officer who is authorized to review an appeal decision or certain decisions of the Chief under the proposed rule. This definition clarifies the distinction between the Appeal Deciding Officer who reviews appealable decisions and the Discretionary Reviewing Officer who reviews appeal decisions or Chief's decisions.

Holder. An individual or entity that holds a valid written authorization to occupy or use NFS lands or resources. The Agency is proposing a corresponding revision to the definition for ''holder'' in 36 CFR part 251, subpart B, governing special use authorizations.

Intervenor. An individual or entity whose request to intervene has been granted by the Appeal Deciding Officer.

Modification. A Responsible Official's written revision of the terms and conditions of a written authorization.

Operator. An individual or entity conducting or proposing to conduct mineral operations. This definition specifically identifies one class of individuals that may participate in an appeal under the proposed rule.

Oral presentation. An informal meeting presided over by the Appeal Deciding Officer during which parties to an appeal may present information in support of their position.

Prospectus. A public announcement published by the Forest Service soliciting competitive applications for a written authorization.

Responsible Official. A Forest Service employee who is authorized to issue a decision that may be appealed under this proposed rule. This term is the same as the one used in 36 CFR parts 215 and 218 to describe the individual who issues a decision that is subject to review under the appeals or predecisional administrative review process in those rules. The term ''Responsible Official'' replaces the term ''Deciding Officer'' in the 251 Appeal Rule.

Responsive statement. The document filed by the Responsible Official with the Appeal Deciding Officer that addresses the issues raised and relief requested in an appeal.

Revocation. The cessation, in whole or in part, of a written authorization, other than a term grazing permit or an instrument for the disposal of mineral materials, by action of a Responsible Official before the end of the specified period of occupancy or use. This definition addresses a type of decision that is appealable under the proposed rule.

Solicited applicant. An individual or entity that has submitted a competitive application in response to a prospectus.

Suspension. A temporary revocation or cancellation of a written authorization.

Termination. The cessation of a written authorization by operation of law or by operation of a fixed or agreed-upon condition, event, or time as specified in the written authorization, which does not require action by a Responsible Official. Examples of termination include the expiration of the authorized term; change in ownership or control of the authorized improvements; or change in ownership or control of the holder of the authorization. For consistency, the definition for ''termination'' in 36 CFR part 251, subpart B, is being revised to match the definition for ''termination'' in the proposed rule. This definition is included to distinguish revocation and cancellation, which involve cessation of a written authorization due to action of the Responsible Official and are appealable, from termination, which involves cessation of a written authorization without action of the Responsible Official and is not appealable.

Written authorization. A term grazing permit, plan of operations, special use authorization, mineral material contract or permit, or other type of written instrument issued by the Forest Service or a lease or permit for leasable minerals issued by the U.S. Department of the Interior that authorizes occupancy or use of NFS lands or resources in accordance with the terms and conditions in the instrument. The Agency is proposing a corresponding change to the definition for ''special use authorization'' in 36 CFR part 251, subpart B, to expressly state that a special use authorization must be in writing.

Section 214.3 Parties to an appeal. This section replaces § 251.86 and states that only holders, operators, solicited applicants, intervenors, and the Responsible Official may be considered a party to an appeal under the proposed rule. The parties eligible to appeal are the same under the proposed rule and the 251 Appeal Rule, except that operators have been added as an eligible party in the proposed rule, and solicited applicants who have been offered a special use authorization and who object to its terms and conditions have been removed as an eligible party from the proposed rule. The Agency does not believe it is appropriate to allow solicited applicants to appeal terms and conditions in special use authorizations because these provisions are standardized nationally and have been approved by the Office of Management and Budget (OMB) as part of

information collection requirements under the Paperwork Reduction Act.

Section 214.4 Decisions that are appealable. Replaces § 251.82 and enumerates the types of decisions that are appealable under the proposed rule.

When § 214.4 is read together with § 214.5, the structure of the proposed rule states that a decision is not appealable unless it is expressly set forth in § 214.4. As a result, the list of appealable decisions in § 214.4 is considerably more extensive than the list of appealable decisions in § 251.82. Enumerating all types of appealable decisions will minimize potential confusion regarding whether a decision is appealable.

Section 214.4 is subdivided based on the type of written authorization. Paragraph (a) lists appealable decisions involving the administration of livestock grazing; paragraph (b) lists appealable decisions involving the administration of mineral exploration and development activities; paragraph (c) lists appealable decisions involving the administration of special uses; and paragraph (d) lists appealable decisions associated with other land uses.

Paragraph (a) enumerates the following four types of appealable decisions involving the administration of livestock grazing activities:

(1) Modification of term grazing permits issued under 36 CFR part 222, subpart A. Issuance of annual operating instructions does not constitute a permit modification and is not an appealable decision;

(2) Suspension or cancellation, other than cancellation resulting from the permittee's waiver to the United States, of term grazing permits issued under 36 CFR part 222, subpart A;

(3) Denial of reauthorization of livestock grazing under a term grazing permit if the holder files an application for a new permit before the existing permit expires; and

(4) Denial of a term grazing permit issued under 36 CFR part 222, subpart C, to a solicited applicant.

Paragraph (b) enumerates the following 9 types of appealable decisions involving the administration of mineral exploration and development activities:

(1) Approval or denial of an initial, modified, or supplemental plan of operations or operating plan; requirement of an increase in bond coverage; requirement of measures to avoid irreparable injury, loss, or damage to surface resources pending modification of a plan of operations or operating plan; or issuance of a notice of noncompliance pursuant to 36 CFR part 228, subpart A or D, or part 292, subpart D, F, or G;

(2) Approval or denial of an operating plan, issuance of a notice of noncompliance, extension, suspension, or cancellation, other than cancellation by mutual agreement, for contracts, permits, or prospecting permits for mineral materials issued under 36 CFR part 228, subpart C;

(3) Approval or denial of a surface use plan of operations, request to supplement a surface use plan of operations, suspension of oil and gas operations, or issuance of a notice of noncompliance pursuant to 36 CFR part 228, subpart E;

(4) Consent or denial of consent to the U.S. Department of the Interior's administration of previously issued leases or permits for leasable minerals other than oil and gas resources;

(5) Suspension, or revocation of an operating plan for Federal lands within the Sawtooth National Recreation Area pursuant to 36 CFR part 292, subpart D;

(6) Suspension of locatable mineral operations on NFS lands within the Hells Canyon National Recreation Area pursuant to 36 CFR part 292, subpart F;

(7) Suspension of locatable mineral operations on NFS lands within the Smith River National Recreation Area or approval of an initial or amended operating plan for exercise of outstanding mineral rights on NFS lands within the Smith River National Recreation Area pursuant to 36 CFR part 292, subpart G;

(8) Except as provided in paragraph (7), determinations of the acceptability of an initial or amended operating plan for exercise of outstanding mineral rights on NFS lands; and

(9) Determinations of the acceptability of an initial or amended operating plan for exercise of reserved mineral rights located on NFS lands.

Paragraph (c) enumerates the following 5 types of appealable special uses decisions:

(1) Modification, suspension, or revocation of a special use authorization, other than acceptance of an operating plan, including:

(i) A special use authorization issued under 36 CFR part 251, subpart B or D, other than modification, suspension, or revocation of a noncommercial group use permit, suspension or revocation of an easement issued pursuant to 36 CFR 251.53(e) or 251.53(l), or revocation with the consent of the holder;

(ii) A special use authorization for ingress and egress to intermingled and adjacent private lands across NFS lands issued under 36 CFR part 212, subpart A;

(iii) A special use authorization issued under 36 CFR part 251, subpart A, that authorizes the exercise of rights reserved in conveyances to the United States;

(iv) A permit and occupancy agreement issued under 36 CFR 213.3 for national grasslands and other lands administered under Title III of the Bankhead-Jones Farm Tenant Act;

(v) A permit issued under 36 CFR 293.13 for access to valid occupancies entirely within a wilderness in the NFS;

(vi) A permit issued under the Archaeological Resources Protection Act of 1979 and 36 CFR part 296 for excavation or removal of archaeological resources; and

(vii) A special use authorization governing surface use associated with the exercise of outstanding mineral rights;

(2) Denial of a special use authorization to a solicited applicant;

(3) Implementation of new land use fees for a special use authorization, other than:

(i) Revision or replacement of a land use fee system or schedule that is implemented through public notice and comment; and

(ii) Annual land use fee adjustments based on an inflation factor that are calculated under an established fee system or schedule in accordance with the terms and conditions of a written authorization;

(4) Assignment of a performance rating to holders of outfitting and guiding or campground concession permits that affects reissuance or extension of a special use authorization; or

(5) Denial of renewal of a special use authorization if it specifically provides for renewal and if the holder requests renewal of the authorization before it expires.

Paragraph (d) enumerates one additional type of appealable decision associated with other land uses: denial or revocation of a certification of compliance issued under 36 CFR part 292, subpart C, related to the use, subdivision, and development of privately owned property within the boundaries of the Sawtooth National Recreation Area.

Section 214.5 Decisions that are not appealable. This section replaces § 251.83. Contrary to the 251 Appeal Rule, which enumerates 15 types of decisions that are not appealable, the proposed rule simply states that any decision not expressly enumerated in § 214.4 is not appealable. This is an easier way to distinguish appealable decisions from those decisions that may not be appealed, to ensure coverage of

all decisions and to eliminate guesswork that occurs when a decision is not included in either an appealable decision list or a non-appealable decision list.

Section 214.6 Election of appeal process. This section replaces § 251.85. This section generally corresponds with and merges § 251.85(a) and (b) and explains that some decisions that are appealable under this part may also be appealable under other Forest Service appeal procedures in different parts of the CFR. The proposed rule states that where multiple appeal options exist, a holder, operator, or solicited applicant must elect one of the appeal procedures and in so doing forego the opportunity to pursue an appeal under the other appeal procedures. References to specific parts of the CFR have been removed in this section to ensure that this election requirement applies to all administrative review procedures offered by the Agency. The proposed rule omits the statement in § 251.85(b) that an appellant who has forfeited the right to appeal under part 217 may still intervene pursuant to that part. This statement was eliminated because 36 CFR part 217 is no longer in the CFR. The proposed rule also makes conforming changes to the election of appeals provision in the administrative appeal regulations at 36 CFR part 215.

Section 214.7 Notice of an appealable decision. This section replaces § 251.84 and describes the mechanism by which the Responsible Official notifies a holder, operator, or solicited applicant that an appealable decision has been issued concerning either a written authorization possessed by a holder or operator or a written authorization for which a competitive application has been submitted by a solicited applicant.

Section 214.7(a) generally corresponds with § 251.84(a) and requires the Responsible Official to include language in a written decision which informs the affected holder, operator, or solicited applicants whether an opportunity to appeal exists. Unlike the 251 Appeal Rule, which contains a provision requiring the Responsible Official to notify ''holders of like instruments'' of the decision if these holders had previously made a written request for that information, the proposed rule limits the Responsible Official's notice obligation to the party or parties directly affected by the decision. As a result, under § 214.11, it is the responsibility of individuals or entities who are not directly affected by the appealable decision to obtain a copy of the decision and to evaluate whether to request participation as an intervenor.

Section 214.7(b) generally corresponds with § 251.84(a) and (b) and specifies what items must be addressed in the notice. For example, the proposed rule requires the notice to the affected holder, operator, or solicited applicant to include:

- The rule or rules under which an appeal may be filed;
- The contents of an appeal;
- The name and mailing address of the Appeal Deciding Officer;
- The filing deadline;
- An expression of the Responsible Official's willingness to meet to discuss the decision; and
- Where applicable, the opportunity to request mediation of certain term grazing permit disputes.

The first two bulleted items above are new and provide the affected holder, operator, or solicited applicant with a better understanding of appeal options and what must be included in an appeal for further review by the Appeal Deciding Officer. The inclusion of this information in the notice of an appealable decision will expedite the appeal process and may reduce the number of appeals that are dismissed based on the filing of an inadequate appeal.

Section 214.7(c) does not have a counterpart in the 251 Appeal Rule and simply requires the Responsible Official to notify the affected holder, operator, or solicited applicant if the decision is not appealable. As the proposed rule provides for notice of appealable decisions, the Forest Service considers it appropriate to inform affected holders, operators, and solicited applicants of decisions that are not appealable. This approach should lead to greater understanding of the administrative review process and reduce the number of appeals that will be dismissed because the decisions are not appealable.

Section 214.8 Levels of review. This section replaces § 251.87 and describes the administrative review procedures applicable to appealable decisions. Unlike the 251 Appeal Rule, which establishes different review procedures depending on whether the appealable decision is made by a District Ranger, Forest or Grassland Supervisor, or Regional Forester, § 214.8 establishes the same review procedures regardless of the position of the Responsible Official who issued the appealable decision.

Specifically, § 251.87(b) and (c) provides for two levels of appeal for appealable decisions made by District Rangers, but only one level of appeal and discretionary review for appealable decisions made by Forest Supervisors and Regional Foresters. Proposed § 214.8(a)(1) would provide for one level of appeal and discretionary review for appealable decisions made by District Rangers, Forest or Grassland Supervisors, and Regional Foresters. Substituting discretionary review for the second level of appeal for appealable decisions made by District Rangers simplifies and expedites the appeals process for the Agency and the public.

Similar to § 251.87(a) of the 251 Appeal Rule, proposed § 214.8(a)(2) and (b)(2) states that decisions made by the Chief are not appealable, but are eligible for discretionary review by the Under Secretary for Natural Resources and Environment if they fall into one of the categories of decisions listed in § 214.4.

There is no counterpart in the proposed rule to § 251.87(d), which provides for discretionary review of certain dismissal decisions because the Agency does not believe that further administrative review of dismissal decisions, which are based primarily on procedural grounds, is an efficient use of limited agency resources.

Section 214.9 Appeal content. This section replaces § 251.90 and enumerates general and specific requirements that must be contained in an appeal, as well as the timeframes for filing an appeal.

While many of the general requirements in § 214.9(a) are identical to the items that must be included in a notice of appeal under § 251.90(b), this section additionally requires an appellant to include an e-mail address, if any; any documents and other information upon which the appeal relies; and a signature and date. This section also requires submission of a copy of the decision being appealed, rather than a ''brief description'' and date of the decision as in the 251 Appeal Rule. Further, like the 251 Appeal Rule, the proposed rule requires an appeal to include a reference to the title or type of written authorization that is the subject of the appealable decision and the date of application for or issuance of the authorization. However, unlike the 251 Appeal Rule, the proposed rule does not require an appeal to include the name of the ''responsible Forest Service officer.''

Section 214.9(b) generally corresponds with § 251.90(c) and identifies additional items that may be included in an appeal depending on the nature of the dispute and the relief being sought by the appellant. In contrast to § 251.90(c), this section requires appellants to include in an appeal a request for an oral presentation, a request for a stay, and, where applicable, a request for

mediation of term grazing permit disputes. Except for grazing mediation, these requests may be made at any time under the 251 Appeal Rule prior to the closing of the appeal record. This proposed change shortens the appeal timeline.

Section 214.9(c) replaces § 251.88(a) and establishes the time frame for filing an appeal. Unlike the 251 Appeal Rule, which establishes 45 days from the date of the notice of the appealable decision as the time within which an appeal must be filed, the proposed rule shortens the timeframe to 30 days with one exception. The exception is the National Forest Roads and Trails Act of 1964, 16 U.S.C. 532 *et seq.,* which states that appeals of decisions to revoke an easement based on abandonment must be filed within 60 days of the revocation decision. The Agency has otherwise shortened the timeframe to file an appeal in recognition of improvements in information and communications technology that have taken place over the last 20 years, which allow for a more expeditious handling of appeals.

Section 214.10 Dismissal of an appeal. This section replaces § 251.92 and enumerates the same eight grounds for dismissal of an appeal as currently identified in the 251 Appeal Rule.

Section 214.10(b) corresponds with § 251.92(b) and requires the Appeal Deciding Officer to give written notice of and explain a decision to dismiss an appeal.

Unlike § 251.92(c), which allows for discretionary review of certain dismissal decisions, the proposed rule does not allow discretionary review of any dismissal decisions because discretionary review of these decisions presents an unnecessary administrative burden.

Section 214.11 Intervention. This section replaces § 251.96 and sets forth the procedures for participation in an appeal by those whose interests may be affected by the appeal but who do not have standing to appeal. Section 214.11(a)(1) generally corresponds with § 251.96(b) and describes the criteria under which an individual is eligible to intervene in an appeal. Unlike the 251 Appeal Rule, which describes an intervenor as ''an applicant for or a holder of a written instrument issued by the Forest Service that is the subject of or affected by the appeal,'' the proposed rule describes an intervenor more simply as a holder, operator, or solicited applicant who claims an interest relating to the subject matter of the decision being appealed and is situated so that disposition of the appeal may impair that interest. For example, the holder of a written authorization that was issued through a competitive process would be eligible to intervene in an appeal filed by an unsuccessful solicited applicant for the authorization.

Section 214.11(a)(2) generally corresponds with § 251.96(a) and requires those wishing to intervene to file a written request with the Appeal Deciding Officer. However, unlike the 251 Appeal Rule, which allows intervention requests to be filed at any time before the appeal record is closed, the proposed rule requires the intervention request to be filed within 15 days of the filing of an appeal. Setting a deadline early in the appeal process for filing intervention requests facilitates the orderly and expeditious handling of appeals.

Section 214.11(b) generally corresponds with § 251.96(b)(1) and (b)(3) and describes the process for requesting intervention in an appeal. In contrast to § 251.96(b)(3), which merely requires the requesting party to show how the decision being appealed would directly affect that party's interests, § 214.11(b) requires the party requesting intervention to include, at a minimum, a description of the requester's interest in the appeal; how disposition of the appeal may impair that interest; the factual and legal allegations in the appeal with which the requester agrees or disagrees; additional facts and issues that are not raised in the appeal that the requester believes are relevant and should be considered; the relief sought by the requester, particularly as it differs from the relief sought by the appellant; a response, where applicable, to the appellant's request for a stay, an oral presentation, or mediation of a term grazing permit dispute; and the requester's signature and date.

Section 214.11(c) is new and allows the appellant and the Responsible Official to submit a written response within 5 days of the filing of the intervention request. Section 214.11(d) generally corresponds with § 251.96(c) with respect to issuance of a decision on an intervention request. Unlike the 251 Appeal Rule, which does not include a timeframe for issuing a decision, the proposed rule requires the Appeal Deciding Officer to decide whether to grant an intervention request within 5 days after a response is due.

Section 214.11 does not include language similar to § 251.96(d), which states that intervention decisions are not appealable, because this statement is unnecessary and duplicative given that the complete list of appealable decisions is specified in § 214.4. Section 214.11 also does not include language similar to § 251.96(e), which requires service of intervention documents on all parties to the appeal, because § 214.15(h) of the proposed rule establishes broad service requirements for all documents filed in an appeal, including those related to a proposed intervention.

Section 214.12 Responsive statement and reply. This section replaces § 251.94. Section 214.12(a) generally corresponds with § 251.94(a) and (b). In contrast to § 251.94(b), which provides for a responsive statement to be filed within 30 days of receipt of the appeal or conclusion of mediation of a term grazing permit dispute, § 214.12(a) provides for a responsive statement to be filed within 20 days of receipt of the appeal or the unsuccessful conclusion of mediation, whichever is later.

Section 214.12(b) generally corresponds with § 251.94(c) with respect to filing a reply to a responsive statement, but gives an appellant (and intervenors where appropriate) 10 days instead of 20 days to file a reply. This approach will provide the appellant (and intervenors) with an opportunity to address contentions in the responsive statement, not to restate the entire appeal (or intervention). This change will shorten the appeal process, yet still provide the appellant (and intervenors) with sufficient time to file a meaningful reply.

Section 214.13 Stays. This section replaces § 251.91 and addresses postponement of implementation of an appealable decision until the appeal has concluded. Unlike the 251 Appeal Rule, the proposed rule establishes two categories of stays, authorized and automatic, establishes the procedures for obtaining an authorized stay, and enumerates the types of decisions that are subject to an automatic stay.

Section 214.13(a) generally corresponds with § 251.91(a) and provides that decisions under appeal shall be implemented during the administrative review process unless a stay has been granted or an automatic stay has gone into effect.

Section 214.13(b) generally corresponds with § 251.91(b) through (g) and addresses authorized stays, which are granted at the discretion of the Appeal Deciding Officer. Unlike § 251.91(b), which allows for a stay request to be filed at any time during the appeal period, § 214.13(b)(1) requires an appellant to include a request for stay in the appeal. In contrast to § 251.91(d), which allows a response to a stay request to be filed by the Deciding Officer and other parties but does not specify when or how the response must be filed, § 214.13(b)(2) provides for the Responsible Official to include a response to a stay request in the responsive statement and for a

prospective intervenor to include a response to a stay request in the intervention request. This approach simplifies and enhances the efficiency of the appeal process. Section 214.13(b)(3) requires the Appeal Deciding Officer to issue a decision on the stay request within 10 days after a responsive statement or an intervention request is filed, whichever is later. The Appeal Deciding Officer is also required to provide a brief explanation of the basis for the decision to grant or deny the stay request.

Section 214.13(c) is new and enumerates three types of decisions that are automatically stayed. The first category includes decisions to issue a written authorization pursuant to a prospectus. In this circumstance, a concession permit is being issued through a competitive process. Issuance of the permit needs to be stayed pending appeal, so as to avoid revocation of the permit if the Appeal Deciding Officer determines that the selection decision is improper. The second category includes decisions to recalculate revenue-based land use fees for a special use authorization pursuant to an audit. In this circumstance, delaying implementation of the revised fee would obviate the need to make a refund if the fee calculation is erroneous. The third category includes decisions to cancel or suspend a term grazing permit for which mediation is available and has been requested.

Section 214.13(d) specifies that authorized and automatic stays remain in effect until a final administrative decision is issued in the appeal, unless they have been modified or lifted pursuant to § 214.13(e), or in the case of mediation, for the duration of that process. This provision simplifies and clarifies the current regulation governing duration of stays at § 251.91(h), which provides that stays remain in effect ''for the 15-day period for determining discretionary review,'' but fails to address the status of the stay beyond that time.

Section 214.13(e) generally corresponds with § 251.91(j). In contrast to § 251.91(j), which allows an Appeal Deciding Officer to change a stay in accordance with its terms or changed circumstances, this section authorizes an Appeal Deciding Officer or Discretionary Reviewing Officer to modify or lift an authorized stay based upon a written request by a party (parties other than the appellant may seek to modify a stay) who demonstrates that the circumstances have changed since the stay was granted and that it is unduly burdensome or unfair to maintain the stay. Section 214.13(e) obviates the need for a separate section similar to § 251.100(e), which allows for a stay to be extended by a reviewing officer during discretionary review. This provision is unnecessary under the proposed rule because stays will remain in effect, unless modified or lifted, until the final administrative decision is made, including issuance of a discretionary review decision.

Section 214.13 does not include language similar to § 251.91(k), which provides that most decisions to grant, deny, lift, or modify a stay are not subject to appeal or discretionary review. This provision is unnecessary given the omission of this type of decision from the list of appealable decisions proposed in § 214.4. As a result, decisions on stay requests are not appealable under § 214.5.

Section 214.14 Conduct of an appeal. This section replaces §§ 251.88(b), 251.88(c), and 251.95. This section consolidates general procedures for the conduct of an appeal currently found at §§ 251.91, 251.94(b) and (c), 251.96(e), 251.99(e), and 251.100(g).

Section 214.14(a), which is new, provides that appeals may be filed in person or by courier, by mail or private delivery service, by facsimile, or by electronic mail.

Section 214.14(b) corresponds generally with § 251.88(b) and states that it is the appellant's responsibility to file an appeal within the relevant time period and that questions regarding timeliness will be determined by the Appeal Deciding Officer based on specific criteria that vary depending on the filing method used. For example, for appeal documents sent via the U.S. Postal Service (USPS), timeliness will be determined by the postmark. Timeliness determinations for appeal documents sent via a private carrier like Federal Express or the United Parcel Service will be determined by the date of receipt by the private carrier. This section clarifies that timeliness determinations will be based on the date when a document is received for shipment regardless of whether the carrier is public, *i.e.,* USPS, or private. The 5 business day delay is to allow sufficient time for any appeal filed through the U.S. Postal Service or private carrier (*i.e.,* postmarked or date of receipt before the end of the appeal filing period) to be received by the reviewing officer. The proposed rule amends similar sections regarding timeliness determinations in 36 CFR parts 215 and 218 to conform with § 214.14(b).

As in § 251.88(c)(2), § 214.14(c) provides that time periods begin on the day after the event or action triggering the time period and that all time periods are computed using calendar days (including Saturdays, Sundays, and Federal holidays). However, if a time period expires on a Saturday, Sunday, or Federal holiday, the expiration date is extended to the end of the next Federal business day.

Section 214.14(d) replaces § 251.89 and specifies which time periods in the proposed rule may be extended by the Appeal Deciding Officer. Section 214.14(d)(1) corresponds to § 251.89(b) and states that the parties to an appeal are responsible for meeting the time periods specified, unless an extension of time has been granted by the Appeal Deciding Officer. Contrary to the 251 Appeal Rule, which is silent on this matter, § 214.14(d)(1) also specifies that extension requests by an appellant, intervenor, or Responsible Official must be in writing and must explain the rationale for the request. These requirements improve accountability and prevent unreasonable and unexplained delays in the processing of appeal decisions.

Section 214.14(d)(2) corresponds with § 251.89(a) and enumerates the filing deadlines that may not be extended. Unlike the 251 Appeal Rule, which prohibits extending only the time period for filing an appeal, the proposed rule also would prohibit extending the time period for deciding whether to conduct discretionary review and for issuing a discretionary review decision.

Section 214.14(d)(3) corresponds with § 251.89(b) and provides that all other time periods may be extended upon a finding of good cause for the extension by the Appeal Deciding Officer. An example of good cause might include the occurrence of severe and unanticipated natural events or other extenuating circumstances that make compliance with the filing deadline extremely burdensome. This section also states that extensions will automatically be granted if the parties jointly represent that they are working together in good faith to resolve the dispute and need additional time to reach a mutually agreeable resolution.

Section 214.14(d)(4) corresponds with § 251.89(b) and requires the Appeal Deciding Officer to issue a decision granting or denying the extension within 10 days after a request has been filed.

Section 214.14(d)(5) is new and states that the Appeal Deciding Officer should avoid granting extensions which add more than 60 days to the appeal process.

Taken as a whole, § 214.14(d) reflects the Agency's understanding that some extensions of filing deadlines may be necessary and perhaps even

unavoidable and provides guidance to the Appeal Deciding Officer on when and for how long to grant extensions.

Section 214.14(e) corresponds with § 251.95(a) and authorizes the Appeal Deciding Officer to issue procedural orders governing the appeal process.

Section 214.14(f) corresponds with § 251.95(b) and authorizes the Appeal Deciding Officer to consolidate appeals of the same or similar decisions involving common issues of fact and law. This section of the proposed rule also authorizes the Appeal Deciding Officer to issue one decision for multiple appeals that involve common issues of fact and law. There is no counterpart in the proposed rule to § 251.95(a)(3) and § 251.95(b)(1), which state, respectively, that decisions involving procedural orders or consolidation decisions are not subject to appeal and further review. These provisions are unnecessary in light of § 214.4, which does not include these decisions in the list of appealable decisions. Consequently, decisions involving procedural orders and consolidation decisions are not appealable under the proposed rule.

Section 214.14(g) corresponds with § 251.95(c) and authorizes the Appeal Deciding Officer to request additional information from the parties to clarify appeal issues and to extend appeal time periods as necessary to allow for submission of the requested information and to give the other parties an opportunity to review and comment on these submissions.

Section 214.14(h) requires all parties to send each other copies of all appeal documents when they are filed with the Appeal Deciding Officer. This section consolidates several sections of the 251 Appeal Rule that use slightly different terminology but essentially require one party to serve documents related to an appeal on all other parties involved in the appeal. Relocating and consolidating these sections into a single provision simplifies procedures, minimizes the potential for confusion, and enhances consistency of administration. This section also makes each party responsible for identifying other parties to the appeal and allows each party to contact the Appeal Deciding Officer for other parties' names and addresses.

Section 214.14(i) is new and requires the Forest Service to post electronic versions of all appeal decisions and discretionary review decisions on the Web site of the national forest or national grassland or region that issued the appealable decision or on the Web site of the Washington Office for Chief's decisions. These postings are required under the Electronic Freedom of Information Act of 1996 and a 1999 settlement agreement in *Wyoming Outdoor Council* v. *United States Department of the Interior,* No. 98–220 (D. Wyo.), in which the Forest Service was a party.

Section 214.14(j) is new and promulgates the Agency's current practice to require each party to bear its own expenses in an appeal, including costs associated with preparing the appeal, participating in and obtaining a transcript of the oral presentation, obtaining information regarding the appeal, and retaining professional consultants or counsel.

Section 214.15 Resolution of issues prior to an appeal decision. This section replaces § 251.93. Section 214.15(a) corresponds with § 251.93(b) and allows the Responsible Official to discuss an appeal with the appellant or other parties to narrow issues, agree on facts, and determine whether one or more of the issues (or perhaps the entire appeal) could be resolved without the expenditure of time and money required to complete the administrative review process.

Section 214.15(b) corresponds to § 251.93(c) and allows the Responsible Official to withdraw an appealable decision, in whole or in part, during an appeal to facilitate informal resolution of a dispute. The Responsible Official is required to notify the Appeal Deciding Officer and the other parties of the withdrawal. The Appeal Deciding Officer will dismiss the appeal under § 214.10 if withdrawal of the decision eliminates all the issues in dispute in the appeal. The proposed rule does not adopt the provision in § 251.93(a), which provides for consultation with holders of written instruments prior to issuing a written decision. This activity takes place prior to initiation of an appeal and is therefore beyond the scope of the proposed rule.

Section 214.16 Oral presentation. This section replaces § 251.97. Section 214.16(a) states that the purpose of an oral presentation is to provide the parties to an appeal with an opportunity to present arguments in support of their position to the Appeal Deciding Officer. The language in § 251.97(a) regarding the informal nature of oral presentations is not included as it does not pertain to the purpose of the oral presentation.

Section 214.16(b) describes the scope of information and argument that may be raised in an oral presentation, which generally reflects the purpose statement of § 251.97(a). Section 214.16(b) also includes a statement allowing new information to be presented in an oral presentation only in those cases where it could not have been raised earlier in the appeal and where it would be unfair and prejudicial to exclude it.

Contrary to § 251.97(b), which allows an appellant to make a request for an oral presentation at any time prior to the closing of the appeal record, § 214.9(b)(1) requires appellants to request an oral presentation in the appeal. If an appellant requests an oral presentation in the appeal, § 214.16(c) requires the Appeal Deciding Officer to grant the request, unless the appeal has been dismissed under § 214.10. Requiring appellants to request an oral presentation in the appeal will facilitate orderly conduct of appeals, including scheduling of the oral presentation.

Section 214.16(d) corresponds with § 251.97(d), which authorizes oral presentations only during appeal of a decision, not during discretionary review. Section 214.16(e) is new and requires the Appeal Deciding Officer to schedule an oral presentation within 10 days of the filing of the reply to the responsive statement. This provision is intended to promote a more thoughtful discussion of the appeal issues in the oral presentation since it will be held shortly after the filing of the appeal, responsive statement, and reply. In addition, this section expedites the appeal process by eliminating the potential for a lengthy delay between the filing of the reply and the oral presentation. The second sentence of § 214.16(e) corresponds to § 251.97(c) and requires the Appeal Deciding Officer to notify the parties of the date, time, and location of and procedures for the oral presentation.

Section 214.16(f) corresponds to the first sentence of § 251.97(c) and provides that only parties to the appeal may participate in the oral presentation and that the oral presentation will be open to the public at the discretion of the Appeal Deciding Officer.

Section 214.16(g) is new and allows for a summary or transcript of an oral presentation to be included in the appeal record if it is submitted to the Appeal Deciding Officer by a party at the end of the oral presentation. A transcript prepared by a certified court reporter may be included in the appeal record if it is filed with the Appeal Deciding Officer within 10 days after the oral presentation and is paid for by those who requested it.

Section 214.17 Appeal record. This section replaces § 251.98. Section 214.17(a) corresponds with § 251.98(a) and requires the Appeal Deciding Officer to maintain the appeal record in one location. Section 214.17(b) corresponds with § 251.98(b) and provides a non-exhaustive list of

documents that should be included in the appeal record.

Section 214.17(c) addresses closure of the appeal record and generally corresponds with § 251.98(d), but takes into account that a transcript of an oral presentation may be submitted 10 days after the oral presentation and still be included as part of the appeal record under § 214.16(g). Therefore, § 214.17(c) states that the appeal record closes the day after a reply is due if no oral presentation is held; the day after an oral presentation is held if no transcript is being prepared; or the day after a transcript of the oral presentation is due if one is being prepared.

In contrast to § 251.98(e), § 214.17(d) clarifies that the appeal record is open for public inspection only to the extent authorized by the Freedom of Information Act, the Privacy Act, and associated regulations at 7 CFR part 1. The inclusion of the qualifying language clarifies that the appeal record may be made available to the public for inspection and disclosure only to the extent allowed by law.

Section 214.18 Appeal decision. This section replaces § 251.99. Section 214.18(a) corresponds with § 251.99(c) and requires the Appeal Deciding Officer to issue the appeal decision within 30 days of the closing of the appeal record.

Section 214.18(b) corresponds with § 251.99(a) and states that the appeal decision must be based solely on the appeal record and the oral presentation, if one is conducted.

Section 214.18(c) corresponds to § 251.99(a) and states that the appeal decision must conform to applicable laws, regulations, policies, and procedures.

Section 214.18(d) corresponds with § 251.99(b) and states that appeal decisions may affirm or reverse, in whole or in part, the appealable decision under review; must specify the basis for affirmation or reversal; and may also include instructions for further action by the Responsible Official.

Section 214.18(e) corresponds with § 251.99(f) and states that except where a decision to conduct discretionary review has been made and a discretionary review decision is pending or has been issued, the appeal decision is USDA's final administrative decision on the matter, and that no further administrative review will take place. If a decision to conduct discretionary review has been made but a discretionary review decision is not issued by the Discretionary Reviewing Officer within 30 days, the appeal decision is the final administrative decision. The Agency is not adopting the provision in § 251.99(d) regarding issuance of a second-level appeal decision within 30 days of receipt of the appeal record from the first level reviewing officer, since the proposed rule does not provide for two levels of appeal.

Section 214.19 Procedures for discretionary review. This section replaces § 251.100 and establishes the procedures for discretionary review of appeal decisions by the line officer one level above the Appeal Deciding Officer and of Chief's decisions by the Under Secretary for Natural Resources and Environment. In contrast to § 251.100, this section does not provide for discretionary review of certain dismissal or stay decisions because the Agency believes it is not appropriate to provide for discretionary review of purely procedural decisions.

Section 214.19 differs from § 251.100 in several ways. First, § 214.19(a)(1) requires the Appeal Deciding Officer to transmit the appeal decision, appeal, and appealable decision to the Discretionary Reviewing Officer one day after the issuance of the appeal decision, while § 251.100(b) requires transmission of only the appeal decision and appealable decision. By including a copy of the appeal in the transmitted documents, it will be easier for the Discretionary Reviewing Officer to identify the issues in dispute and determine whether discretionary review is warranted. This approach will simplify, expedite, and reduce the expense of the appeal process. Under § 214.19(a)(2), one day after a Chief's decision that is eligible for discretionary review under § 214.8(b)(2), the Chief will have to submit the decision to the Discretionary Reviewing Officer. Since Chief's decisions are not appealable, there will not be an appeal decision or appeal of a Chief's decision to transmit to the Discretionary Reviewing Officer.

Like § 251.100(a), § 214.19(b) requires the Discretionary Reviewing Officer to decide whether to conduct discretionary review based, at a minimum, on the degree of controversy surrounding the decision, the potential for litigation, and the extent to which the decision establishes precedent or new policy. However, unlike § 251.100(a), which acknowledges the potential that petitions or requests for discretionary review may be submitted by an appellant or intervenor, the proposed rule is silent on this issue. A petition or request is not necessary to trigger discretionary review. The decision as to whether to conduct discretionary review is entirely within the purview of the Discretionary Reviewing Officer, based on evaluation of specific criteria.

Section 214.19(c) states that the time frame for determining whether to exercise discretionary review starts to run upon the Discretionary Reviewing Officer's receipt of the appeal decision, appeal, and appealable decision or Chief's decision. Section 214.19(c) also simplifies and in some cases shortens the time periods in § 251.100(c). Section 251.100(c) gives the Discretionary Reviewing Officer 15 days from receipt of the appeal decision and the appealable decision to decide whether to conduct discretionary review. However, the 251 Appeal Rule provides that the Discretionary Reviewing Officer may request the appeal record within that 15-day period to assist in deciding whether to conduct discretionary review. Once that request is made, the Appeal Deciding Officer has 5 days to transmit the appeal record to the Discretionary Reviewing Officer, who then has 15 days from receipt of the appeal record to decide whether to conduct discretionary review.

In contrast, § 214.19(c) gives the Discretionary Reviewing Officer 30 days from receipt of an appeal decision, appeal, and appealable decision or Chief's decision to decide whether to conduct discretionary review. The Discretionary Reviewing Officer may request the appeal record at any time during this 30-day period to assist in deciding whether to conduct discretionary review. If that request is made, the appeal record must be transmitted to the Discretionary Reviewing Officer within 5 days. However, no additional time is added to the 30-day period if a request for the appeal record is made. Consequently, the proposed rule encourages a Discretionary Reviewing Officer to request the appeal record promptly if there is any uncertainty as to whether discretionary review may be warranted based upon evaluation of the appeal decision, appeal, and appealable decision or Chief's decision. Prompt requests for the appeal record will expedite the process of determining whether to conduct discretionary review.

Section 214.19(d) requires the Discretionary Reviewing Officer to notify the parties in writing of a decision to conduct discretionary review and gives the Discretionary Reviewing Officer the option to notify the parties of a decision not to conduct discretionary review prior to the end of the 30-day period. This approach makes it clear when the administrative review process has concluded for exhaustion purposes.

In addition, § 214.19(d) replaces the provisions in § 251.100(c) regarding the

consequences of taking no action during the discretionary review period. In contrast to § 251.100(c), which provides that if no action is taken during that period, the parties will be notified that the appeal decision stands as USDA's final administrative decision, this section does not require the Discretionary Reviewing Officer to notify the parties that no action has been taken during the 30-day review period. If no action is taken during the discretionary review period, the appeal decision or Chief's decision will constitute USDA's final administrative decision without notification to the parties. This approach eliminates the ambiguity that exists under the 251 Appeal Rule when the 30-day period for issuing a discretionary review decision has expired, but the parties have not yet been notified of the Discretionary Reviewing Officer's decision.

Section 214.19(e) consolidates provisions from § 251.100(c), (d), (f), and (g) regarding issuance of discretionary review decisions. Specifically, like § 251.100(f), § 214.19(e) requires the Discretionary Reviewing Officer to issue a discretionary review decision within 30 days after deciding to conduct discretionary review; like § 251.100(d), § 214.19(e) requires discretionary review to be conducted exclusively on the appeal record; and like § 251.100(c) and (g), § 214.19(e) provides that if the Discretionary Reviewing Officer fails to issue a discretionary review decision within 30 days after notification of the decision to conduct discretionary review, the appeal decision or Chief's decision will constitute USDA's final administrative decision. Section 214.19(e) also provides that the Discretionary Reviewing Officer's decision will constitute USDA's final administrative decision.

There is no counterpart in this section of the proposed rule to § 251.100(e), which allows for extension of stays during the discretionary review process. As discussed earlier, these extensions are unnecessary under the proposed rule, because stays will remain in effect under § 214.13(d) until a final administrative decision is made.

Section 214.20 Exhaustion of administrative remedies. This section replaces § 251.101 and states that judicial review of an appealable decision is premature until the plaintiff has exhausted administrative remedies in part 214. However, this section omits the statement in § 251.101 regarding waiver of the exhaustion requirement by the Chief. Since section 212(e) of the Federal Crop Insurance and Department of Agriculture Reorganization Act (7 U.S.C. § 6912(e)) requires exhaustion of the Department's administrative remedies, the Chief lacks the discretion to waive this requirement.

Section 214.21—Information collection requirements. The Agency has added this section because information that has to be included in an appeal under proposed § 214.9 is subject to the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR part 1320. Public comment is being sought on this information collection requirement, as discussed in the Regulatory Certifications section. See the Addresses section for instructions on how to submit comments on the information collection requirement. The OMB control number for this information collection requirement will be included in the final rule.

Section 214.22 Applicability and effective date. This section replaces § 251.102 and states that the proposed rule will apply only prospectively, *i.e.,* decisions will be subject to its provisions only on or after the effective date of the final rule. Decisions issued prior to the effective date of the final rule will continue to be governed by the provisions of the 251 Appeal Rule.

3. Conforming Substantive Changes to Other Parts of Title 36 of the CFR

Part 222, Subpart D—Mediation of term grazing disputes. This proposed rule establishes a new Subpart D to the Forest Service's range management regulations that will contain substantially all of § 251.103 of the 251 Appeal Rule. This provision was added to the 251 Appeal Rule in 1999 following enactment of the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994, which added grazing disputes on NFS lands to the list of issues eligible for mediation under USDA-certified State mediation programs. The Agency is proposing to relocate this section for two reasons. First, mediation of term grazing permit disputes is separate from the administrative appeal process and is conducted by a mediator affiliated with a State mediation program certified by USDA. If requested and submitted concurrently with an appeal, mediation sets aside the administrative appeal and may render completion of the administrative appeal process unnecessary. Second, mediation of term grazing permit disputes is unique to the range management program and does not apply to decisions involving any other types of written authorizations issued by the Forest Service. Appropriate cross-references will be included in 36 CFR part 214 and 36 CFR part 222, subpart D, to ensure that the Agency and the public understand the linkage between the grazing mediation and administrative appeal procedures.

4. Conforming Technical Changes to Other Parts of Title 36 of the CFR

The following nonsubstantive, technical changes will be made to other parts of Title 36 of the CFR for consistency with the proposed rule:

1. Part 251, subpart C, will be removed in its entirety and will be reserved for additional special uses regulations.

2. Any references in other parts of Title 36 to 36 CFR part 251, subpart C, will be changed to 36 CFR part 214. These references appear at 36 CFR §§ 212.8(d)(5)(iii), 215.11(d), 215.14(b)(5), 228.14, 228.107(c), 241.22(f), 251.60(a)(2)(ii) and (h)(2), 251.126, 254.4(g), 254.13(b), 254.14(b)(6), and 292.15(l).

3. Section 212.8(d)(5) will be reorganized and reworded slightly to match the corresponding provision at § 251.60(h)(1) governing revocation of easements granted under the act of October 13, 1964 (16 U.S.C. § 534).

4. The last two sentences of § 215.1(b) will be removed. Section 215.1 governs the purpose and scope of part 215. The last two sentences of § 215.1(b) duplicate what is contained in § 215.11(d) regarding election of an appeal process.

5. The definitions of ''appeal,'' ''appeal deciding officer,'' ''appeal record,'' ''appellant,'' and ''responsible official'' in § 215.2 will be revised to conform, to the extent possible, with the definitions of those terms in § 214.2.

6. Section 215.11(d), governing election of an appeal process under part 215, will be revised to match § 214.6, the provision governing election of an appeal process under part 214.

7. Section 215.14(b)(5), governing contents of an appeal under part 215, will be revised to match § 214.9(a)(3), governing contents of an appeal under part 214.

8. Section 215.15(c), governing timeliness determinations of appeal documents under part 215, will be revised to match § 214.14(b), governing timeliness determinations for appeal documents under part 214.

9. The definitions of ''objection,'' ''objector,'' ''responsible official,'' and ''reviewing officer'' in § 218.2 will be revised slightly to conform, to the extent possible, with the definitions of the same or analogous terms in § 214.2. For example, the term ''objection'' in § 218.2 is analogous to the term ''appeal'' in § 214.2, and the term ''objector'' in

§ 218.2 is analogous to the term ''appellant'' in § 214.2.

10. Section 218.10(c), governing timeliness determinations of objection documents under part 218, will be revised to match § 214.14(b), governing timeliness determinations for appeal documents under part 214.

11. Under part 214, revocation and cancellation, where the Responsible Official takes action to end a written authorization, are appealable, but termination, where a written authorization ends by operation of law or in accordance with its terms, is not appealable. In several parts of Title 36 that authorize decisions that will be appealable under part 214, ''terminate'' or ''termination'' is used in the context that ''revoke'' or ''cancel'' or ''revocation'' or ''cancellation'' are used in part 214. Changes in terminology will be made in these other parts for consistency with part 214.

Specifically, in § 212.8(d)(5), governing revocation of easements granted under the act of October 13, 1964 (16 U.S.C. 534), ''terminate'' will be changed to ''revoke,'' and ''terminated'' will be changed to ''revoked.''

With regard to contracts for mineral materials, in § 228.65(b)(4), ''terminate'' will be changed to ''cancel.'' In the heading and text of § 228.66(c), ''termination'' will be changed to ''cancellation,'' and ''terminated'' will be changed to ''cancelled.'' ''Cancellation'' and ''cancel,'' rather than ''revocation'' and ''revoke,'' will be used in these provisions because they involve contracts, and the former terms are more appropriate in that context. In addition, ''cancellation'' and ''cancel'' are used in corresponding § 228.55.

In § 241.22(e), which governs determinations that proposed activities are consistent with the conservation of fish, wildlife, and their habitat in the Chugach National Forest, ''terminate'' will be changed to ''revoke.''

In § 251.15(a)(2)(iv) and (a)(3), which govern exercise of mineral rights reserved in conveyances to the United States, ''termination'' will be changed to ''revocation,'' and minor, nonsubstantive revisions for clarity will be made. When permits governing the exercise of reserved mineral rights are issued, a copy of the regulations at 36 CFR part 251, subpart A, is attached to the permit. For any of these permits issued before the effective date of the final rule, the Agency will interpret ''termination'' in the regulations attached to the permit to mean ''revocation'' under 36 CFR part 214, which will be appealable under that part.

In § 254.15(c)(2), which governs land exchanges, ''terminating'' will be changed to ''revoking,'' and minor changes will be made for consistency with the corresponding revocation authority in § 251.60(a)(2)(i)(D).

In § 292.18(f), which governs operating plans for mineral activities on Federal lands in the Sawtooth National Recreation Area, ''terminate'' will be changed to ''revoke,'' and minor, nonsubstantive revisions will be made.

5. Regulatory Certifications

Regulatory Impact

This proposed rule has been reviewed under USDA procedures and Executive Order 12866, Regulatory Planning and Review. It has been determined that this is not a significant rule. This proposed rule will not have an annual effect of $100 million or more on the economy, nor will the proposed rule adversely affect productivity, competition, jobs, the environment, public health or safety, or State and local governments. This proposed rule will not interfere with any action taken or planned by another agency or raise new legal or policy issues. Finally, this proposed rule will not alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of beneficiaries of those programs.

Moreover, this proposed rule has been considered in light of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The Agency has determined that the proposed rule will not have a significant economic impact on a substantial number of small entities as defined by that Act. Therefore, a regulatory flexibility analysis is not required for this proposed rule.

Environmental Impact

This proposed rule will revise the procedures and requirements for the administrative appeal of certain decisions related to written authorizations for the occupancy or use of NFS lands and resources. Forest Service regulations at 36 CFR 220.6(d)(2) exclude from documentation in an environmental assessment or environmental impact statement ''rules, regulations, or policies to establish servicewide administrative procedures, program processes, or instruction.'' The Agency's preliminary determination is that this proposed rule falls within this category of actions and that no extraordinary circumstances exist which would require preparation of an environmental assessment or environmental impact statement.

Energy Effects

This proposed rule has been reviewed under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. The Agency has determined that this proposed rule will not constitute a significant energy action as defined in the Executive Order.

Controlling Paperwork Burdens on the Public

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), the Forest Service is requesting approval of the new information collection requirement associated with this proposed rule.

Title: Appeal of Decisions Relating to Occupancy or Use of National Forest System Lands and Resources.

OMB Number: 0596—New.

Expiration Date of Approval: 3 years from approval date.

Type of Request: New information collection.

Abstract: This appeal process modifies, renames, and relocates to a new part in the CFR the appeal process for decisions related to occupancy or use of NFS lands and resources. This updated regulation will simplify the appeal process, shorten the appeal period, and reduce the cost of appeal for certain types of Forest Service decisions affecting occupancy or use of NFS lands and resources. The information collected will be used by the Forest Service to determine if the decision that was appealed should be affirmed or reversed in whole or in part.

These appeal procedures are limited to holders, operators, and solicited applicants as defined in the proposed rule, who therefore are the only individuals or entities subject to the information collection requirement.

The information collection required for the administrative appeal process in 36 CFR part 214 is approved and assigned OMB Control No. 0596–New.

Estimated Number of Respondents: 160.

Estimated Number of Responses per Respondent: 1.

Estimated Number of Total Annual Responses: 160.

Estimated Total Annual Burden on Respondents: 1,280 hours.

Comments: Comments are invited on (1) Whether the proposed information collection requirement is necessary for proper performance of the functions of the Agency, including whether the information will have practical utility; (2) the accuracy of the Agency's estimate of the burden of the proposed information collection requirement,

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 information collection requirement on those who will respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Federalism

The Agency has considered this proposed rule under Executive Order 13132 on federalism. The Agency has determined that the proposed rule conforms with the federalism principles set out in this executive order; will not impose any compliance costs on the States; and will not have substantial direct effects on the States, on the relationship between the Federal government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, the Agency has concluded that this proposed rule does not have federalism implications.

Consultation and Coordination With Indian Tribal Governments

Pursuant to Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, the Forest Service is committed to government-to-government consultation on Agency policy that could have an impact on tribes. In that spirit, information about the proposed rule was sent to the Regional Offices, with guidance to distribute the information to tribes in their region and to follow up with visits to tribes if requests for consultation were received. A total of 120 days was provided for this process.

No requests for government-to-government consultation were made, and a small number of comments was received. A few respondents asked for early notification and consultation on actions affecting tribal treaty or other legal rights. No changes were made to the proposed rule as a result of the comments received.

This proposed rule does not have substantial direct or unique effects on Indian tribes. This proposed rule is revising administrative appeal regulations for decisions relating to occupancy or use of NFS lands and resources. Tribal governments may participate in the administrative appeal process by requesting to intervene in an appeal of a decision that may adversely affect tribal rights.

No Takings Implications

The Agency has analyzed this proposed rule in accordance with the principles and criteria contained in Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights. The Agency has determined that this proposed rule will not pose the risk of a taking of private property.

Civil Justice Reform

This proposed rule has been reviewed under Executive Order 12988 on civil justice reform. Upon adoption of this proposed rule, (1) All State and local laws and regulations that conflict with this rule or that impede full implementation of the rule will be preempted; (2) no retroactive effect will be given to this proposed rule; and (3) this proposed rule will not require the use of administrative proceedings before parties could file suit in court challenging its provisions.

Unfunded Mandates

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), the Agency has assessed the effects of this proposed rule on State, local, and tribal governments and the private sector. This proposed rule will not compel the expenditure of $100 million or more by any State, local, or tribal government or anyone in the private sector. Therefore, a statement under section 202 of the act is not required.

List of Subjects

36 CFR Part 212

Highways and roads, National forests, Public lands—rights-of-way, and Transportation.

36 CFR Part 214

Administrative practice and procedure, National forests.

36 CFR Part 215

Administrative practice and procedure, National forests.

36 CFR Part 218

Administrative practice and procedure, National forests.

36 CFR Part 222

Range management, National forests, National grassland.

36 CFR Part 228

Environmental protection, Mines, National forests, Oil and gas exploration, Public lands—mineral resources, Public lands—rights-of-way, Reporting and recordkeeping requirements, Surety bonds, Wilderness areas.

36 CFR Part 241

Fish, Intergovernmental relations, National forests, Wildlife, Wildlife refuges.

36 CFR Part 251

Administrative practice and procedure, Electric power, National forests, Public lands—rights-of-way, Reporting and recordkeeping requirements, Water resources.

36 CFR Part 254

Community facilities, National forests.

36 CFR Part 292

Mineral resources, Recreation and recreation areas.

Therefore, for the reasons set forth in the preamble, the Forest Service proposes to amend Title 36 Chapter II of the CFR to read as follows:

PART 212—ADMINISTRATION OF THE FOREST TRANSPORTATION SYSTEM

1. The authority citation for Part 212 continues to read as follows:

Authority: 16 U.S.C. 551, 23 U.S.C. 205.

2. In § 212.8, revise paragraph (d)(5) to read as follows:

§ 212.8 Permission to cross lands and easements owned by the United States and administered by the Forest Service.

* * * * *

(d) * * *

(5)(i) The Chief may revoke any easement granted under the provisions of the Act of October 13, 1964 (78 Stat. 1089, 16 U.S.C. 534):

(A) By consent of the owner of the easement;

(B) By condemnation; or

(C) Upon abandonment after a 5-year period of nonuse by the owner of the easement.

(ii) Before any easement is revoked upon abandonment, the owner of the easement shall be given notice and, upon the owner's request made within 60 days after receipt of the notice, shall be given an appeal in accordance with the provisions of 36 CFR part 214.

3. Add a new part 214 to read as follows:

PART 214—APPEAL OF DECISIONS RELATING TO OCCUPANCY OR USE OF NATIONAL FOREST SYSTEM LANDS AND RESOURCES

Sec.

214.1 Purpose and scope.
214.2 Definitions.
214.3 Parties to an appeal.

214.4 Decisions that are appealable.
214.5 Decisions that are not appealable.
214.6 Election of appeal process.
214.7 Notice of an appealable decision.
214.8 Levels of review.
214.9 Appeal content.
214.10 Dismissal of an appeal.
214.11 Intervention.
214.12 Responsive statement and reply.
214.13 Stays.
214.14 Conduct of an appeal.
214.15 Resolution of issues prior to an appeal decision.
214.16 Oral presentation.
214.17 Appeal record.
214.18 Appeal decision.
214.19 Procedures for discretionary review.
214.20 Exhaustion of administrative remedies.
214.21 Information collection requirements.
214.22 Applicability and effective date.

Authority: 7 U.S.C. 1011(f); 16 U.S.C. 472, 551.

§ 214.1 Purpose and scope.

(a) *Purpose.* This part provides a fair and deliberate process by which holders, operators, and solicited applicants may appeal certain written decisions issued by Responsible Officials involving written instruments authorizing the occupancy or use of National Forest System lands and resources.

(b) *Scope.* This part specifies who may appeal, decisions that are appealable and not appealable, the responsibilities of parties to an appeal, and the time periods and procedures that govern the conduct of appeals under this part.

§ 214.2 Definitions.

Appeal. A document filed with an Appeal Deciding Officer in which an individual or entity seeks review of a Forest Service decision under this part.

Appeal Deciding Officer. The Forest Service employee who is one organizational level above the Responsible Official and who is authorized to issue an appeal decision under this part.

Appeal decision. The final written decision issued by an Appeal Deciding Officer on an appeal filed under this part which affirms or reverses a Responsible Official's appealable decision in whole or in part, explains the basis for the decision, and provides additional instructions to the parties as necessary.

Appeal record. Documentation and other information filed with the Appeal Deciding Officer within the relevant time period by parties to the appeal and upon which review of an appeal is conducted.

Appellant. An individual or entity that has filed an appeal under this part.

Cancellation. The invalidation, in whole or in part, of a term grazing permit or an instrument for the disposal of mineral materials.

Discretionary Reviewing Officer. The U.S. Department of Agriculture (USDA) or Forest Service employee authorized to review an appeal decision by an Appeal Deciding Officer or a decision by the Chief under this part.

Holder. An individual or entity that holds a valid written authorization.

Intervenor. An individual or entity whose request to intervene has been granted by the Appeal Deciding Officer.

Modification. A Responsible Official's written revision of the terms and conditions of a written authorization.

Operator. An individual or entity conducting or proposing to conduct mineral operations.

Oral presentation. An informal meeting conducted by the Appeal Deciding Officer during which parties to an appeal may present information in support of their position.

Prospectus. An announcement published by the Forest Service soliciting competitive applications for a written authorization.

Responsible Official. The Forest Service employee who issued a decision that may be appealed under this part.

Responsive statement. The document filed by the Responsible Official with the Appeal Deciding Officer that addresses the issues raised and relief requested in an appeal.

Revocation. The cessation, in whole or in part, of a written authorization, other than a grazing permit or an instrument for the disposal of mineral materials, by a Responsible Official before the end of the specified period of occupancy or use.

Solicited applicant. An individual or entity that has submitted a competitive application in response to a prospectus.

Suspension. A temporary revocation or cancellation of a written authorization.

Termination. The cessation of a written authorization by operation of law or by operation of a fixed or agreed-upon condition, event, or time as specified in the authorization, which does not require a decision by a Responsible Official to take effect.

Written authorization. A term grazing permit, plan of operations, special use authorization, mineral material contract or permit, or other type of written instrument issued by the Forest Service or a lease or permit for leasable minerals issued by the U.S. Department of the Interior that authorizes the occupancy or use of National Forest System lands or resources and specifies the terms and conditions under which the occupancy or use may occur.

§ 214.3 Parties to an appeal.

Parties to an appeal under this part are limited to holders, operators, solicited applicants, intervenors, and the Responsible Official.

§ 214.4 Decisions that are appealable.

To be appealable under this part, a decision must be issued by a Responsible Official in writing and must fall into one of the following categories:

(a) *Livestock grazing.*

(1) Modification of a term grazing permit issued under 36 CFR part 222, subpart A. Issuance of annual operating instructions does not constitute a permit modification and is not an appealable decision;

(2) Suspension or cancellation, other than cancellation resulting from the permittee's waiver to the United States, of a term grazing permit issued under 36 CFR part 222, subpart A;

(3) Denial of reauthorization of livestock grazing under a term grazing permit if the holder files an application for a new permit before the existing permit expires; or

(4) Denial of a term grazing permit to a solicited applicant under 36 CFR part 222, subpart C.

(b) *Minerals.* (1) Approval or denial of an initial, modified, or supplemental plan of operations or operating plan; requirement of an increase in bond coverage; requirement of measures to avoid irreparable injury, loss, or damage to surface resources pending modification of a plan of operations or operating plan; or issuance of a notice of noncompliance pursuant to 36 CFR part 228, subpart A or D, or part 292, subpart D, F, or G;

(2) Approval or denial of an operating plan, issuance of a notice of noncompliance, extension, suspension, or cancellation, other than cancellation by mutual agreement, for contracts, permits, or prospecting permits for mineral materials issued under 36 CFR part 228, subpart C;

(3) Approval or denial of a surface use plan of operations, request to supplement a surface use plan of operations, suspension of oil and gas operations, or issuance of a notice of noncompliance pursuant to 36 CFR part 228, subpart E;

(4) Consent or denial of consent to the U.S. Department of the Interior's administration of previously issued leases or permits for leasable minerals other than oil and gas resources;

(5) Suspension or revocation of an operating plan for Federal lands within the Sawtooth National Recreation Area pursuant to 36 CFR part 292, subpart D;

(6) Suspension of locatable mineral operations on National Forest System lands within the Hells Canyon National Recreation Area pursuant to 36 CFR part 292, subpart F;

(7) Suspension of locatable mineral operations on National Forest System lands within the Smith River National Recreation Area or approval of an initial or amended operating plan for exercise of outstanding mineral rights on National Forest System lands within the Smith River National Recreation Area pursuant to 36 CFR part 292, subpart G;

(8) Except as provided in paragraph (7), determinations of the acceptability of an initial or amended operating plan for exercise of outstanding mineral rights on National Forest System lands; or

(9) Determinations of the acceptability of an initial or amended operating plan for exercise of reserved mineral rights located on National Forest System lands.

(c) *Special uses.* (1) Modification, suspension, or revocation of a special use authorization, other than acceptance of an operating plan, including:

(i) A special use authorization issued under 36 CFR part 251, subpart B or D, other than modification, suspension, or revocation of a noncommercial group use permit, suspension or revocation of an easement issued pursuant to 36 CFR 251.53(e) or 251.53(l), or revocation with the consent of the holder;

(ii) A special use authorization for ingress and egress to intermingled and adjacent private lands across National Forest System lands issued under 36 CFR part 212, subpart A;

(iii) A special use authorization issued under 36 CFR part 251, subpart A, that authorizes the exercise of rights reserved in conveyances to the United States;

(iv) A permit and occupancy agreement issued under 36 CFR 213.3 for national grasslands and other lands administered under Title III of the Bankhead-Jones Farm Tenant Act;

(v) A permit issued under 36 CFR 293.13 for access to valid occupancies entirely within a wilderness in the National Forest System.

(vi) A permit issued under the Archaeological Resources Protection Act of 1979 and 36 CFR part 296 for excavation or removal of archaeological resources; and

(vii) A special use authorization governing surface use associated with the exercise of outstanding mineral rights;

(2) Denial of a special use authorization to a solicited applicant based on the process used to select a successful applicant;

(3) Implementation of new land use fees for a special use authorization, other than:

(i) Revision or replacement of a land use fee system or schedule that is implemented through public notice and comment; and

(ii) Annual land use fee adjustments based on an inflation factor that are calculated under an established fee system or schedule in accordance with the terms and conditions of a written authorization;

(4) Assignment of a performance rating that affects reissuance or extension of a special use authorization; or

(5) Denial of renewal of a special use authorization if it specifically provides for renewal and if the holder requests renewal of the authorization before it expires.

(d) *Other land uses.* Denial or revocation of a certification of compliance issued under 36 CFR part 292, subpart C, related to the use, subdivision, and development of privately owned property within the boundaries of the Sawtooth National Recreation Area.

§ 214.5 Decisions that are not appealable.

Holders, operators, and solicited applicants may not appeal any decisions issued by a Responsible Official that are not expressly set forth in § 214.4.

§ 214.6 Election of appeal process.

Decisions may not be appealed by an appellant under more than one part of this chapter. Parties eligible to appeal a decision under more than one part in this chapter must elect the part under which they will pursue their appeal. Once an election is made, parties may not appeal the decision under the parts they did not elect.

§ 214.7 Notice of an appealable decision.

(a) The Responsible Official shall include language in each written decision which notifies the affected holder, operator, or solicited applicant whether an opportunity to appeal the decision exists.

(b) If the decision is appealable, the notice must specify the regulations under which an appeal may be filed, the contents of an appeal, the name and mailing address of the Appeal Deciding Officer, and the filing deadline. The notice shall also include a statement indicating the Responsible Official's willingness to meet with the affected holder, operator, or solicited applicant to discuss the decision and, where applicable, informing term grazing permit holders of the opportunity to request mediation in accordance with 36 CFR 222.60–222.66.

(c) If the decision is not appealable, the Responsible Official must include a statement in the written decision informing the affected holder, operator, or solicited applicant that further administrative review of the decision is not available.

§ 214.8 Levels of review.

(a) *Appeal.* (1) One level of appeal is available for appealable decisions made by District Rangers, Forest or Grassland Supervisors, and Regional Foresters. If a District Ranger is the Responsible Official, the appeal is filed with the Forest or Grassland Supervisor. If a Forest or Grassland Supervisor is the Responsible Official, the appeal is filed with the Regional Forester. If a Regional Forester is the Responsible Official, the appeal is filed with the Chief of the Forest Service.

(2) No appeal is available for decisions made by the Chief.

(b) *Discretionary review.* (1) Appeal decisions issued by Forest or Grassland Supervisors, Regional Foresters, or the Chief are eligible for discretionary review. If a Forest or Grassland Supervisor is the Appeal Deciding Officer, discretionary review is conducted by the Regional Forester. If a Regional Forester is the Appeal Deciding Officer, discretionary review is conducted by the Chief. If the Chief is the Appeal Deciding Officer, discretionary review is conducted by the Under Secretary for Natural Resources and Environment.

(2) Decisions made by the Chief that fall into one of the categories enumerated in 36 CFR 214.4 are eligible for discretionary review by the Under Secretary for Natural Resources and Environment.

§ 214.9 Appeal content.

(a) *General requirements for the contents of an appeal.* All appeals must include:

(1) The appellant's name, mailing address, daytime telephone number, and e-mail address, if any;

(2) A copy of the decision being appealed;

(3) The title or type of written authorization and the date of application for or issuance of the written authorization, if applicable;

(4) A statement of how the appellant is adversely affected by the decision being appealed;

(5) A statement of the relevant facts underlying the decision being appealed;

(6) A discussion of issues raised by the decision being appealed, including identification of any laws, regulations, or policies that were allegedly violated in reaching the decision being appealed;

(7) A statement as to whether and how the appellant has attempted to resolve the issues under appeal with the Responsible Official and the date and outcome of those efforts;

(8) A statement of the relief sought;

(9) Any documents and other information upon which the appellant relies; and

(10) The signature of the appellant and the date.

(b) *Specific requirements for the contents of an appeal.* In addition to the general requirements in § 214.9(a), the following specific requirements must be included in an appeal, where applicable:

(1) A request for an oral presentation under § 214.16;

(2) A request for a stay under § 214.13;

(3) A request to participate in a state mediation program regarding certain term grazing permit disputes under 36 CFR part 222, subpart D; and

(4) The regulation under which the appeal is being filed if there is an option to file under more than one.

(c) *Time frame for filing an appeal.* An appeal must be filed with the Appeal Deciding Officer within 30 days of the date of the decision, except that an appeal of a decision revoking an easement for abandonment pursuant to the Act of October 13, 1964, 16 U.S.C. 534, must be filed within 60 days of the date of the decision.

§ 214.10 Dismissal of an appeal.

(a) The Appeal Deciding Officer shall dismiss an appeal without review when one or more of the following applies:

(1) The appeal is not filed within the required time period.

(2) The person or entity that filed the appeal is not a holder, an operator, or a solicited applicant of a written authorization that is the subject of the appealable decision.

(3) The decision is not appealable under this part.

(4) The appeal does not meet the content requirements specified in § 214.9(a), provided that an appeal may not be dismissed for failure to include an appraisal report which has not been completed by the filing deadline.

(5) The appellant withdraws the appeal.

(6) The Responsible Official withdraws the written decision that was appealed.

(7) An informal resolution of the dispute is reached pursuant to § 214.15 or a mediated agreement of a term grazing dispute is achieved pursuant to 36 CFR part 222, subpart D.

(8) The requested relief cannot be granted under applicable facts, laws, regulations, or policies.

(b) The Appeal Deciding Officer shall give written notice of the dismissal of an appeal and shall set forth the reasons for dismissal.

§ 214.11 Intervention.

(a) *Eligibility to intervene.* To participate as an intervenor in appeals under this part, a party must:

(1) Be a holder, a solicited applicant, or an operator who claims an interest relating to the subject matter of the decision being appealed and is so situated that disposition of the appeal may impair that interest; and

(2) File a written request to intervene with the Appeal Deciding Officer within 15 days after an appeal has been filed.

(b) *Request to intervene.* A request to intervene must include:

(1) A description of the requester's interest in the appeal and how disposition of the appeal may impair that interest;

(2) A discussion of the factual and legal allegations in the appeal with which the requester agrees or disagrees;

(3) A description of additional facts and issues that are not raised in the appeal that the requester believes are relevant and should be considered;

(4) A description of the relief sought, particularly as it differs from the relief sought by the appellant;

(5) Where applicable, a response to the appellant's request for a stay of the decision being appealed;

(6) Where applicable, a response to the appellant's request for an oral presentation;

(7) Where applicable, a response to the appellant's request for mediation of a term grazing permit dispute under 36 CFR part 222, subpart D; and

(8) The requester's signature and the date.

(c) *Response to a request to intervene.* The appellant and Responsible Official shall have 5 days from receipt of a request to intervene to file a written response with the Appeal Deciding Officer.

(d) *Intervention decision.* The Appeal Deciding Officer shall have 5 days after the date a response to a request to intervene is due to issue a decision granting or denying the request. The Appeal Deciding Officer's decision shall be in writing and shall briefly explain the basis for granting or denying the request. The Appeal Deciding Officer shall deny a request to intervene or shall withdraw a decision granting intervenor status as moot if the corresponding appeal is dismissed under § 214.10.

§ 214.12 Responsive statement and reply.

(a) *Responsive statement.* The Responsible Official shall prepare a responsive statement addressing the factual and legal allegations in the appeal. The responsive statement and any supporting documentation shall be filed with the Appeal Deciding Officer within 20 days of receipt of the appeal or the unsuccessful conclusion of mediation conducted pursuant to 36 part 222, subpart D, whichever is later.

(b) *Reply.* Within 10 days of receipt of the responsive statement, the appellant and intervenors, if any, may file a reply with the Appeal Deciding Officer addressing the contentions in the responsive statement.

§ 214.13 Stays.

(a) An appealable decision shall be implemented unless an authorized stay is granted under § 214.13(b) or an automatic stay goes into effect under § 214.13(c).

(b) *Authorized stays.* Except where a stay automatically goes into effect under § 214.13(c), the Appeal Deciding Officer may grant a written request to stay the decision that is the subject of an appeal under this part.

(1) *Stay request.* To obtain a stay, an appellant must include a request for a stay in the appeal pursuant to § 214.9(b)(2) and a statement explaining the need for a stay. The statement must include, at a minimum:

(i) A description of the adverse impact to the appellant if a stay is not granted;

(ii) A description of the adverse impact to National Forest System lands and resources if a stay is not granted; or

(iii) An explanation as to how a meaningful decision on the merits of the appeal could not be achieved if a stay is not granted.

(2) *Stay response.* The Responsible Official may support, oppose, or take no position in the responsive statement regarding the appellant's stay request. Intervenors may support, oppose, or take no position in the intervention request regarding the appellant's stay request.

(3) *Stay decision.* The Appeal Deciding Officer shall issue a decision granting or denying the stay request within 10 days after a responsive statement or an intervention request is filed, whichever is later. The stay decision shall be in writing and shall briefly explain the basis for granting or denying the stay request.

(c) *Automatic stays.* The following decisions are automatically stayed once an appeal is filed by a holder, operator, or solicited applicant:

(1) Decisions to issue a written authorization pursuant to a prospectus;

(2) Decisions to recalculate revenue-based land use fees for a special use

authorization pursuant to an audit issued after November 10, 2011; and

(3) Decisions to cancel or suspend a term grazing permit subject to mediation under 36 CFR 222.60 and for which mediation is requested in accordance with that provision.

(d) *Stay duration.* Authorized stays and automatic stays under § 214.13(c)(1) and (c)(2) shall remain in effect until a final administrative decision is issued in the appeal, unless they are modified or lifted in accordance with § 214.13(e). Automatic stays under § 214.13(c)(3) shall remain in effect for the duration of the mediation period as provided in 36 CFR 222.62.

(e) *Modification or lifting of a stay.* The Appeal Deciding Officer or a Discretionary Reviewing Officer may modify or lift an authorized stay based upon a written request by a party who demonstrates that the circumstances have changed since the stay was granted and that it is unduly burdensome or unfair to maintain the stay.

§ 214.14 Conduct of an appeal.

(a) *Method of filing.* Appeal documents may be filed in person or by courier, by mail or private delivery service, by facsimile, or by electronic mail.

(b) *Evidence of timely filing.* Parties to an appeal are responsible for ensuring timely filing of appeal documents. Questions regarding whether an appeal document has been timely filed shall be resolved by the Appeal Deciding Officer based on the following indicators:

(1) The date of the U.S. Postal Service postmark for an appeal received before the close of the fifth business day after the appeal filing date;

(2) The electronically generated posted date and time for e-mail and facsimiles;

(3) The shipping date for delivery by private carrier for an appeal received before the close of the fifth business day after the appeal filing date; or

(4) The official agency date stamp showing receipt of hand delivery.

(c) *Computation of time.* (1) A time period in this part begins on the first day following the event or action triggering the time period.

(2) All time periods shall be computed using calendar days, including Saturdays, Sundays, and Federal holidays. However, if a time period ends on a Saturday, Sunday, or Federal holiday, the time period is extended to the end of the next Federal business day.

(d) *Extensions of time.* (1) *In general.* Parties, Appeal Deciding Officers, and Discretionary Reviewing Officers shall meet the time periods specified in this part, unless an extension of time has been granted under this section. Extension requests from parties shall be made in writing, shall explain the need for the extension, and shall be transmitted to the Appeal Deciding Officer.

(2) *Time periods that may not be extended.* The following time periods may not be extended:

(i) The time period for filing an appeal;

(ii) The time period to decide whether to conduct discretionary review of an appeal decision or a Chief's decision; and

(iii) The time period to issue a discretionary review decision.

(3) *Time periods that may be extended.* Except as provided in § 214.14(d)(2), all time periods in this part may be extended upon written request by a party and a finding of good cause for the extension by the Appeal Deciding Officer. Written requests for extensions of time will be automatically granted by the Appeal Deciding Officer where the parties represent that they are working in good faith to resolve the dispute and that additional time would facilitate negotiation of a mutually agreeable resolution.

(4) *Decision.* The Appeal Deciding Officer shall have 10 days to issue a decision granting or denying the extension request. The decision shall be in writing and shall briefly explain the basis for granting or denying the request.

(5) *Duration.* Ordinarily extensions that add more than 60 days to the appeal period should not be granted.

(e) *Procedural orders.* The Appeal Deciding Officer may issue procedural orders as necessary for the orderly, expeditious, and fair conduct of an appeal under this part.

(f) *Consolidation of appeals.* (1) The Appeal Deciding Officer may issue an order consolidating multiple appeals of the same decision or of similar decisions involving common issues of fact and law and issue one appeal decision.

(2) The Appeal Deciding Officer may issue one decision for appeals filed under this part and other parts of this chapter that involve common issues of fact and law.

(3) The Responsible Official may prepare one responsive statement for consolidated appeals.

(g) *Requests for additional information.* The Appeal Deciding Officer may ask a party for additional information to clarify appeal issues. If necessary, the Appeal Deciding Officer may extend appeal time periods to allow for submission of the additional information and to give the other parties an opportunity to review and comment on it.

(h) *Service of documents.* (1) Parties shall send copies of all documents filed in an appeal to all other parties to the appeal at the same time the original is filed with the Appeal Deciding Officer, including the appellant's sending a copy of the appeal to the Responsible Official. Each party is responsible for identifying other parties to the appeal and may contact the Appeal Deciding Officer for assistance regarding their names and addresses. Documents shall not be considered by the Appeal Deciding Officer until they have been sent to all parties to the appeal.

(2) All decisions and orders issued by the Appeal Deciding Officer and the Discretionary Reviewing Officer related to the appeal shall be sent to all parties to the appeal.

(i) *Posting of Final Decisions.* Once a final appeal decision or discretionary review decision has been issued, it shall be posted on the Web site of the national forest or national grassland or region that issued the appealable decision or on the Web site of the Washington Office for Chief's decisions.

(j) *Expenses.* Each party to an appeal shall bear its own expenses, including costs associated with preparing the appeal, participating in an oral presentation, obtaining information regarding the appeal, and retaining professional consultants or counsel.

§ 214.15 Resolution of issues prior to an appeal decision.

(a) The Responsible Official may discuss an appeal with a party or parties to narrow issues, agree on facts, and explore opportunities to resolve one or more of the issues in dispute by means other than issuance of an appeal decision.

(b) The Responsible Official who issued a decision under appeal may withdraw the decision, in whole or in part, during an appeal to resolve one or more issues in dispute. The Responsible Official shall notify the parties to the appeal and the Appeal Deciding Officer of the withdrawal. If the withdrawal of the decision eliminates all the issues in dispute in the appeal, the Appeal Deciding Officer shall dismiss the appeal under § 214.10.

§ 214.16 Oral presentation.

(a) *Purpose.* The purpose of an oral presentation is to provide parties to an appeal with an opportunity to present their arguments regarding the appeal to the Appeal Deciding Officer.

(b) *Scope.* Oral presentations shall be limited to clarifying or elaborating upon

information that has already been filed with the Appeal Deciding Officer. New information may be presented only if it could not have been raised earlier in the appeal and if it would be unfair and prejudicial to exclude it.

(c) *Requests.* A request for an oral presentation included in an appeal shall be granted by the Appeal Deciding Officer unless the appeal has been dismissed under § 214.10.

(d) *Availability.* Oral presentations may be conducted during appeal of a decision, but not during discretionary review.

(e) *Scheduling and rules.* The Appeal Deciding Officer shall conduct the oral presentation within 10 days of the date a reply to the responsive statement is due. The Appeal Deciding Officer shall notify the parties of the date, time, and location of the oral presentation and the procedures to be followed.

(f) *Participation.* All parties to an appeal are eligible to participate in the oral presentation. At the discretion of the Appeal Deciding Officer, non-parties may observe the oral presentation, but are not eligible to participate.

(g) *Summaries and transcripts.* A summary of an oral presentation may be included in the appeal record only if it is submitted to the Appeal Deciding Officer by a party at the end of the oral presentation. A transcript of an oral presentation prepared by a certified court reporter may be included in the appeal record if the transcript is filed with the Appeal Deciding Officer within 10 days of the date of the oral presentation and if the transcript is paid for by those who requested it.

§ 214.17 Appeal record.

(a) *Location.* The Appeal Deciding Officer shall maintain the appeal record in one location.

(b) *Contents.* The appeal record shall consist of information filed with the Appeal Deciding Officer, including the appealable decision, appeal, intervention request, responsive statement, reply, oral presentation summary or transcript, procedural orders and other rulings, and any correspondence or other documentation related to the appeal as determined by the Appeal Deciding Officer.

(c) *Closing of the record.*

(1) The Appeal Deciding Officer shall close the appeal record on:

(i) The day after the date the reply to the responsive statement is due if no oral presentation is conducted;

(ii) The day after the oral presentation is conducted if no transcript of the oral presentation is being prepared; or

(iii) The day after a transcript of the oral presentation is due if one is being prepared.

(2) The Appeal Deciding Officer shall notify all parties to the appeal of closing of the record.

(d) *Inspection by the public.* The appeal record is open for public inspection in accordance with the Freedom of Information Act, the Privacy Act, and 7 CFR part 1.

§ 214.18 Appeal decision.

(a) Appeal decisions made by the Appeal Deciding Officer shall be issued within 30 days of the date the appeal record is closed.

(b) The appeal decision shall be based solely on the appeal record and oral presentation, if one is conducted.

(c) The appeal decision shall conform to all applicable laws, regulations, policies, and procedures.

(d) The appeal decision may affirm or reverse the appealable decision, in whole or in part. The appeal decision must specify the basis for affirmation or reversal and may include instructions for further action by the Responsible Official.

(e) Except where a decision to conduct discretionary review has been made and a discretionary review decision has been issued, the appeal decision shall constitute USDA's final administrative decision.

§ 214.19 Procedures for discretionary review.

(a) *Initiation.* (1) One day after issuance of an appeal decision, the Appeal Deciding Officer shall send a copy of the appeal decision, appeal, and appealable decision to the Discretionary Reviewing Officer to determine whether discretionary review of the appeal decision should be conducted.

(2) One day after issuance of a Chief's decision that is eligible for discretionary review under § 214.8(b)(2), the Chief shall send the decision to the Discretionary Reviewing Officer to determine whether discretionary review should be conducted.

(b) *Criteria for determining whether to conduct discretionary review.* In deciding whether to conduct discretionary review, the Discretionary Reviewing Officer should, at a minimum, consider the degree of controversy surrounding the decision, the potential for litigation, and the extent to which the decision establishes precedent or new policy.

(c) *Time period.* Upon receipt of the appeal decision, appeal, and appealable decision or Chief's decision, the Discretionary Reviewing Officer shall have 30 days to determine whether to conduct discretionary review and may request the appeal record or the record related to the Chief's decision during that time to assist in making that determination. If a request for the record is made, it must be transmitted to the Discretionary Reviewing Officer within 5 days.

(d) *Notification.* The Discretionary Reviewing Officer shall notify the parties and the Appeal Deciding Officer in writing of a decision to conduct discretionary review. The Discretionary Reviewing Officer may notify the parties and the Appeal Deciding Officer of a decision not to conduct discretionary review within 30 days. If the Discretionary Reviewing Officer takes no action within 30 days of receipt of the appeal decision, appeal, and appealable decision or Chief's decision, the appeal decision or Chief's decision shall constitute USDA's final administrative decision.

(e) *Issuance of a discretionary review decision.* The Discretionary Reviewing Officer shall have 30 days to issue a discretionary review decision after notification of the parties and Appeal Deciding Officer has occurred pursuant to § 214.19(d). Discretionary review shall be limited to the record. No additional information shall be considered by the Discretionary Reviewing Officer. The Discretionary Reviewing Officer's decision shall constitute USDA's final administrative decision. If a discretionary review decision is not issued within 30 days following the notification of the decision to conduct discretionary review, the appeal decision or Chief's decision shall constitute USDA's final administrative decision.

§ 214.20 Exhaustion of administrative remedies.

Judicial review of a decision that is appealable under this part is premature unless the plaintiff has exhausted the administrative remedies under this part.

§ 214.21 Information collection requirements.

The rules of this part governing appeal of decisions relating to occupancy or use of National Forest System lands and resources specify the information that an appellant must provide in an appeal. Therefore, these rules contain information collection requirements as defined in 5 CFR part 1320. These information collection requirements are assigned Office of Management and Budget Control Number 0596–New.

§ 214.22 Applicability and effective date.

This part prescribes the procedure for administrative review of appealable

decisions and Chief's decisions set forth in § 214.4 issued on or after **[Date 30 days from date of publication of the final rule in the FEDERAL REGISTER].**

PART 215—NOTICE, COMMENT, AND APPEAL PROCEDURES FOR NATIONAL FOREST SYSTEM PROJECTS AND ACTIVITIES

4. The authority citation for part 215 continues to read as follows:

Authority: 16 U.S.C. 472, 551; sec. 322, Pub. L. 102–381 (Appeals Reform Act), 106 Stat. 1419 (16 U.S.C. 1612 note).

5. In § 215.1, revise paragraph (b) to read as follows:

§ 215.1 Purpose and scope.

* * * * *

(b) *Scope.* Notice of proposed actions and opportunity to comment provide an opportunity for the public to provide meaningful input prior to the decision on projects and activities implementing land management plans. The rules of this part complement other opportunities to participate in the Forest Service's project and activity planning, such as those provided by the National Environmental Policy Act of 1969 (NEPA) and its implementing regulations at 40 CFR parts 1500–1508 and 36 CFR part 220; the National Forest Management Act (NFMA) and its implementing regulations at 36 CFR part 219; and the regulations at 36 CFR part 216 governing public notice and comment for certain Forest Service directives.

6. In § 215.2, revise the definitions for ''Appeal,'' *''Appeal Deciding Officer,'' ''Appeal Record,'' ''Appellant,'' and ''Responsible Official''* to read as follows:

§ 215.2 Definitions.

* * * * *

Appeal—A document filed with an Appeal Deciding Officer in which an individual or entity seeks review of a Forest Service decision under this part.

Appeal Deciding Officer—The U.S. Department of Agriculture (USDA) or Forest Service employee who is one organizational level above the Responsible Official and who is authorized to issue an appeal decision under this part.

* * * * *

Appeal Record—Documentation and other information filed with the Appeal Deciding Officer within the relevant time period by parties to an appeal and upon which review of an appeal is conducted.

* * * * *

Appellant—An individual or entity that has filed an appeal of a decision under this part.

* * * * *

Responsible Official—The Forest Service employee who issued a decision that may be appealed under this part.

7. In § 215.11, revise paragraph (d) to read as follows:

§ 215.11 Decisions subject to appeal.

* * * * *

(d) Decisions may not be appealed by an appellant under more than one part of this chapter. Parties eligible to appeal a decision under more than one part in this chapter must elect the part under which they will pursue their appeal. Once an election is made, parties may not appeal the decision under the parts they did not elect.

8. In § 215.14, revise paragraph (b)(5) to read as follows:

§ 215.14 Appeal content.

* * * * *

(b) * * *

(5) The regulation under which the appeal is being filed if there is an option to file under more than one;

* * * * *

9. In § 215.15, revise paragraph (c) to read as follows:

§ 215.15 Appeal time periods and process.

* * * * *

(c) *Evidence of timely filing.* Parties to an appeal are responsible for ensuring timely filing of appeal documents. Questions regarding whether an appeal document has been timely filed shall be resolved by the Appeal Deciding Officer based on the following indicators:

(1) The date of the U.S. Postal Service postmark for an appeal received before the close of the fifth business day after the appeal filing date;

(2) The electronically generated posted date and time for e-mail and facsimiles;

(3) The shipping date for delivery by private carrier for an appeal received before the close of the fifth business day after the appeal filing date; or

(4) The official agency date stamp showing receipt of hand delivery.

* * * * *

PART 218—PREDECISIONAL ADMINISTRATIVE REVIEW PROCESSES

10. The authority citation for part 218 continues to read as follows:

Authority: Pub. L. 108–148; 117 Stat. 1887 (Healthy Forests Restoration Act of 2003).

11. In § 218.2, revise the definitions for *''Objection,'' ''Objector,'' ''Responsible official,'' and ''Reviewing officer''* to read as follows:

§ 218.2 Definitions.

* * * * *

Objection: A document filed with a reviewing officer by an individual or entity seeking predecisional administrative review of a proposed authorized hazardous fuel reduction project as defined in the HFRA.

* * * * *

Objector: An individual or entity that has filed an objection to a proposed authorized hazardous fuel reduction project.

* * * * *

Responsible official: The Forest Service employee who may approve proposed authorized hazardous fuel reduction projects subject to objections under this part.

Reviewing officer: The U.S. Department of Agriculture (USDA) or Forest Service employee who is one organizational level above the responsible official and who is authorized to review objections filed under this part.

12. In § 218.10, revise paragraph (c) to read as follows:

§ 218.10 Objection time periods and process.

* * * * *

(c) *Evidence of timely filing.* Participants in the objection process are responsible for ensuring timely filing of objection documents. Questions regarding whether an objection document has been timely filed shall be resolved by the reviewing officer based on the following indicators:

(1) The date of the U.S. Postal Service postmark for an objection received before the close of the fifth business day after the objection filing date;

(2) The electronically generated posted date and time for e-mail and facsimiles;

(3) The shipping date for delivery by private carrier for an objection received before the close of the fifth business day after the objection filing date; or

(4) The official agency date stamp showing receipt of hand delivery.

PART 222—RANGE MANAGEMENT

13. The authority citation for part 222 is revised to read as follows:

Authority: 7 U.S.C. 1010–1012; 7 U.S.C. 5101–5106; 16 U.S.C. 551, 572, 580l; 31 U.S.C. 9701; 43 U.S.C. 1751, 1752, 1901; E.O. 12548 (51 FR 5985).

14. The authority citation for subpart C of part 222 is revised to read as follows:

Authority: 16 U.S.C. 551; 31 U.S.C. 9701; 43 U.S.C. 1751, 1752, 1901; E.O. 12548 (51 FR 5985).

15. Add a new subpart D to Part 222 to read as follows:

Subpart D—Mediation of Term Grazing Permit Disputes

Sec.
222.60 Decisions subject to mediation
222.61 Parties.
222.62 Stay of appeal.
222.63 Confidentiality.
222.64 Records.
222.65 Costs.
222.66 Ex parte communications.

Authority: 7 U.S.C. 5101–5106; 16 U.S.C. 472,551.

Subpart D—Mediation of Term Grazing Permit Disputes

§ 222.60 Decisions subject to mediation.

The holder of a term grazing permit issued in a State with a mediation program certified by the U.S. Department of Agriculture may request mediation of a dispute relating to a decision to suspend or cancel the permit as authorized by 36 CFR 222.4(a)(2)(i), (ii), (iv), and (v) and (a)(3) through (a)(6). Any request for mediation must be included in an appeal of the decision to suspend or cancel the permit filed in accordance with 36 CFR part 214.

§ 222.61 Parties.

Only the following may be parties to mediation of a term grazing permit dispute:

(a) A mediator authorized to mediate under a State mediation program certified by the U.S. Department of Agriculture;

(b) The Chief, Forest Service, or other Forest Service employee who made the decision being mediated or his or her designee;

(c) The holder whose term grazing permit is the subject of the decision and who has requested mediation in an appeal filed in accordance with the procedures at 36 CFR part 214;

(d) That holder's creditors, if applicable; and

(e) Legal counsel, if retained. The Forest Service will have legal representation in the mediation only if the holder has legal representation in the mediation.

§ 222.62 Stay of appeal.

If an appellant requests mediation of a decision subject to mediation under § 222.60 in an appeal filed under 36 CFR part 214, the Appeal Deciding Officer shall immediately notify all parties to the appeal that all appeal deadlines are automatically stayed for 45 days to allow for mediation. If a mediated agreement is not reached in 45 days, the Appeal Deciding Officer may extend the automatic stay for another 15 days if there is a reasonable possibility that a mediated agreement can be achieved within that timeframe. If an agreement is not achieved at the end of the 45- or 60-day mediation process, the Appeal Deciding Officer shall immediately notify all parties to the appeal that mediation was unsuccessful, that the stay has expired, and that the time periods and procedures applicable to an appeal under 36 CFR part 214 are reinstated.

§ 222.63 Confidentiality.

Mediation sessions and dispute resolution communications as defined in 5 U.S.C. 571(5) shall be confidential. Any mediation agreement signed by a Forest Service official and the holder of a term grazing permit is subject to public disclosure.

§ 222.64 Records.

Notes taken or factual material shared during mediation sessions shall not be included in the appeal record prepared in accordance with the procedures at 36 CFR part 214.

§ 222.65 Costs.

The Forest Service shall cover only those costs incurred by its own employees in mediation sessions.

§ 222.66 Ex parte communications.

The Chief, Forest Service, or other Forest Service employee who made the decision being mediated or his or her designee shall not discuss mediation with the Appeal Deciding Officer, except to request an extension of time or to communicate the results of mediation.

PART 228—MINERALS

16. The authority citation for part 228 is revised to read as follows:

Authority: 16 U.S.C. 478, 551; 30 U.S.C. 226, 352, 601, 611; 94 Stat. 2400.

Subpart A—Locatable Minerals

17. Revise § 228.14 to read as follows:

§ 228.14 Appeals.

Appeal of decisions of an authorized officer made pursuant to this subpart is governed by 36 CFR part 214 or 215.

Subpart C—Disposal of Mineral Materials

18. In § 228.65, revise paragraph (b)(4) to read as follows:

§ 228.65 Payment for sales.

* * * * *

(b) * * *

(4) If the purchaser fails to make payments when due, the contract will be considered breached, the authorized officer will cancel the contract, and all previous payments will be forfeited without prejudice to any other rights and remedies of the United States.

* * * * *

19. In § 228.66 revise paragraph (c) to read as follows:

§ 228.66 Refunds.

* * * * *

(c) *Cancellation.* (1) If the contract is cancelled by the authorized officer for reasons which are beyond the purchaser's control; or

(2) If the contract is cancelled by mutual agreement. This refund provision is not a warranty that a specific quantity of material exists in the sale area.

Subpart E—Oil and Gas Resources

20. In § 228.107, revise paragraph (c) to read as follows:

§ 228.107 Review of surface use plan of operations.

* * * * *

(c) *Notice of decision.* The authorized Forest officer shall give public notice of the decision on a surface use plan of operations and include in the notice that the decision is subject to appeal under 36 CFR part 214 or 215.

* * * * *

PART 241—FISH AND WILDLIFE

21. The authority citation for Part 241 continues to read as follows:

Authority: 16 U.S.C. 472, 539, 551, 683.

Subpart B—Conservation of Fish, Wildlife, and Their Habitat, Chugach National Forest, Alaska

22. In § 241.22, revise paragraphs (e) and (f) to read as follows:

§ 241.22 Consistency determinations.

* * * * *

(e) Subject to valid existing rights, the responsible Forest Officer may revoke, suspend, restrict, or require modification of any activity if it is determined that such measures are required to conserve wildlife, fish, or their habitat within areas of the Chugach National Forest subject to this subpart. Prior to taking action to revoke, suspend, restrict, or require modification of an activity under this section, the responsible Forest Officer shall give affected parties reasonable prior notice and an opportunity to comment, unless it is determined that

doing so would likely result in irreparable harm to conservation of fish, wildlife, and their habitat.

(f) Decisions made pursuant to this section are subject to appeal only as provided in 36 CFR part 214.

* * * * *

PART 251—LAND USES

23. The authority citation for part 251 continues to read as follows:

Authority: 16 U.S.C. 472, 479b, 551, 1134, 3210, 6201–13; 30 U.S.C. 1740, 1761–1771.

Subpart A—Miscellaneous Land Uses

24. The authority citation for part 251, subpart A, continues to read as follows:

Authority: 7 U.S.C. 1011; 16 U.S.C. 518, 551, 678a; Pub. L. 76–867, 54 Stat. 1197.

25. Amend § 251.15 to revise paragraphs (a)(2)(iv) and (a)(3) to read as follows:

§ 251.15 Conditions, rules, and regulations to govern exercise of mineral rights reserved in conveyances to the United States.

(a) * * *

(2) * * *

(iv) Failure to comply with the terms and conditions of the permit shall be cause for revocation of all rights to use, occupy, or disturb the surface of the lands covered by the permit, but in the event of revocation, a new permit shall be issued upon application when the causes for revocation of the preceding permit have been satisfactorily remedied and the United States has been reimbursed for any damages it has incurred from the noncompliance.

(3) All structures, other improvements, and materials shall be removed from the lands within one year after the date of revocation of the permit.

* * * * *

Subpart B—Special Uses

26. The authority citation for part 251, subpart B, continues to read as follows:

Authority: 16 U.S.C. 460l–6a, 460l–6d, 472, 497b, 497c, 551, 580d, 1134, 3210; 30 U.S.C. 185; 43 U.S.C. 1740, 1761–1771.

27. In § 251.51, revise the definitions for ''Holder,'' ''Revocation,'' *''Special use authorization,'' and ''Termination''* to read as follows:

§ 251.51 Definitions.

* * * * *

Holder—an individual or entity that holds a valid special use authorization.

* * * * *

Revocation—the cessation, in whole or in part, of a special use authorization by action of an authorized officer before the end of the specified period of use or occupancy for reasons set forth in § 251.60(a)(1)(i), (a)(2)(i), (g), and (h) of this subpart.

* * * * *

Special use authorization—a written permit, term permit, lease, or easement that authorizes use or occupancy of National Forest System lands and specifies the terms and conditions under which the use or occupancy may occur.

* * * * *

Termination—the cessation of a special use authorization by operation of law or by operation of a fixed or agreed-upon condition, event, or time as specified in the authorization, which does not require a decision by an authorized officer to take effect, such as expiration of the authorized term; change in ownership or control of the authorized improvements; or change in ownership or control of the holder of the authorization.

* * * * *

28. In § 251.54, revise the last sentence of paragraph (g)(3)(iii) to read as follows:

§ 251.54 Proposal and application requirements and procedures.

* * * * *

(g) * * *

(3) * * *

(iii) * * * A denial of an application in paragraphs (g)(3)(ii)(A) through (g)(3)(ii)(H) of this section constitutes final agency action, is not subject to administrative appeal, and is immediately subject to judicial review.

* * * * *

29. In § 251.60, revise paragraphs (a)(1)(ii), (a)(2)(ii), and (h)(2) to read as follows:

§ 251.60 Termination, revocation, and suspension.

(a) * * *

(1) * * *

(ii) *Judicial review.* Revocation or suspension of a special use authorization under this paragraph constitutes final agency action, is not subject to administrative appeal, and is immediately subject to judicial review.

* * * * *

(2) * * *

(ii) *Administrative review.* Except for revocation or suspension of an easement issued pursuant to § 251.53(e) or § 251.53(l) of this subpart, revocation or suspension of a special use authorization under this paragraph is subject to appeal pursuant to 36 CFR part 214.

* * * * *

(h) * * *

(2) Before any such easement is revoked upon abandonment, the owner of the easement shall be given notice and, upon the owner's request made within 60 days after receipt of the notice, shall be given an appeal in accordance with the provisions of 36 CFR part 214.

* * * * *

Subpart C—[Removed and Reserved]

30. Remove and reserve subpart C of part 251.

Subpart E—Revenue-Producing Visitor Services in Alaska

31. The authority citation for part 251, subpart E, continues to read as follows:

Authority: 16 U.S.C. 3197.

32. Revise § 251.126 to read as follows:

§ 251.126 Appeals.

Decisions related to the issuance of special use authorizations in response to written solicitations by the Forest Service under this subpart or related to the modification of special use authorizations to reflect historical use are subject to administrative appeal under 36 CFR part 214.

PART 254—LANDOWNERSHIP ADJUSTMENTS

Subpart A—Land Exchanges

33. The authority citation for part 254, subpart A, is revised to read as follows:

Authority: 7 U.S.C. 428a(a) and 1011; 16 U.S.C. 484a, 485, 486, 516, 551, 555a; 43 U.S.C. 1701, 1715, 1716, 1740.

34. In § 254.4, revise paragraph (g) to read as follows:

§ 254.4 Agreement to initiate an exchange.

* * * * *

(g) The withdrawal from an exchange proposal by the authorized officer at any time prior to the notice of decision pursuant to § 254.13 of this subpart is not appealable under 36 CFR part 214 or 215.

35. In § 254.13, revise paragraph (b) to read as follows:

§ 254.13 Approval of exchanges; notice of decision.

* * * * *

(b) The decision to approve or disapprove an exchange proposal shall be subject to appeal as provided under 36 CFR part 214 or 215 for 45 days after the date of publication of a notice of availability of the decision.

36. In § 254.14, revise paragraph (b)(6) to read as follows:

§ 254.14 Exchange agreement.

* * * * *

(b) * * *

(6) In the event of an appeal under 36 CFR part 214 or 215, a decision to approve an exchange proposal pursuant to § 254.13 of this subpart is upheld; and

* * * * *

37. In § 254.15, revise the last sentence of paragraph (c)(2) to read as follows:

§ 254.15 Title standards.

* * * * *

(c) * * *

(2) * * * If an agreement cannot be reached, the authorized officer shall consider other alternatives to accommodate the authorized use or shall determine whether there are specific and compelling reasons in the public interest for revoking the authorization for that use pursuant to 36 CFR 251.60.

PART 292—NATIONAL RECREATION AREAS

Subpart C—Sawtooth National Recreation Area—Private Lands

38. The authority citation for part 292, subpart C, continues to read as follows:

Authority: Sec. 4(a), Act of Aug. 22, 1972 (86 Stat. 613).

39. In § 292.15, revise paragraph (l) to read as follows:

§ 292.15 General provisions—procedures.

* * * * *

(l) Denial or revocation of a certification of compliance under this subpart is subject to appeal under 36 CFR part 214.

Subpart D—Sawtooth National Recreation Area—Federal Lands

40. The authority citation for part 292, subpart D, is revised to read as follows:

Authority: 16 U.S.C. 460aa–10, 478, 551.

41. In § 292.18, revise paragraph (f) to read as follows:

§ 292.18 Mineral resources.

* * * * *

(f) *Operating plans—suspension, revocation, or modification.* The authorized officer may suspend or revoke authorization to operate in whole or in part where such operations are causing substantial impairment which cannot be mitigated. At any time during operations under an approved operating plan, the operator may be required to modify the operating plan to minimize or avoid substantial impairment of the values of the SNRA.

* * * * *

Dated: September 16, 2011.

Thomas L. Tidwell,

Chief, Forest Service.

[FR Doc. 2011–24366 Filed 10–7–11; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Part 160

[USCG–2010–0048]

RIN 1625–AB46

Lifesaving Equipment: Production Testing and Harmonization With International Standards

AGENCY: Coast Guard, DHS.

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to amend the interim rule addressing lifesaving equipment published in this same issue of the **Federal Register** to harmonize Coast Guard regulations for inflatable liferafts and inflatable buoyant apparatuses with recently adopted international standards affecting capacity requirements for such lifesaving equipment. The Coast Guard seeks comments on this proposal.

DATES: Comments and related material must either be submitted to our online docket via *http://www.regulations.gov* on or before November 25, 2011 or reach the Docket Management Facility by that date.

ADDRESSES: You may submit comments identified by docket number USCG–2010–0048 using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* 202–493–2251.

(3) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

Viewing incorporation by reference material: You may inspect the material proposed for incorporation by reference at U.S. Coast Guard Headquarters, 2100 Second Street, SW., STOP 7126, Washington, DC 20593–7126 between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–372–1385. Copies of the material are available as indicated in the ''Incorporation by Reference'' section of this preamble.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call Mr. Kurt Heinz, Commercial Regulations and Standards Directorate, Office of Design and Engineering Standards, Lifesaving and Fire Safety Division (CG–5214), Coast Guard, telephone 202–372–1395, or e-mail *Kurt.J.Heinz@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Ms. Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

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I. Public Participation and Request for Comments

The Coast Guard encourages you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted, without change, to *http://www.regulations.gov* and will include any personal information you have provided.

A. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2010–0048), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online, or by fax, mail, or hand delivery, but please use only one of these means. The Coast Guard recommends that you include your name and a mailing address, an e-mail address, or a phone number in the body of your document so that the Coast Guard can contact you if the Coast Guard has questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov* and click on the ''submit a comment'' box, which will then become highlighted in blue. Insert ''USCG–2010–0048'' in the Keyword box, click ''Search'', and then click on the balloon shape in the Actions column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

The Coast Guard will consider all comments and material received during the comment period and may change this proposed rule in view of your comments.

B. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov* at any time, and click on the ''read comments'' box, which will then become highlighted in blue. Enter the docket number for this rulemaking (USCG–2010–0048) in the Keyword box, and click ''Search''. Click the ''Open Docket Folder'' in the ''Actions'' column. If you do not have access to the Internet, you may view the docket by visiting the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Coast Guard has an agreement with the Department of Transportation to use the Docket Management Facility.

C. Privacy Act

Anyone can 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 a Privacy Act notice regarding our public dockets in the January 17, 2008 issue of the **Federal Register** (73 FR 3316).

D. Public Meeting

The Coast Guard does not currently plan to hold a public meeting. But you may submit a request for one to the Docket Management Facility at the address under **ADDRESSES** explaining why one would be beneficial. If the Coast Guard determines that one would aid this rulemaking, the Coast Guard will hold one at a time and place announced by a later notice in the **Federal Register**.

II. Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
IMO International Maritime Organization
ISO International Organization for Standardization
LSA Life-saving Appliance
MSC Maritime Safety Committee of the International Maritime Organization
NEPA National Environmental Policy Act 1969 (42 U.S.C. 4321–4370f)
NPRM Notice of Proposed Rulemaking
NTTAA National Technology Transfer and Advancement Act (15 U.S.C. 272 note)
OIRA Office of Information and Regulatory Affairs
OMB Office of Management and Budget
SNPRM Supplemental Notice of Proposed Rulemaking
SOLAS International Convention for Safety of Life at Sea, 1974, as amended
§ Section symbol
USCG United States Coast Guard

III. Regulatory History

On August 31, 2010, the Coast Guard published a notice of proposed rulemaking (NPRM) titled ''Lifesaving Equipment: Production Testing and Harmonization With International Standards'' in the **Federal Register**. *See* 75 FR 53458. In this same issue of the **Federal Register,** the Coast Guard is publishing an interim rule titled ''Lifesaving Equipment: Production Testing and Harmonization with International Standards; Interim Rule'' (Interim Rule) making effective changes proposed in the NPRM.

The Coast Guard is issuing this supplemental notice of proposed rulemaking (SNPRM) to address amendments to international standards affecting capacity requirements for inflatable liferaft and inflatable buoyant apparatuses that were recently adopted by the International Maritime Organization (IMO) and will enter into force on January 1, 2012. The IMO amendments to the international standards affect the Interim Rule, published elsewhere in this issue of the **Federal Register**, regarding inflatable liferafts and inflatable buoyant apparatuses. The IMO amendments affect capacity requirements for such liferafts, and by extension buoyant apparatuses, but do not affect any other part of the Interim Rule.

IV. Background

As discussed in the ''Background'' section of the Interim Rule, the Coast Guard is charged with ensuring that lifesaving equipment used on vessels subject to inspection by the United States meets specific design, construction, and performance standards, including those found in the International Convention for the Safety of Life at Sea, 1974, as amended, (SOLAS), Chapter III ''Life-saving appliances and arrangements.'' *See* 46 U.S.C. 3306. The Coast Guard carries out this charge through the approval of lifesaving equipment per 46 CFR part 2, subpart 2.75. The approval process includes: pre-approving lifesaving equipment designs, overseeing prototype construction, witnessing prototype testing, and monitoring production of the equipment for use on U.S. vessels. *See* 46 CFR part 159. At each phase of the approval process, the Coast Guard sets specific standards to which lifesaving equipment must be built and tested.

The Coast Guard's specific standards for inflatable liferafts are found in 46 CFR part 160, subparts 160.151 (Inflatable Liferafts (SOLAS)) and 160.051 (Inflatable Liferafts for Domestic Service). The Coast Guard's specific standards for inflatable buoyant apparatuses are found in 46 CFR part 160, subpart 160.010 (Buoyant Apparatus for Merchant Vessels). Current subpart 160.151 satisfies SOLAS requirements, and current subparts 160.051 and 160.010 require compliance with the standards in subpart 160.151, with some specifically listed exceptions. *See* 46 CFR 160.051–1 and 160.010–3(a).

Subpart 160.151 implements SOLAS requirements by incorporating by reference the IMO standards referenced by Chapter III of SOLAS. The primary IMO standards referenced by Chapter III of SOLAS are the ''Revised recommendation on testing of life-saving appliances'' (Recommendation on Testing), IMO Resolution MSC.81(70), and the ''International Life-saving Appliance Code'' (LSA Code), IMO Resolution MSC.48(66). IMO updates these standards by adopting

MSC resolutions promulgating amendments to these standards.

In the Interim Rule published elsewhere in this issue of the **Federal Register**, the Coast Guard revises subpart 160.151 to, among other revisions, update the version of the Recommendation on Testing incorporated by reference, and incorporate by reference for the first time the LSA Code. Interim 46 CFR 160.151–5(d)(5) incorporates by reference the LSA Code ''as amended by resolutions MSC.207(81), MSC.218(82), and MSC.272(85),'' and the Recommendation on Testing ''as amended by IMO Resolutions MSC.226(82) and MSC.274(85).'' Interim subparts 160.051 and 160.010 retain the requirement for compliance with the standards in subpart 160.151, which will now also include the updated versions of the Recommendation on Testing and the LSA Code.

IMO recently adopted two new MSC resolutions further amending the LSA Code and the Recommendation on testing: ''Adoption of Amendments to the International Life-Saving Appliance (LSA) Code'' (MSC.293(87)) and ''Adoption of Amendments to the Revised Recommendation on Testing of Life-Saving Appliances'' (MSC.295(87)).

Resolution MSC.293(87) amends the LSA Code, and enters into force on January 1, 2012. This resolution increases the assumed average mass of liferaft occupants from 75 kg to 82.5 kg for inflatable liferaft design and approval testing purposes.[1]

Resolution MSC.295(87) amends the Recommendation on Testing and enters into force on January 1, 2012. This resolution specifies revisions necessary to account for this assumed average mass increase with respect to certain existing tests. The tests required by the Recommendation on Testing, Part 1 (Prototype Tests), affected by Resolution MSC.295(87) are: the jump test, loading and seating test, davit-launched liferaft boarding test, damage test, righting test, and davit-launched inflatable liferaft strength tests.

The Coast Guard proposes to revise the Interim Rule to include the increased average mass of liferaft occupants and to require liferaft performance under subpart 160.151 to comply with the revisions to tests necessitated by the occupant weight increase. This proposed revision to subpart 160.151 would also, by extension, affect liferaft performance under subpart 160.051 and inflatable buoyant apparatus performance under subpart 160.010.

V. Discussion of Proposed Rule

The Coast Guard proposes to revise interim § 160.151–5(d)(5) to incorporate by reference the LSA Code ''as amended by resolutions MSC.207(81), MSC.218(82), MSC.272(85), and MSC.293(87),'' and the Recommendation on Testing ''as amended by IMO Resolutions MSC.226(82), MSC.274(85), and MSC.295(87).'' Revising these incorporations by references would affect the tests in interim §§ 160.151–27, 160.151–29, 160.151–31, and 160.151–57, which refer to the Recommendation on Testing. This proposal would require manufacturers to conduct those tests on prototype and production liferafts for Coast Guard approval under subpart 160.151 (SOLAS liferafts) using the new 82.5 kg assumed average mass of liferaft occupants instead of the current 75 kg assumed average mass. This rule would not impact liferafts currently in service. As stated in the NPRM, liferafts in service that were approved under the regulations revised by the interim rule would not have to be replaced, provided that they remain in serviceable condition. However, when they become non-serviceable, and thus must be replaced, they would have to be replaced with a liferaft that conforms to the revised regulations in effect at the time of replacement (i.e. the interim rule, as amended by any final rule resulting from this SNPRM).

The Coast Guard proposes to make this proposed rule effective on January 1, 2012, the same date MSC.293(87) and MSC.295(87) enter into force.

Under this proposed rule, any manufacturer of SOLAS liferafts wanting to continue manufacturing such liferafts under a Certificate of Approval issued under subpart 160.151, or seeking Coast Guard approval under subpart 160.151, would have to provide the Coast Guard, prior to January 1, 2012, documentation that the applicable tests in subpart 160.151 have been successfully conducted taking into account the new 82.5 kg standard. This requirement can be met by submitting records of new tests based on the increased weight to maintain the current occupancy rating, or by submitting calculations to support a reduced occupancy rating based on the total weight used in the tests performed during initial approval. The Coast Guard would document compliance with Resolutions MSC.293(87) and MSC.295(87) by means of either amended Certificates of Approval under subpart 160.151 or by letter where large numbers of such Certificates of Approval are involved. The Coast Guard seeks comments on this proposal.

The proposal to incorporate by reference Resolutions MSC.293(87) and MSC.295(87) in interim § 160.151–5(d)(5) would also affect interim subparts 160.051 and 160.010. As discussed above, liferafts for Coast Guard approval under subpart 160.051 (domestic service liferafts) and inflatable buoyant apparatuses for Coast Guard approval under subpart 160.010 must meet the requirements in subpart 160.151 with some exceptions specifically listed in subparts 160.051 and 160.010. *See* § 160.051–5 (''To obtain Coast Guard approval, each Coast Service inflatable liferaft must comply with subpart 160.151, with the following exceptions * * *'') and § 160.051–7 (''To obtain Coast Guard approval, each A and B inflatable liferaft must comply with the requirements in subpart 160.151, with the following exceptions * * *''); and § 160.010–3(a) (''To obtain Coast Guard approval, an inflatable buoyant apparatus must comply with subpart 160.151, with the following exceptions * * *''). None of the specifically listed exemptions address occupant weight or are affected by Resolutions MSC.293(87) and MSC.295(87).

Although incorporating by reference Resolutions MSC.293(87) and MSC.295(87) in interim § 160.151–5(d)(5) would affect interim subparts 160.051 and 160.010, the proposed rule would only affect any new approval sought under subparts 160.051 or 160.010, if this proposal is made final. The language in subparts 160.051 and 160.010 that requires compliance with subpart 160.151 only addresses obtaining Coast Guard approval, and a manufacturer obtains Coast Guard approval when seeking a new approval. Coast Guard approval is evidenced by a Certificate of Approval (COA), which is valid for a period of 5 years. After receiving a COA, the manufacturer must renew the COA before it expires, but renewal of a COA is not considered obtaining Coast Guard approval.

[1] Although the numbers are similar, the assumed average occupant mass of 82.5 kg (181.5 lbs) adopted by IMO for survival craft design and approval testing purposes and the average passenger weight of 185 lbs used in the Coast Guard's Passenger Weight and Inspected Vessel Stability Requirements Final Rule (75 FR 78064) are not related. The Passenger Weight Final Rule updated regulations that address vessel stability and the assumed average passenger weights that directly affect vessel stability. This rule, however, would use the assumed average occupant mass of 82.5 kg (181.5 lbs) to address safe loading of inflatable liferafts and buoyant apparatuses, and does not address vessel stability. The IMO-adopted assumed average occupant mass is the international consensus standard, and the Coast Guard views this IMO standard as the best standard in this context.

Therefore, under this proposed rule, manufacturers of domestic service liferafts and manufacturers of inflatable buoyant apparatuses seeking a new approval under subpart 160.051 or subpart 160.010 on or after January 1, 2012 would have to conduct the applicable tests taking into account the new 82.5 kg standard. Manufacturers that already have a COA issued under subpart 160.051 or subpart 160.010 prior to January 1, 2012, however, would not have to comply with the new tests required by the Recommendation on Testing, as amended by Resolution MSC.295(87) for those approved products. Those manufacturers of domestic service liferafts approved under subpart 160.051 prior to January 1, 2012, and manufacturers of inflatable buoyant apparatuses approved under subpart 160.010 prior to January 1, 2012, could continue production of such lifesaving equipment using the 75 kg assumed average mass for occupants.

The Coast Guard proposes to permit manufacturers of domestic service liferafts and manufacturers of inflatable buoyant apparatuses with COA issued under subpart 160.051 or subpart 160.010 prior to January 1, 2012, to continue production of such lifesaving equipment using the 75 kg assumed average mass because of the differences between SOLAS liferafts and domestic service liferafts and inflatable buoyant apparatuses. SOLAS liferafts are carried on international voyages and as such must comply with IMO requirements. Domestic service liferafts and inflatable buoyant apparatuses are carried only on coastwise and other non-ocean or non-international routes and are not subject to SOLAS requirements. While the Coast Guard considers the IMO standards for this lifesaving equipment, as discussed above and in the Interim Rule, to be appropriate for all U.S. flag vessels regardless of voyage, the Coast Guard is aware of the burden of re-testing domestic service liferafts and inflatable buoyant apparatuses to address the SOLAS increased assumed average mass for occupants. However, the Coast Guard still desires a consistent standard across lifesaving appliances in keeping with the harmonization goal of the Interim Rule, as reflected in the current requirement that liferafts and inflatable buoyant apparatuses for approval under subparts 160.051 and 160.010 comply with subpart 160.151. To balance the burden of re-testing domestic service liferafts and inflatable buoyant apparatuses with the Coast Guard's determination that IMO standards for lifesaving equipment are appropriate for all U.S. flag vessels regardless of voyage, the Coast Guard proposes to not affect current production of domestic service liferafts and inflatable buoyant apparatuses already approved under subparts 160.051 or 160.010. Therefore, the proposed rule would retain the current regulatory text in subparts 160.051 and 160.010 to require manufacturers of domestic service liferafts or inflatable buoyant apparatuses to comply with subpart 160.151 when seeking new Coast Guard approval only.

Manufacturers who wish to standardize across their product lines may opt to re-test domestic service liferafts and buoyant apparatuses approved under subparts 160.051 or 160.010 prior to January 1, 2012, to demonstrate compliance with Resolutions MSC.293(87) and MSC.295(87). The Coast Guard would document compliance with Resolutions MSC.293(87) and MSC.295(87) by means of either amended Certificates of Approval under subpart 160.015 or subpart 160.010, as applicable, or by letter where large numbers of such Certificates of Approval are involved.

VI. Incorporation by Reference

Material proposed for incorporation by reference appears in proposed 46 CFR 160.151–5. You may inspect this material at U.S. Coast Guard Headquarters where indicated under **ADDRESSES**. Copies of the material are available from the sources listed in paragraph (d) of that section.

Before publishing a binding rule, the Coast Guard will submit this material to the Director of the Federal Register for approval of the incorporation by reference.

VII. Regulatory Analyses

The Coast Guard developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below, the Coast Guard summarizes these analyses based on 14 of these statutes or executive orders.

A. Executive Order 12866 and Executive Order 13563

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget (OMB) has not reviewed it under that Order.

As mentioned previously within this preamble, the Coast Guard is issuing this SNPRM regarding inflatable liferafts and inflatable buoyant apparatuses concurrently with an Interim Rule published elsewhere in this issue of the **Federal Register**.

This SNPRM addresses the change in the international standard for occupant weight used in testing equipment in order to establish the rated capacity of inflatable liferafts and inflatable buoyant apparatuses. The occupant weight or 'assumed average occupant mass' would be revised from the current 75 kg to the new weight standard of 82.5 kg and would, if the Coast Guard finalizes this proposed rule, become effective on January 1, 2012.

The Coast Guard issues a Certificate of Approval for inflatable liferafts and inflatable buoyant apparatuses under the applicable subpart in 46 CFR part 160 after successful testing of those appliances by their manufacturers. A Certificate of Approval specifies the number of occupants (or rated capacity) for which the inflatable liferaft or inflatable buoyant apparatus is designed and has been successfully tested, and the Certificate must be renewed every 5 years. New testing is not required to renew a current Certificate but new approval requests require testing before a Certificate can be issued.

Costs

While this proposed rule would require manufacturers to conduct prototype and production tests for inflatable liferafts and inflatable buoyant apparatuses manufactured on or after January 1, 2012 using the new weight standard, it would limit re-testing of currently approved equipment, thus limiting the cost impact of the proposed rule on manufacturers. And, as discussed in *section V. Discussion of Proposed Rule,* this proposed rule would not apply to liferafts currently in service aboard U.S. vessels, thus no vessel would incur replacement costs for liferafts because of this proposed rule. A summary of changes to the baseline testing requirements is shown in Table 1.

TABLE 1—SUMMARY OF CHANGES

Testing type	Existing equipment (approval prior to January 1, 2012)		New equipment (approval after January 1, 2012)	
	Testing	Impacts	Testing	Impacts
SOLAS Inflatable Liferaft (160.151)				
Prototype testing.	Manufacturers must obtain a new Certificate of Approval certifying rated occupancy using the new weight standard. Manufactures may either re-test or have a certification made using previous test results adjusted for the new weight standard. Testing costs are negligible on a unit cost basis.	Units with rated capacity of less than 6 occupants are ineligible for SOLAS service. Costs of testing unchanged as nature of the test is unchanged.	All tests use the new weight standard to establish occupancy rating. Costs of testing unchanged as nature of the test is unchanged.	Units with rated capacity of less than 6 occupants are ineligible for SOLAS service.
Production Testing.	All tests use the new weight standard to establish occupancy rating.	Costs of testing unchanged as nature of the test is unchanged.	All tests use the new weight standard to establish occupancy rating.	Costs of testing unchanged as nature of the test is unchanged.
Non-SOLAS Inflatable Liferaft (160.051)				
Prototype testing.	Existing Certificates of Approval may be renewed without retesting.	No cost or benefit as the use of the new weight standard is optional.	All tests use the new weight standard to establish occupancy rating.	Costs of testing unchanged as nature of the test is unchanged.
Production Testing.	No cost or benefit. The use of the new weight standard is optional for equipment manufactured under an existing Certificate of Approval		All tests use the new weight standard to establish occupancy rating.	Costs of testing unchanged as nature of the test is unchanged.
Inflatable Buoyant Apparatus (160.010)				
Prototype testing.	Existing Certificates of Approval may be renewed without retesting.	No cost or benefit as the use of the new weight standard is optional.	All tests use the new weight standard to establish occupancy rating.	Costs of testing unchanged as nature of the test is unchanged.
Production Testing.	No cost or benefit. The use of the new weight standard is optional for equipment manufactured under an existing Certificate of Approval.		All tests use the new weight standard to establish occupancy rating.	Costs of testing unchanged as nature of the test is unchanged.

SOLAS Inflatable Liferafts (160.151)

As shown in Table 1, manufacturers of SOLAS inflatable liferafts approved under subpart 160.151 (SOLAS liferafts) manufactured on or after January 1, 2012 would be allowed the option of either re-testing using the new occupant weight standard or requesting certification for a lower rated occupancy (adjusted for the new occupant weight standard) based on the certification testing submitted for their current approval.

The principal cost impact for manufacturers of SOLAS liferafts will be for currently manufactured inflatable liferafts whose rated capacity is six using the current 75 kg occupant weight standard. Since SOLAS requires that inflatable liferafts have a minimum capacity of six, any SOLAS liferaft currently rated for six occupants would have to be re-tested under the new weight standard and any of these liferafts that did not meet the requirements for six occupants at the new weight standard could no longer be used on SOLAS vessels.

Currently, there are 10 manufacturers that produce 109 models of SOLAS liferafts. Of these, there are 11 liferaft models (from eight manufacturers) whose rated capacity is six (Table 2). These 11 models would be required to re-test to maintain their SOLAS certification. Three of these eight manufacturers are U.S. firms and they each produce one model of inflatable liferaft with a rated occupancy of six occupants. Of those three models, one model is designed primarily for use in aircraft under a Federal Aviation Administration approval number. The three models produced by U.S. firms and the eight models manufactured by foreign firms would have to be re-tested in order to verify a minimum occupancy rating under the new weight standard to be used on SOLAS vessels. From estimates obtained from industry, we estimate the costs of re-testing for compliance with the new weight standard at approximately $1,800 for each model.

We estimate the total cost to industry to re-test all current SOLAS liferaft models as $19,800—$14,400 for foreign manufacturers and $5,400 for U.S.-owned manufacturers.

TABLE 2—SOLAS LIFERAFTS

Manufacturer	Number of manufacturers	Total number of models of liferaft produced	Total number of models of liferaft produced with an occupancy rating of 6	Cost to re-test each SOLAS liferaft	Total cost to retest
Foreign owned	7	104	8	$1,800	$14,400
U.S. owned	3	5	3	1,800	5,400
Total	10	109	11	1,800	$19,800

Non-SOLAS Inflatable Liferafts (160.051) and Inflatable Buoyant Apparatus (160.010)

As shown in Table 1, manufacturers of domestic service inflatable liferafts under subpart 160.051 (domestic service liferafts) and inflatable buoyant apparatuses under subpart 160.010 manufactured on or after January 1, 2012, under current Certificates of Approval, would have the option of using either the old 75 kg or the new 82.5 kg occupant weight standard. If a manufacturer of domestic service liferafts or a manufacturer of inflatable buoyant apparatuses with current Certificates of Approval chooses to use the new weight standard, it would also have the option of either re-testing using the new occupant weight standard or requesting re-certification for a lower number of occupants (adjusted for the new occupant weight standard). Manufacturers of domestic inflatable liferafts under subpart 160.051 or buoyant apparatuses under 160.010 would be required to use the new occupant weight standard only when testing domestic inflatable liferafts or buoyant apparatuses approved after January 1, 2012.

In terms of the cost of the regulation:

1. While prototype testing for all SOLAS liferafts on or after January 1, 2012, would have to employ the new weight standard, there is no additional cost in performing the required tests due to the change in the testing weight because the nature of the test remains the same.

2. Production testing of all SOLAS liferafts on or after January 1, 2012 would require testing using the new weight standard. As with prototype testing, there is no additional cost in performing the required tests due to the change in the testing weight because the nature of the test remains the same.

3. For production testing of SOLAS liferafts, the manufacturer may either request a certification with a lower maximum occupancy based on the new weight standard or re-test the equipment for certification of its current rated capacity using the new weight standard.

4. The 11 models (three models made by U.S. manufacturers) of SOLAS inflatable liferafts whose current rated capacity is six occupants, would have to verify that they meet the minimum SOLAS requirements for a capacity of six occupants at the new weight standard if they wish to continue their current SOLAS approval status.

5. For both prototype and production testing of domestic service inflatable liferafts and inflatable buoyant apparatuses approved by the Coast Guard prior to January 1, 2012, the manufacturer may test under either the 75 kg or the 82.5 kg occupant weight standard with no change to testing based on the new weight standard.

6. For prototype and production testing of domestic service inflatable liferafts and inflatable buoyant apparatuses approved on or after January 1, 2012, the manufacturer must test under the 82.5 kg occupant weight standard.

For inflatable liferafts approved under subpart 160.051 prior to January 1, 2012 and inflatable buoyant apparatuses approved under subpart 160.010 prior to January 1, 2012, the costs of testing equipment at the higher weight standard would be voluntary, as domestic liferafts and inflatable buoyant apparatuses may be certified using either weight standard. Likewise, equipment manufactured under a current Certificate of Approval would only be required to be re-tested if the manufacturer elected to retain their current rated capacity for their equipment under the higher weight standard. However, manufacturers have the option to reduce the current rated capacities of their equipment to comply with the new weight standard, provided that the resulting capacity does not conflict with the minimum required capacity applicable to that equipment.

Prototype and production testing of all SOLAS liferafts approved under subpart 160.151 would be required using the higher 82.5 kg occupant weight standard. The Coast Guard has no evidence to suggest that testing at the higher weight standard would involve additional testing costs for manufacturers because the nature of the test remains the same.

Benefits

The principal benefit of the proposed rule is the protection of life at sea by establishing capacity standards for inflatable liferafts and inflatable buoyant apparatuses reflecting a global increase in mariner weights. Additionally, the proposed rule ensures compliance with internationally applicable standards for SOLAS adopted by IMO where non-compliance would exclude the use of inflatable liferafts manufactured under part 160.151 aboard SOLAS vessels.

The Coast Guard urges interested parties to submit comments that specifically address the economic impacts of this supplemental rulemaking. Comments can be made as indicated in the **ADDRESSES** section.

B. Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), the Coast Guard has considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

We have identified three U.S.-owned entities involved in the manufacture of SOLAS liferafts manufactured under subpart 160.151. All are business entities, and all are small entities. For these three small entities, the testing requirements using the new weight standard would apply to: prototypes (new designs) submitted after January 1, 2012; production testing of designs submitted after January 1, 2012; and for currently manufactured equipment that manufacturers wish to have certified at their current rated occupancy using the new weight standards (as opposed to certification with a lower occupant capacity based on the higher testing weight). For new prototypes and production of products approved after

January 1, 2012, the Coast Guard has no evidence to suggest that testing at the higher weight standard would involve additional costs for manufacturers. For manufacturers seeking certification of equipment currently approved under subpart 160.151 (SOLAS liferafts), testing to verify compliance with the rated capacity at the higher testing weight would be voluntary for those whose current rated capacity is above six. For manufacturers of these models, there would be the option of testing for certification at the new weight standard, or requesting a revised approval for a reduced capacity based on the results of previously submitted tests. For manufacturers seeking certification of equipment currently approved under subpart 160.151 whose rated capacity is six, re-testing at the higher occupant weight would be required in order to retain their SOLAS approval status since SOLAS inflatable liferafts must have a minimum rated capacity of at least six. For the three models of liferafts currently approved under subpart 160.151, the cost estimates for certification testing, obtained from industry sources, are approximately $1,800 per liferaft for a total of $5,400 (3 liferaft models × $1,800 testing cost per model).

For manufacturers of equipment for domestic service only, we have identified three entities involved in the manufacture of domestic service liferafts and inflatable buoyant apparatus manufactured under subparts 160.051 and 160.010, respectively. All are business entities, and all are small entities. These entities would not be required to re-test equipment to retain Coast Guard approval, and could manufacture equipment under either weight standard with no affect to the rated capacities of their equipment.

Based on this information, the Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment to the Docket Management Facility at the address under **ADDRESSES**. In your comment, explain why you think it qualifies and how and to what degree this proposed rule would economically affect it.

C. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), the Coast Guard wants to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please consult Mr. Kurt Heinz, Commercial Regulations and Standards Directorate, Office of Design and Engineering Standards, Lifesaving and Fire Safety Division (CG–5214), Coast Guard, telephone 202–372–1395, or e-mail *Kurt.J.Heinz@uscg.mil.* The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

Small businesses may send comments on the actions of Federal employees who enforce or otherwise determine compliance with Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

D. Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

E. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them.

The U.S. Supreme Court has long recognized the field preemptive impact of the Federal regulatory regime for inspected vessels. *See, e.g., Kelly* v. *Washington ex rel Foss,* 302 U.S. 1 (1937) and the consolidated cases of *United States* v. *Locke and Intertanko* v. *Locke,* 529 U.S. 89, 113–116 (2000). Therefore, the Coast Guard's view is that regulations issued under the authority of 46 U.S.C. 3306 in the areas of design, construction, alteration, repair, operation, superstructures, hulls, fittings, equipment, appliances, propulsion machinery, auxiliary machinery, boilers, unfired pressure vessels, piping, electric installations, accommodations for passengers and crew, sailing school instructors, sailing school students, lifesaving equipment and its use, firefighting equipment, its use and precautionary measures to guard against fire, inspections and tests related to these areas and the use of vessel stores and other supplies of a dangerous nature have preemptive effect over State regulation in these fields, regardless of whether the Coast Guard has issued regulations on the subject or not, and regardless of the existence of conflict between the State and Coast Guard regulation.

While it is well settled that States may not regulate in categories in which Congress intended the Coast Guard to be the sole source of a vessel's obligations, as these categories are within a field foreclosed from regulation by the States (see *U.S.* v. *Locke,* above), the Coast Guard recognizes the key role state and local governments may have in making regulatory determinations. Additionally, Sections 4 and 6 of Executive Order 13132 require that for any rules with preemptive effect, the Coast Guard will provide elected officials of affected state and local governments and their representative national organizations the notice and opportunity for appropriate participation in any rulemaking proceedings, and to consult with such officials early in the rulemaking process. Therefore, we invite affected state and local governments and their representative national organizations to indicate their desire for participation and consultation in this rulemaking process by submitting comments to the docket using one of the methods specified under **ADDRESSES**. In accordance with Executive Order 13132, the Coast Guard will provide a federalism impact statement to document (1) the extent of the Coast Guard's consultation with State and local officials that submit comments to this proposed rule, (2) a summary of the nature of any concerns raised by state or local governments and the Coast Guard's position thereon, and (3) a statement of the extent to which the concerns of State and local officials have been met.

F. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. This proposed rule would not result in such an expenditure.

G. Taking of Private Property

This proposed rule would not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

H. Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

I. Protection of Children

The Coast Guard has analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This proposed rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

J. Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

K. Energy Effects

The Coast Guard has analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. The Coast Guard has determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

L. Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through OMB, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule uses the following voluntary consensus standards:

- International Life-Saving Appliance Code, (IMO Resolution MSC.48(66)), as amended by IMO Resolutions MSC.207(81), MSC.218(82), MSC.272(85), and MSC.293(87);
- IMO Resolution MSC.81(70), Revised recommendation on testing of life-saving appliances, as amended by IMO Resolutions MSC.226(82), MSC.274(85), and MSC.295(87).

The proposed sections that reference these standards and the locations where these standards are available are listed in 46 CFR 160.151–5.

If you disagree with our analysis of the voluntary consensus standards listed above or are aware of voluntary consensus standards that might apply but are not listed, please send a comment to the docket using one of the methods under **ADDRESSES**. In your comment, please explain why you disagree with our analysis and/or identify voluntary consensus standards the Coast Guard has not listed that might apply.

M. Coast Guard Authorization Act Sec. 608 (46 U.S.C. 2118(a))

Section 608 of the Coast Guard Authorization Act of 2010 (Pub. L. 111–281) adds new section 2118 to 46 U.S.C. Subtitle II (Vessels and Seamen), Chapter 21 (General). New section 2118(a) sets forth requirements for standards established for approved equipment required on vessels subject to 46 U.S.C. Subtitle II (Vessels and Seamen), Part B (Inspection and Regulation of Vessels). Those standards must be ''(1) based on performance using the best available technology that is economically achievable; and (2) operationally practical.'' *See* 46 U.S.C. 2118(a). This rulemaking addresses lifesaving equipment for Coast Guard approval that is required on vessels subject to 46 U.S.C. Subtitle II, Part B, and the Coast Guard has ensured this proposed rule satisfies the requirements of 46 U.S.C. 2118(a), as necessary.

N. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. A preliminary environmental analysis checklist supporting this determination is available in the docket where indicated under the ''Public Participation and Request for Comments'' section of this preamble. This proposed rule involves regulations which are editorial, regulations concerning equipping of vessels, and regulations concerning vessel operation safety standards. This proposed rule is categorically excluded under Section 2.B.2, Figure 2–1, paragraphs (34)(a) and (d) of the Instruction and under paragraph 6(a) of the ''Appendix to National Environmental Policy Act: Coast Guard Procedures for Categorical Exclusions, Notice of Final Agency Policy'' (67 FR 48243, July 23, 2002). We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 46 CFR Part 160

Marine safety, Incorporation by reference, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 46 CFR part 160 as follows:

PART 160—LIFESAVING EQUIPMENT

1. The authority citation for part 160 continues to read as follows:

Authority: 46 U.S.C. 2103, 3306, 3703 and 4302; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; 49 CFR 1.46.

Subpart 160.151—Inflatable Liferafts (SOLAS)

2. Amend § 160.151–5 by adding paragraphs (d)(5) and (d)(6) to read as follows:

§ 160.151–5 Incorporation by reference.

* * * * *

(d) * * *

(5) Resolution MSC.293(87), Adoption of Amendments to the International Life-Saving Appliance (LSA) Code, (May 21, 2010), IBR approved for §§ 160.151–7, 160.151–15, 160.151–17, 160.151–21, 160.151–29, and 160.151–33 (''Resolution MSC.293(87)'').

(6) Resolution MSC.295(87), Adoption of Amendments to the Revised Recommendation on Testing of Life-Saving Appliances (Resolution MSC.81(70)), (May 21, 2010), IBR approved for §§ 160.151–21, 160.151–27, 160.151–29, 160.151–31, and 160.151–57 (''Resolution MSC.295(87)'').

* * * * *

§ 160.151–7 [Amended]

3. Amend § 160.151–7 by removing the words ''IMO LSA Code'' wherever they appear and adding, in their place, the words ''IMO LSA Code, as amended by Resolution MSC.293(87),''.

§ 160.151–15 [Amended]

4. Amend § 160.151–15 by removing the words ''IMO LSA Code'' wherever they appear and adding, in their place, the words ''IMO LSA Code, as amended by Resolution MSC.293(87),''.

§ 160.151–17 [Amended]

5. Amend § 160.151–17 by removing the words ''IMO LSA Code'' wherever they appear and adding, in their place, the words ''IMO LSA Code, as amended by Resolution MSC.293(87),''.

§ 160.151–21 [Amended]

6. Amend § 160.151–21 as follows:

a. Remove the words ''IMO LSA Code'' wherever they appear and add, in their place, the words ''IMO LSA Code, as amended by Resolution MSC.293(87),''; and

b. In paragraph (f), remove the words ''IMO Revised recommendation on testing'' and add, in their place, the words ''IMO Revised recommendation on testing, as amended by Resolution MSC.295(87),''.

§ 160.151–27 [Amended]

7. Amend § 160.151–27 by removing the words ''IMO Revised recommendation on testing'' wherever they appear and adding, in their place, the words ''IMO Revised recommendation on testing, as amended by Resolution MSC.295(87),''.

§ 160.151–29 [Amended]

8. Amend § 160.151–29 as follows:

a. In the introductory text, remove the words ''IMO LSA Code'' and add, in their place, the words ''IMO LSA Code, as amended by Resolution MSC.293(87),''; and

b. In the introductory text, remove the words ''IMO Revised recommendation on testing'' and add, in their place, the words ''IMO Revised recommendation on testing, as amended by Resolution MSC.295(87),''.

§ 160.151–31 [Amended]

9. Amend § 160.151–31 by removing the words ''IMO Revised recommendation on testing'' wherever they appear and adding, in their place, the words ''IMO Revised recommendation on testing, as amended by Resolution MSC.295(87),''.

§ 160.151–33 [Amended]

10. Amend § 160.151–33 by removing the words ''IMO LSA Code'' wherever they appear and adding, in their place, the words ''IMO LSA Code, as amended by Resolution MSC.293(87),''.

§ 160.151–57 [Amended]

11. Amend § 160.151–57 by removing the words ''IMO Revised recommendation on testing'' wherever they appear and adding, in their place, the words ''IMO Revised recommendation on testing, as amended by Resolution MSC.295(87),''.

Dated: September 22, 2011.

J.G. Lantz,

Director of Commercial Regulations and Standards, U.S. Coast Guard.

[FR Doc. 2011–25032 Filed 10–7–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R2–ES–2011–0081; MO92210–0–0008]

Endangered and Threatened Wildlife and Plants; 12-Month Finding on a Petition To List Amoreuxia gonzalezii, Astragalus hypoxylus, and Erigeron piscaticus as Endangered or Threatened

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of 12-month petition finding.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce a 12-month finding on a petition to list *Amoreuxia gonzalezii* (Santa Rita yellowshow), *Astragalus hypoxylus* (Huachuca milk-vetch), and *Erigeron piscaticus* (Fish Creek fleabane) as endangered or threatened with critical habitat under the Endangered Species Act of 1973, as amended (Act). After review of the best scientific and commercial information available, we find that listing *Amoreuxia gonzalezii, Astragalus hypoxylus,* and *Erigeron piscaticus* is not warranted at this time. However, we ask the public to submit to us any new information that becomes available concerning the threats to *Amoreuxia gonzalezii, Astragalus hypoxylus,* and *Erigeron piscaticus* or their habitats at any time.

DATES: The finding announced in this document was made on October 11, 2011.

ADDRESSES: This finding is available on the Internet at *http://www.regulations.gov* at Docket Number FWS–R2–ES–2011–0081. Supporting documentation we used in preparing this finding is available for public inspection, by appointment, during normal business hours by contacting the U.S. Fish and Wildlife Service, Arizona Ecological Services Field Office, 2321 W. Royal Palm Road, Suite 103, Phoenix, AZ 85021; telephone (602) 242–0210; facsimile (602) 242–2513. If you use a telecommunications device for the deaf (TDD), please call the Federal Information Relay Service (FIRS) at (800) 877–8339. Please submit any new information, comments, or questions concerning this finding to the above street address.

FOR FURTHER INFORMATION CONTACT: Steve Spangle, Field Supervisor, U.S. Fish and Wildlife Service, Arizona Ecological Services Field Office, 2321 W. Royal Palm Road, Suite 103, Phoenix, AZ 85021; telephone (602) 242–0210; facsimile (602) 242–2513. If you use a telecommunications device for the deaf (TDD), please call the Federal Information Relay Service (FIRS) at (800) 877–8339.

SUPPLEMENTARY INFORMATION:

Background

Section 4(b)(3)(B) of the Act (16 U.S.C. 1531 *et seq.*) requires that, for any petition to revise the Federal Lists of Threatened and Endangered Wildlife and Plants that contain substantial scientific or commercial information indicating that listing a species may be warranted, we make a finding within 12 months of the date of receipt of the petition. In this finding, we will determine that the petitioned action is: (a) Not warranted, (b) warranted, or (c) warranted, but immediate proposal of a regulation implementing the petitioned action is precluded by other pending proposals to determine whether species are endangered or threatened, and expeditious progress is being made to add or remove qualified species from the Lists of Endangered and Threatened Wildlife and Plants. Section 4(b)(3)(C) of the Act requires that we treat a petition for which the requested action is found to be warranted but precluded as though resubmitted on the date of such finding, that is, requiring a subsequent finding to be made within 12 months. We must publish these 12-month findings in the **Federal Register**.

Previous Federal Actions

Amoreuxia gonzalezii, Astragalus hypoxylus, and Erigeron piscaticus were formerly Category 2 candidate species, which are taxa for which information in our possession indicated that proposing to list was possibly appropriate, but for which persuasive data on biological

vulnerability and threats were not available to support a proposed listing rule (58 FR 51144; September 30, 1993). The designation of Category 2 candidate species was discontinued in 1996; therefore, these species are not currently considered candidates.

On June 25, 2007, we received a formal petition dated June 18, 2007, from Forest Guardians (now WildEarth Guardians), requesting that we do the following: (1) Consider for listing all full species in our Southwest Region ranked as G1 or G1G2 by the organization NatureServe, except those that are currently listed, proposed for listing, or candidates; and (2) list each species under the Act as either endangered or threatened and designate critical habitat. The petitioners presented two tables that collectively listed 475 species for consideration and requested that the Service incorporate all analyses, references, and documentation provided by NatureServe in its online database *http://www.natureserve.org/* into the petition. The petition clearly identified itself as a petition and included the appropriate identification information, as required in 50 CFR 424.14(a). We acknowledged the receipt of the petition in a letter to WildEarth Guardians dated July 11, 2007.

On December 16, 2009, we made a 90-day finding (74 FR 66866) that the petition presented substantial scientific information indicating that listing 67 of the 475 species may be warranted; *Amoreuxia gonzalezii, Astragalus hypoxylus,* and *Erigeron piscaticus* were in that group of 67 species. For *Amoreuxia gonzalezii,* the petition listed urban and mining development and herbivory as threats to the species and its habitat, along with competition from nonnative species. For *Astragalus hypoxylus,* the petition listed degradation of habitat from livestock grazing and impacts from recreation, as well as indirect effects to bees, which may be the primary pollinator of this species. For *Erigeron piscaticus,* the petition listed recreational impacts, poor watershed conditions, flooding, and small population size as threats to the species and its habitat. The 90-day finding initiated a status review for these three plants (74 FR 66866; December 16, 2009). This notice constitutes the 12-month finding on the June 18, 2007, petition to list *Amoreuxia gonzalezii, Astragalus hypoxylus,* and *Erigeron piscaticus* as endangered or threatened.

Evaluation of the Status of Each of the Three Plant Species

Section 4 of the Act (16 U.S.C. 1533) and implementing regulations (50 CFR part 424) set forth procedures for adding species to, removing species from, or reclassifying species on the Federal Lists of Endangered and Threatened Wildlife and Plants. Under section 4(a)(1) of the Act, a species may be determined to be endangered or threatened based on any of the following five factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

In making these findings, information pertaining to each species in relation to the five factors provided in section 4(a)(1) of the Act is discussed below. In considering what factors might constitute threats to a species, we must look beyond the exposure of the species to a particular factor to evaluate whether the species may respond to the factor in a way that causes actual impacts to the species. If there is exposure to a factor and the species responds negatively, the factor may be a threat, and during the status review, we attempt to determine how significant a threat it is. The threat is significant if it drives, or contributes to, the risk of extinction of the species such that the species warrants listing as endangered or threatened as those terms are defined by the Act. However, the identification of factors that could impact a species negatively may not be sufficient to compel a finding that the species warrants listing. The information must include evidence sufficient to suggest that the potential threat has the capacity (*i.e.,* it should be of sufficient magnitude and extent) to affect the species' status such that it meets the definition of endangered or threatened under the Act.

Evaluation of the Status of Each of the Three Plant Species

For each of the three species, we provide a description of the species and its life-history and habitat, an evaluation of threats for that species, and our finding that the petitioned action is warranted or not for that species.

Species Information for *Amoreuxia gonzalezii*

Species Description

Amoreuxia gonzalezii is an herbaceous perennial (plant living 3 or more years) in the Bixaceae family (Lipstick tree). The plant has a thickened starchy to woody rootstock, erect stems to 50 centimeters (cm) (20 inches (in)) in height, and long-petioled (long-stalked) leaves that are deeply parted into five to seven spathulate (spoon-shaped) lobes (Poppendieck 1981, p. 24). The inflorescences (clusters of flowers) are few-flowered terminal cymes (branched flower clusters) with salmon- to yellow-colored flowers with maroon marks at the base of the upper and lower petals (Hodgson 1994, p. 3). The densely silky hair of the ovary is one of two main characteristics that separate this species from its more common relative *A. palmatifida* (Hodgson 1994, p. 4). The second characteristic separating the two species is the mature fruit. The capsule in *A. gonzalezii* is ellipsoid and the seeds spherical; in *A. palmatifida,* the capsules are ovoid with reniform (kidney-shaped) seeds (Hodgson 1993, p. 27). Recent molecular work by Fulton (2011, pers. comm.) verifies that *A. gonzalezii* is a valid taxon, and we consider the species a listable entity.

Habitat and Biology

Amoreuxia gonzalezii is the farthest north-occurring species within this tropical and sub-tropical genus found primarily in South America (the primary center of diversification), Central America, and Mexico (Poppendieck 1981, p. 24). Northern Mexico is the secondary center of diversification for the genus and contains the majority of documented locations of *A. gonzalezii* (Hodgson 1994, p. 5). In Mexico, *A. gonzalezii* is found in tropical areas in foothills thornscrub and tropical deciduous forest. Rainfall amounts range from 28 cm per year (11 in) near the coast (thornscrub) to 60 cm (24 in) in tropical deciduous forest. Freezes are very uncommon, and the bulk of rainfall occurs from July through mid-September. The plants in these vegetation communities are rainfall sensitive; in other words, the shrubs and trees leaf out only when the rains begin, and drop their leaves when the rainy season ends, usually in October (Yetman and Van Devender 2002, pp. 9–12). Geology of collection sites varies from granitic, to quartz, to shale with quartz nodules and intrusives (molten igneous rock that is forced into cracks or between other layers of rocks). In the state of Sonora in Mexico, *A. gonzalezii* has been collected from the vicinity of Álamos, Choquincahui, El Oasis, Guirocoba, Magdalena, Moctezuma, Onavas, Santa Ana, Tónichi, and Yocogigua, as well as the Curea-Guadalupe Tayopa area. In the state of Sinaloa in Mexico, the plant was

described from near Choix in the north. The specimens were found on both shallow and steep hill slopes at elevations from 160 to775 meters (m) (525 to 2542 feet (ft)).

In the United States, *Amoreuxia gonzalezii* has been collected from the Devil's Cashbox area in the Santa Rita Mountains and Thomas Canyon in the Baboquivari Mountains (Southwest Environmental Information Network 2011). Both locations are in southeastern Arizona. We believe that the Arizona locations represent the northernmost distribution of this species. The Santa Rita *A. gonzalezii* plants are on lands administered by the Coronado National Forest, Nogales Ranger District. The plants occur in the foothills at an elevation of 1,311 to 1,402 m (4,300 to 4,599 ft) on steep limestone slopes and ridgetops. The habitat is described as the transition zone between Upper Sonoran desertscrub and grassland (NatureServe 2010). The collection from the granitic Baboquivari Mountains was from the sandy bank of a small drainage on private land at 1,280 to 1,371 m (4,198 to 4,497 ft) elevation. This site was described as an oak woodland and grassland (Southwest Environmental Information Network 2011).

Very little is known about the biology of this species. *Amoreuxia gonzalezii* has a drought avoidance adaptation and only produces stems, leaves, flowers, and fruits following monsoon rains; it remains dormant under the ground the remainder of the year (Coronado National Forest 1991, p. 3). Flowering occurs from July through September; flowers remain open only in the morning hours, closing by 11:00 a.m. (Hodgson 1994, p.7). The species is an obligate outcrosser (needs pollen from another individual to successfully produce seed) and may be pollinated by unknown species of bees (Hodgson 1994, p. 7). Fruits develop in late July and August, maturing in September to mid-October (Hodgson 1994, p. 7). Both flower and fruit production is dependent on the quantity of summer precipitation. *Amoreuxia gonzalezii* also reproduces vegetatively (asexually) from thick, tuberous or woody roots (Hodgson 2001, p. 94).

In 1987 and 1988, staff from the Desert Botanical Garden (Garden) collected 142 seeds from the Devil's Cashbox area as part of the Center for Plant Conservation National Collection program for conserving rare plants and their seeds. The Garden's purpose was to determine viability of stored seed and increase the number of plants in their living collection (Desert Botanical Garden 1991, p. 1). An additional 72 seeds were collected by Garden staff from one population in Sonora, Mexico at an unknown date prior to 1991. In greenhouse trials, the Garden had variable low rates of success, from 0 to 43 percent, in germinating 4-year-old seed stored both at room temperature and in a freezer facility. Viability of the seed bank and germination success in the wild is unknown, though Hodgson did report finding 10 seedlings in 1991 in the Devil's Cashbox area (Southwest Environmental Information Network 2011). In a greenhouse experiment, 4 plants produced 7 fruits with a total of 232 seeds (Hodgson 1994, p. 7). Assuming this may be optimum fruiting potential given ample water and greenhouse care, the small population sizes from known populations (4to 24 individuals) may produce few seeds in typical years. There are no monitoring plots or current research in any of the populations in Arizona and Mexico.

Abundance

There are virtually no population estimates for any locations in Mexico, although Hodgson (1994, p. 7) reported that one population in Mexico in 1988 had ''well over two dozen'' individuals. The information is not much better for the Arizona populations. Population estimates for the Santa Rita population ranged from 14 individuals in 1988 (Southwest Environmental Information Network, 2011), to 4 individuals in 1989 (Hodgson 1989, p. 2), and 25 individuals in 1991 (Southwest Environmental Information Network, 2011). Hodgson (1994, p. 7) reports fewer than 24 individuals from 2 micro-populations in the Santa Rita Mountains. There were an estimated six to eight individuals in the Thomas Canyon population (Toolin 2011, pers. comm.) in the 1990s. Thomas Canyon was surveyed in 2011 and 30 plants were found (M. Baker 2011, pers. comm.).

In summary, there is very little ecological information available regarding *Amoreuxia gonzalezii.* The species is found in Mexico, and the United States, where the Arizona locations seem to represent the northernmost locations for this species. The best available scientific information does not indicate that this species was more widespread or that known populations have been extirpated. Both populations in Arizona seem to support a few individuals that are widely scattered over appropriate habitat. The species' growth is tied to the summer rains (monsoon), and in the fall, the plants become dormant. It seems likely that this species is more abundant in Mexico, and may be more closely tied with the thornscrub and tropical deciduous forest plant communities, which are more humid, and where many plant species grow in response to summer rainfall.

Five-Factor Evaluation for *Amoreuxia gonzalezii*

In making this finding, information pertaining to *Amoreuxia gonzalezii* in relation to the five factors provided in section 4(a)(1) of the Act is discussed below.

Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Potential factors that may affect the habitat or range of *Amoreuxia gonzalezii* are discussed in this section, including: (1) Nonnative, invasive species; (2) fire; (3) development; (4) mining; (5) watershed degradation; (6) drought; and (7) climate change.

Nonnative, Invasive Species

Throughout the Sonoran Desert ecosystem, invasions of the introduced *Pennisetum ciliare* (buffelgrass), *Bromus rubens* (red brome), *Eragrostis lehmanniana* (Lehmann lovegrass), *Schismus barbatus* (Mediterranean grass), and *Pennisetum setaceum* (crimson fountaingrass) have altered nutrient regimes; species composition and structure; and fire frequency, duration, intensity, and magnitude (Brooks and Pyke 2001, p. 5). Although most of these species were intentionally introduced as forage for livestock, erosion control, or as ornamentals, each is now considered invasive and a threat to this ecosystem. Species such as *P. ciliare* are expected to increase their range even with continued and predicted drought events (Ward *et al.* 2006, p. 724). It is generally thought that invasion by exotic annual grasses will continue unchecked in the Sonoran Desert ecosystem in the future, reducing native biodiversity through direct competition and alteration of nutrient and disturbance regimes (Franklin and Molina-Freaner 2010, p. 1671).

Although exotic grasses are reported to threaten *Amoreuxia gonzalezii* (Hodgson 1989, p. 3), no exotic grasses were noted within the Devil's Cashbox habitat during field surveys in May 2011 (Service 2011a, p. 1). We have reviewed the best available scientific information on exotic plants in or near populations of *A. gonzalezii* in Thomas Canyon and in Mexico. In order to verify the identification and location of plants, specimens are collected, pressed and placed on sheets that are stored in herbaria. The labels on herbarium sheets often note associated plant species that

are found in association with the collected specimen. There are no exotic species noted as associates on any of the 12 specimen herbarium sheets located at the Arizona State University, University of Arizona, or the Sonoran University Herbarium collections, nor were any exotics noted in the Devil's Cashbox and Sonora *A. gonzalezii* habitat descriptions in Hodgson 1994 (pp. 5–6). Therefore, the best available information does not provide evidence that nonnative invasive species are a threat to the continued existence of *A. gonzalezii* or are likely to become so.

Fire

There has been no scientific study on the impacts of fire on *Amoreuxia gonzalezii.* This species is present aboveground in July through October, and is dormant the remainder of the year. Because fires in Arizona usually burn in the premonsoon season (May–June), it seems unlikely that fire would affect this species (Alford *et al.* 2005, p. 453). In addition, the plant has a large starchy root, which is protected underground. It is possible that the root would be protected from surface fire, allowing the plant to resprout after fire. In summary, given the limited available information about the effect of fire on *A. gonzalezii,* we have determined that fire is not a threat to the continued existence of *A. gonzalezii,* or is likely to become so.

Development

The Santa Rita *Amoreuxia gonzalezii* population is located below the Smithsonian Fred Whipple Observatory, located on Mt. Hopkins. There is a visitor center for the observatory located at the base of Mt. Hopkins, and Hodgson (1989, p. 4) noted that during the construction of the visitor center, disturbance came very close to some *A. gonzalezii* plants on the Devil's Cashbox ridge, but none of the plants were harmed during construction. Hodgson (1994, p. 9) noted that communication is vital among researchers, land managers, and potential developers in regards to development near populations of *A. gonzalezii.* Available information does not indicate any other development planned for this area, and the area is fairly remote. In addition, the population is on National Forest land, where development is not likely to occur. There is also no information indicating any development near the Thomas canyon site, nor any development near *Amoreuxia* populations in Mexico. We have evaluated and determined, on the basis of the best available scientific and commercial data, that development is not a threat to the continued existence of *A. gonzalezii,* nor is it likely to become so.

Mining

NatureServe (2010) reports mining as a threat to this species, perhaps due to the proximity of two active mining claims to the south of the Devil's Cashbox plants (Ahern 2011, pers. comm.). There are currently no known direct impacts of active or proposed mines on any known population of *Amoreuxia gonzalezii* in the United States; these impacts are unknown for populations in Mexico. Hodgson (2001, p. 93) notes that *A. gonzalezii* tubers were collected frequently by native peoples from ''a graphite mine site'' in Mexico, implying no negative impact on the plant from this particular mine. It is unknown if the mine was active or inactive at the times of harvesting. In summary, based upon our review of the best available information, we conclude that mining is not a threat to the continued existence of *A. gonzalezii,* nor is it likely to become so.

Watershed Degradation

Improper livestock grazing can lead to habitat degradation and watershed degradation. Overgrazing removes the vegetative cover which can lead to erosion. The Santa Rita population is located within the Agua Caliente grazing allotment on the Nogales Ranger District. Degradation of habitat due to livestock grazing was noted as a threat by NatureServe (2010) to *Amoreuxia gonzalezii,* although this was not evident in a 2011 visit to the Devil's Cashbox area (Service 2011a, p. 1). The area that was assessed during that visit had no signs of livestock trailing, or sign of livestock. The Forest Service reports that this allotment, comprised of one pasture, is permitted for a 110 cow-calf operation (Lockwood 2011, pers. comm.). The grazing season is May to November, but only 40 cows are presently grazing due to drought conditions (Lockwood 2011, pers. comm.). The ridges where the plants are located are quite steep, and it is unlikely that cattle graze in these locations. The status of livestock grazing with regard to the Thomas Canyon population is unknown, and no information is available regarding livestock grazing near *Amoreuxia* populations in Mexico. After reviewing the best available scientific information, we have determined that watershed degradation as a result of livestock grazing is not a threat to the continued existence of this species, nor is it likely to become so.

Drought

Amoreuxia gonzalezii is dependent upon monsoon rains both for growth and the production of flowers and fruits (Hodgson 1989, p. 3). Hodgson (2001, p. 94) states that, ''With little precipitation, few fruits are produced from very depauperate plants.'' The Thomas Canyon location experienced less than average monsoon precipitation in 27 of 49 recorded years (July to August, period of record for average was 1961–2010, Kit Peak Weather Station, WRCC 2011). Similarly, the Devil's Cashbox area has had less than average monsoon precipitation during 33 of 63 recorded years (period of record for average was 1946–2010, Tumacacori National Historic Park (NHP) Weather Station, WRCC 2011). In both locations, monsoon patterns varied yearly, with periods of below-average precipitation never exceeding 7 consecutive years (Tumacacori NHP 1998–2004), thus giving *A. gonzalezii* periods of recovery.

The climate pattern in the vicinity of Álamos at the southern end of the *Amoreuxia gonzalezii* range in Sonora is very similar to Arizona, with the Álamos-El Veranito weather station reporting below-average monsoon precipitation in 14 of 28 recorded years (July to August, period of record for average was 1977–2009, Comisión Nacional del Agua (CNA), 2011). At the near center of *A. gonzalezii's* Sonora range, the Carbo Weather station reported below average monsoon precipitation in 30 of 50 recorded years, 10 of which were consecutive from 1960–1969 (July to August, period of record for average was 1960–2009, CNA, 2011).

It is not known whether *Amoreuxia gonzalezii* is drought-tolerant, but the observation that plants are still present in sites that have experienced reduced summer precipitation leads us to conclude that the species is at least adapted to drought conditions. *A. gonzalezii* has fleshy underground tubers, which can store food and water, and that is an adaptation for dealing with drought. The best available information does not indicate that drought is a threat to the continued existence of *A. gonzalezii,* and the plant may have some adaptations for dealing with drought; therefore, we conclude that drought is not a threat to this species, or is likely to become so.

Climate Change

''Climate'' refers to an area's long-term average weather statistics (typically for at least 20- or 30-year periods), including the mean and variation of surface variables such as temperature,

precipitation, and wind; ''climate change'' refers to a change in the mean or variability of climate properties that persists for an extended period (typically decades or longer), whether due to natural processes or human activity (Intergovernmental Panel on Climate Change (IPCC) 2007a, p. 78). Although changes in climate occur continuously over geological time, changes are now occurring at an accelerated rate. For example, at continental, regional and ocean basin scales, recent observed changes in long-term trends include: a substantial increase in precipitation in eastern parts of North American and South America, northern Europe, and northern and central Asia, and an increase in intense tropical cyclone activity in the North Atlantic since about 1970 (IPCC 2007a, p. 30); and an increase in annual average temperature of more than 2 °F (1.1°C) across the U.S. since 1960 (Global Climate Change Impacts in the United States (GCCIUS) 2009, p. 27). Examples of observed changes in the physical environment include: an increase in global average sea level, and declines in mountain glaciers and average snow cover in both the northern and southern hemispheres (IPCC 2007a, p. 30); substantial and accelerating reductions in Arctic sea-ice (*e.g.,* Comiso *et al.* 2008, p. 1), and a variety of changes in ecosystem processes, the distribution of species, and the timing of seasonal events (*e.g.,* GCCIUS 2009, pp. 79–88).

The IPCC used Atmosphere-Ocean General Circulation Models and various greenhouse gas emissions scenarios to make projections of climate change globally and for broad regions through the 21st century (Meehl *et al.* 2007, p. 753; Randall *et al.* 2007, pp. 596–599), and reported these projections using a framework for characterizing certainty (Solomon *et al.* 2007, pp. 22–23). Examples include: (1) It is virtually certain there will be warmer and more frequent hot days and nights over most of the earth's land areas; (2) it is very likely there will be increased frequency of warm spells and heat waves over most land areas, and the frequency of heavy precipitation events will increase over most areas; and (3) it is likely that increases will occur in the incidence of extreme high sea level (excludes tsunamis), intense tropical cyclone activity, and the area affected by droughts (IPCC 2007b, p. 8, Table SPM.2). More recent analyses using a different global model and comparing other emissions scenarios resulted in similar projections of global temperature change across the different approaches (Prinn *et al.* 2011, pp. 527, 529).

All models (not just those involving climate change) have some uncertainty associated with projections due to assumptions used, data available, and features of the models; with regard to climate change this includes factors such as assumptions related to emissions scenarios, internal climate variability and differences among models. Despite this, however, under all global models and emissions scenarios, the overall projected trajectory of surface air temperature is one of increased warming compared to current conditions (Meehl *et al.* 2007, p. 762; Prinn *et al.* 2011, p. 527). Climate models, emissions scenarios, and associated assumptions, data, and analytical techniques will continue to be refined, as will interpretations of projections, as more information becomes available. For instance, some changes in conditions are occurring more rapidly than initially projected, such as melting of Arctic sea ice (Comiso *et al.* 2008, p. 1; Polyak *et al.* 2010, p. 1797), and since 2000, the observed emissions of greenhouse gases, which are a key influence on climate change, have been occurring at the mid- to higher levels of the various emissions scenarios developed in the late 1990s and used by the IPCC for making projections (*e.g.,* Raupach *et al.* 2007, Figure 1, p. 10289; Manning *et al.* 2010, Figure 1, p. 377; Pielke *et al.* 2008, entire). Also, the best scientific and commercial data available indicates that average global surface air temperature is increasing and several climate-related changes are occurring and will continue for many decades even if emissions are stabilized soon (*e.g.* Meehl *et al.* 2007, pp. 822–829; Church *et al.* 2010, pp. 411–412; Gillett *et al.* 2011, entire).

Changes in climate can have a variety of direct and indirect impacts on species, and can exacerbate the effects of other threats. Rather than assessing ''climate change'' as a single threat in and of itself, we examine the potential consequences to species and their habitats that arise from changes in environmental conditions associated with various aspects of climate change. For example, climate-related changes to habitats, predator-prey relationships, disease and disease vectors, or conditions that exceed the physiological tolerances of a species, occurring individually or in combination, may affect the status of a species. Vulnerability to climate change impacts is a function of sensitivity to those changes, exposure to those changes, and adaptive capacity (IPCC 2007, p. 89; Glick *et al* 2011, pp. 19–22). As described above, in evaluating the status of a species, the Service uses the best scientific and commercial data available, and this includes consideration of direct and indirect effects of climate change. As is the case with all potential threats, if a species is currently affected or is expected to be affected by one or more climate-related impacts, this does not necessarily mean the species is an endangered or threatened species as defined under the Act. If a species is listed as endangered or threatened, this knowledge regarding its vulnerability to, and impacts from, climate-associated changes in environmental conditions can be used to help devise appropriate strategies for its recovery.

While projections from global climate model simulations are informative and in some cases are the only or the best scientific information available, various downscaling methods are being used to provide higher-resolution projections that are more relevant to the spatial scales used to assess impacts to a given species (see Glick *et al,* 2011, pp. 58–61).

Regional landscapes can be examined by analyzing climate models that operate at small spatial scales; however, this approach involves some uncertainty. The uncertainty arises due to various factors related to difficulty in applying climate modeling to a smaller scale or unknown information, including regional weather patterns, local physiographic conditions, and fine-scale weather factors. Also, climate models do not model biological responses, such as life stages of individual species, generation time of species, and species' reactions to changing carbon dioxide levels not being included in the models. Most climate models do not incorporate a variety of plant-related factors that could be informative in determining how climate change could affect plant species (*e.g.,* effect of elevated carbon dioxide on plant water-use efficiency, the physiological effects on species of exceeding the assumed (modeled) bioclimatic limit, the life stage at which the limit affects the species (seedling versus adult), the lifespan of the species, and the movement of other organisms into the species' range) (Shafer *et al.* 2001, p. 207).

For southern Arizona, the most current downscaled climate projections are available with ⅛ degree resolution (approximately 12 km x 12 km) from the Coupled Model Intercomparision Project (Maurer *et al.* 2007, entire). A West-Wide Climate Risk Assessment (Bureau of Reclamation 2011) has been completed, but the focus of this study

was downscaled surface water projections for major river systems in the West. As such, it is less useful for predicting upland effects from future climate change scenarios, although stream flow is highly correlated with precipitation and temperature, which also affect upland ecosystems. Downscaled climate projections represent a consensus of multiple climate models, but climate models alone are not able to account for the myriad of biological processes that may affect a species that only inhabits a narrow range, as local effects may reduce or amplify the large-scale patterns that are projected over the larger spatial resolution of the global climate models (Ray *et al.* 2010, p. 24). In summary, global and regional climate models can play an important role in characterizing general changes to climate, which is a major determinant of species distributions, so that the potential impacts on natural systems can be assessed (Shafer *et al.* 2001, p. 213). However, they are less able to assess local impacts to species with a limited range, such as the three plants discussed in this finding.

Climate change is likely to affect the long-term survival and distribution of native species, such as *Amoreuxia gonzalezii,* through changes in temperature and precipitation. Hot extremes, heat waves, and heavy precipitation will increase in frequency, with the Southwest experiencing the greatest temperature increase in the continental United States (Karl *et al.* 2009, pp. 28, 129). In the southwestern United States, average temperatures increased approximately 1.5 °F (0.8 °C) compared to a 1960 to 1979 baseline (Karl *et al.* 2009, p. 129). By the end of this century, temperatures are expected to warm a total of 4 to 10 °F (2 to 5 °C) in the Southwest (Karl *et al.* 2009, p. 129).

Annual mean precipitation levels are expected to decrease in western North America and especially the southwestern States by midcentury (IPCC 2007, p. 8; Seager *et al.* 2007, p. 1181). The levels of aridity of recent drought conditions and perhaps those of the 1950s drought years will become the new climatology for the southwestern United States (Seager *et al.* 2007, p. 1181). As mentioned previously, southern Arizona is currently experiencing drought conditions, and there has been a decline in winter precipitation over the last 34 years.

Atmospheric levels of carbon dioxide are expected to double before the end of the 21st century, which may increase the dominance of invasive grasses leading to increased fire frequency and severity across western North America (Brooks and Pyke 2002, p. 3; IPCC 2002, p. 32; Walther *et al.* 2002, p. 391). Elevated levels of carbon dioxide lead to increased invasive annual plant biomass, invasive seed production, and pest outbreaks (Smith *et al.* 2000, pp. 80–81; IPCC 2002, pp. 18, 32; Ziska *et al.* 2005, p. 1328) and will put additional stressors on rare plants already suffering from the effects of elevated temperatures and drought.

In summary, climate change is affecting and will affect temperature and precipitation events in the future. We expect that *Amoreuxia gonzalezii* may be negatively affected by climate change with respect to drought or alteration in summer precipitation. However, we believe that *A. gonzalezii* is adapted to arid conditions, and the species has survived previous periods of low summer rainfall in Arizona. Although we believe climate change will impact plants in the future, the best available information does not allow us to determine the magnitude and scope of the potential effects on a local scale to *A. gonzalezii,* and therefore, we conclude that climate change is not a threat to the continued existence of this species, nor is it likely to become so.

Summary of Factor A

In conclusion, based on our review of the best available scientific and commercial information, we have determined that nonnative invasive species, fire, development, mining, and watershed degradation are not threats to *Amoreuxia gonzalezii.* Nonnative invasive species are not present in or near *A. gonzalezii* populations; therefore, they are not a threat to the species. The best available information does not indicate that fire, development, mining, or watershed degradation are threats to the species. Drought may influence the population structure of *A. gonzalezii,* but we conclude that drought is not a threat to the species because the species has some adaptations for living in arid environments and has survived periods of reduced summer precipitation. We acknowledge that climate change, particularly the predictions of less frequent, but perhaps more intense, summer precipitation, and increasing temperatures in the Southwest, will affect individuals populations of *A. gonzalezii.* However, the species is adapted to arid conditions, and therefore we have determined that climate change is not a threat to *A. gonzalezii.* Thus, the present or threatened destruction, modification, or curtailment of its habitat or range is not a threat to *A. gonzalezii.*

Factor B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Hodgson (2001, p. 91) notes that roots, young leaves, fruits, and seeds of *Amoreuxia gonzalezii* are edible. She says that, historically, the plant had been collected in great amounts and was ''once an important food source to various southwestern people.'' For example, the Onavas Pimas Tribe historically harvested this species frequently, although more recently, harvest is only incidental (Hodgson 2001, p. 92). The tubers are collected and roasted by the Seri Indians on Tiburon Island, and by residents of Baja California. Evidently, the tubers of this species can be broken up and new plants will grow from the tuber pieces. In 1959, the noted anthropologist Homer Aschmann (Hodgson 2001, p. 94) observed with the similar and sympatric species *Amoreuxia palmatifida* that ''when the larger aboriginal population [native peoples of Mexico] exploited more regularly the flats where they grow, a larger yield of roots may have been maintained,'' implying that local peoples who relied on *Amoreuxia* for food may have enhanced populations by disturbing the soil and cutting roots. He stated that areas that were visited more regularly looked as if they had been plowed; the more disturbance, the more *A. palmatifida* grew. Both *A. palmatifida* and *A. gonzalezii* were historically, and continue to be, used by native peoples in a similar fashion, although we are unaware of this type of harvesting in Arizona. In summary, *A. gonzalezii* plants and roots have been used historically in parts of Mexico. There is no information regarding the current use of this species in Mexico, or its use in Arizona. Therefore, based on our review of the best available information, we have determined that collection of the plants or the roots is not a threat to *A. gonzalezii,* or is likely to become so.

Amoreuxia gonzalezii is not a plant of horticultural interest. There is no documentation of any instances where *A. gonzalezii* was collected from the wild other than as voucher specimens to document occurrences (*http://ag.arizona.edu/herbarium*) or seed collection for the purposes of conserving the species. Therefore, based on the best available information, we have determined that collection is not a threat to the continued existence of the species, or is likely to become so.

Factor C. Disease or Predation

There is no information indicating that disease affects *Amoreuxia*

gonzalezii. However, *A. gonzalezii* is very palatable to cattle and other ungulates (Hodgson 2001, p. 94). While some of the known locations in Arizona occur on steep limestone cliffs largely precluding cattle herbivory, plants in other locations are more susceptible. Hodgson (1989, p. 2) noted finding *Amoreuxia* plants in the Devil's Cashbox area with inflorescences (flowers) eaten. She was unable to ascertain if these plants were *A. gonzalezii,* or the more common *A. palmatifida* because the plants had no fruit (Hodgson 1989, p. 2). She also noted 13 missing plants from the Devil's Cashbox area just weeks after a previous site visit in 1990 (Hodgson 1989, p. 7). It is unknown how susceptible populations in Mexico are to grazing pressure. During a 1988 visit to a population of *A. gonzalezii* outside of Moctezuma, Sonora, Hodgson (1989, p. 2) noted that most plants had been browsed or grazed. Grazing precludes sexual reproduction and, if it occurs on a frequent basis, may lead to reduced seed production (Hodgson 1994, p. 9). However, *A. gonzalezii* also reproduces asexually; hence, the populations are not totally dependent on seed production for reproduction (Hodgson 2001, p. 94). Our review of the best available information did not produce any evidence that the long-term viability of *A. gonzalezii* populations in Arizona and Mexico has been affected by grazing, and therefore, we conclude that grazing is not a threat to this species.

It has been suggested that javelinas (hoofed mammals in the peccary family) dig up the roots of *Amoreuxia gonzalezii* and that this may constitute a threat to the species (NatureServe 2010). The Service (2011a, p. 1) saw no evidence of this during the 2011 site visit, and there is no information available on how often javelina dig up the plants, or on what the long-term effects are to the populations. In addition, if the plants respond to digging by producing more plants, javelinas rooting in the soil may promote asexual reproduction. Therefore, after review of the best available information, we conclude that javelina digging up the plants and eating the roots of *A. gonzalezii* is not a threat to the species.

Based on the best available information, we have determined that disease and predation are not threats to the continued existence of *Amoreuxia gonzalezii,* nor are they likely to become so.

Factor D. The Inadequacy of Existing Regulatory Mechanisms

Amoreuxia gonzalezii is not protected by Arizona Native Plant Law (Arizona Revised Statutes, Chapter 7 1993, entire). It does not appear under any of the law's four categories of protection, although previously it was given consideration to be included for protection within the ''Salvage Restricted Protected Native Plants'' (Hodgson 1994, p. 9), a level of protection that Hodgson considered inadequate. It was, however, never placed on this list (Hodgson 2011, pers. comm.). This means that the populations that occur on private land in Arizona have no protections. However, regardless of any protection under the Arizona Native Plant Law, our five-factor analysis suggests that *A. gonzalezii* populations are not subject to negative impacts at such a level that would place the species at risk. Evidence of this can be found in the Thomas Canyon population, which is on private property, and remains intact, as evidenced by surveys completed this year. Although *A. palmatifida* and *A. wrightii* are on the list of protected animals and plants for Mexico, *A. gonzalezii* is not listed and therefore receives no management considerations within its Mexican range (SEMARNAT 2008). Even so, we have determined that populations in Mexico are not subject to negative impacts at a level that would place the species overall at risk.

Amoreuxia gonzalezii is considered by the Forest Service to be a ''sensitive species'' in the Coronado National Forest. A sensitive species is defined as one not yet warranting listing as endangered or threatened, but which is sufficiently rare that its future survival is of concern (Forest Service Manual (FSM) 2670). The management of sensitive species is described in FSM 2670, and the management objectives are to develop and implement management practices to ensure that species do not become endangered or threatened because of Forest Service actions; maintain viable populations of all native and desired nonnative wildlife, fish, and plant species in habitats distributed throughout their geographic range on National Forest System lands; and develop and implement management objectives for populations or habitat of sensitive species or both.

In addition, the Forest Service has to consider the effects of their actions on the viability of sensitive species through the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et. seq.*) process. As defined by Forest Service policy, actions must not result in loss of species viability or create significant trends toward the need for Federal listing. *A. gonzalezii* receives these protective measures through NEPA on Coronado National Forest land.

In summary, *Amoreuxia gonzalezii* populations in the Coronado National Forest are protected by their status as sensitive species. We believe that the requirement to consider the species' long-term viability in the NEPA planning process provides adequate protection for the populations of *A. gonzalezii* in the Coronado National Forest. Any one factor in our analysis may constitute a threat; however, it is the combined analysis of all the potential threats to the species that determine whether a species warrants listing as an endangered or threatened species under the Act. In this case, there is no indication of actions or potential threats to the species on private land or in Mexico that rise to a level such that listing is warranted. As such, we conclude that the best available information indicates that *A. gonzalezii* is not threatened by inadequate existing regulatory mechanisms.

Factor E. Other Natural or Manmade Factors Affecting Its Continued Existence

Amoreuxia gonzalezii has been classified as the global rank of G1, Critically Imperiled, by NatureServe (2010) due to the small number of small populations globally, palatability to cattle, and threat of exotic annual grasses. Even though there are only 2 occurrences in the United States, there seem to be at least 12 occurrences in Mexico. There have been no systematic surveys in Mexico, and very few population estimates.

Information on a species' rarity is relevant to the conservation status of a species. Generally speaking, a species that has a geographically restricted range is likely to be more susceptible to environmental threats (*e.g.,* fire, flood, drought, human land use), should they occur, than a species that is not rare, because one fire or flood could affect a larger total percentage of the range of a rare species than of a widespread species. However, there is no available information in this case to evaluate whether any environmental threats are currently acting upon this potentially rare species in a negative way, or are reasonably likely to act on it in the future. The fact that a rare species is potentially vulnerable to stochastic processes does not necessarily mean that it is reasonably likely to experience, or have its status affected by, a given

stochastic process within timescales that are meaningful under the Act.

A species that has always been rare, yet continues to survive, could be well-equipped to continue to exist into the future. Many naturally rare species have persisted for long periods within small geographic areas, and many naturally rare species exhibit traits that allow them to persist despite their small population sizes. Consequently, the fact that a species is rare does not necessarily indicate that it may be in danger of extinction in the foreseeable future.

The best available information provides no evidence that effects often associated with small populations that were not naturally rare, such as inbreeding depression or genetic drift, may be occurring in *A. gonzalezii* populations. There is also no evidence that potential effects to the species or its habitat may be more significant than historically present such that a naturally rare species, such as *A. gonzalezii,* would be at risk. Therefore, we conclude that overall rarity and small population size are not a threat to *A. gonzalezii,* nor are they likely to become so.

Finding for *Amoreuxia gonzalezii*

As required by the Act, we evaluated the five factors in assessing whether *Amoreuxia gonzalezii* is endangered or threatened throughout all or a significant portion of its range. We examined the best scientific and commercial information available regarding the past, present, and future threats faced by *A. gonzalezii.* We reviewed the petition, information available in our files, other available published and unpublished information, and we consulted with recognized species experts.

There are no obvious threats to *Amoreuxia gonzalezii* or its habitat. The species has been used historically as a food source by indigenous people, but we have no information that collection and use of the plants and tubers are currently a threat to the species or likely to become so. Long-term drought and reduced summer rainfall will likely affect individual plants and populations. However, the plants are tolerant of moderate disturbance, and the species is adapted to arid condition, as evidenced by the plants' survival during recent periods of reduced summer rainfall. Based on the limited information available, we conclude that drought is not threat to this species or likely to become so. Climate change will likely affect the status of A. *gonzalezii* in the future; however, the limited information available that can be applied at a local scale does not suggest that climate change is likely to threaten the species. Regarding other factors potentially affecting *A. gonzalezii,* including nonnative, invasive species; fire; development; mining; and watershed degradation, the best available scientific information provides no evidence indicating that they are currently threatening the species or likely to do so in the future. Similarly, there is no evidence that overutilization, disease, or predation are affecting this species. In addition, we have determined that small population size is also not a threat to the species because the species appears to be naturally rare and there are no potential threats acting on the species above historical levels. Further, because we have determined there are no threats on the species, and none likely, existing regulatory mechanisms are adequate.

Based on our review of the best available scientific and commercial information pertaining to the five factors, we find that the potential threats are not of sufficient imminence, intensity, or magnitude to indicate that *Amoreuxia gonzalezii* is in danger of extinction (endangered) or likely to become endangered within the foreseeable future (threatened), throughout all of its range.

Significant Portion of the Range

Having determined that *Amoreuxia gonzalezii* is not in danger of extinction, or likely to become so, throughout all of its range, we must next consider whether there are any significant portions of the range where *A. gonzalezii* is in danger of extinction or is likely to become endangered in the foreseeable future.

The Act defines an endangered species as one ''in danger of extinction throughout all or a significant portion of its range,'' and a threatened species as one ''likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' The term ''significant portion of its range'' is not defined by the statute. For the purposes of this finding, a portion of a species' range is ''significant'' if it is part of the current range of the species, and it provides a crucial contribution to the representation, resiliency, or redundancy of the species. For the contribution to be crucial, it must be at a level such that, without that portion, the species would be in danger of extinction. We also considered the historical range of the species, and have determined that the current range is no different from the historical range. Therefore, there has been no loss of the historical range, and no further analysis of the historical range is required.

In determining whether *Amoreuxia gonzalezii* is endangered or threatened in a significant portion of its range, we considered status first to determine if any threats or potential threats acting individually or collectively endanger or threaten the species in a portion of its current range. We evaluated the current range of *A. gonzalezii* to determine if there is any apparent geographic concentration of the primary stressors potentially affecting the species including nonnative, invasive plants; fire; development; mining; watershed degradation; and drought. We have analyzed the stressors to the degree possible, and determined that they are essentially uniform throughout the species' range. We also found the stressors are not of sufficient imminence, intensity, magnitude, or geographically concentrated such that it warrants evaluating whether a portion of the range is significant under the Act. We do not find that *A. gonzalezii* is in danger of extinction now, nor is likely to become endangered within the foreseeable future, throughout all or a significant portion of its range. Therefore, listing *A. gonzalezii* as an endangered or threatened species under the Act is not warranted at this time.

We request that you submit any new information concerning the distribution and status of, or threats to, *Amoreuxia gonzalezii* to our U.S. Fish and Wildlife Service Office (see **ADDRESSES** section) whenever it becomes available. New information will help us monitor *A. gonzalezii* and encourage its conservation. If an emergency situation develops for *A. gonzalezii,* or any other species, we will act to provide immediate protection.

Species Information for *Astragalus hypoxylus*

Species Description

Barneby (1964, pp. 1028–1029) and Warren *et al.* (1991, pp. 3–4) describe *Astragalus hypoxylus* as an herbaceous perennial, in the Fabaceae (Pea) family. The species forms a compact mat of stems that typically lay flat against the ground, although the outer ends of the stems may turn up. The mat can be up to 15 cm (6 in) in diameter. The species forms a tap root that is dense and fibrous. The alternate leaves are compound with 11 to 13 ovate leaflets that are each 2 to 4.5 millimeters (mm) (0.1 to 0.2 in) long. The leaflets are bicolored; the undersides are gray with sparse tiny hairs; the tops of the leaflets are yellowish-green, smooth, and

hairless. The leaflets have a distinct fold along the midrib.

The inflorescence is very compact and ball-shaped, approximately 1 cm (0.4 in) in diameter and 1 to 1.5 cm (0.4 to 0.6 in) long and looks somewhat like clover flowers. The flowers are approximately 6 mm (0.2 in) long with petals that are whitish, with light purple tips. The flower stalks are erect above the vegetative mat. Fruits are small, oval pods 7 to 9 mm (0.3 to 0.35 in) long and 2 to 2.5 mm (0.1 to 0.16 in) diameter. The pods are yellowish at the base and purplish towards the tip when ripe. The pods do not split open, but drop whole from the plant (Warren *et al.* 1991, pp. 3–4).

Astragalus hypoxylus most closely resembles *A. parvus* (no common name) and *A. nothoxys* (sheep milkvetch). *Astragalus parvus* is only known from Mexico, but *A. nothoxys* may be found with *A. hypoxylus* (Johnson *et al.* 1992, p. 3). There are field characteristics that differentiate the two species. *A. nothoxys* has much longer flowering stalks, and the inflorescence is spread out along the flowering stems, unlike the compact, clover-like flowers of *A. hypoxylus.* The seed pods of *A. nothoxyus* are longer, narrower, three-sided, and green when fully ripe, while those of *A. hypoxylus* are oval and yellowish-purple when ripe. There has never been any disagreement in the scientific literature regarding the taxonomy of this species; thus we consider *A. hypoxylus* to be a valid taxon and a listable entity.

Habitat and Biology

Levin (1987, pp. 170–171) described the habitat that supports *Astragalus hypoxylus* as ''stony openings in pine-oak juniper woodland, restricted to limestone derived soils.'' Van Devender (1986, pers. comm.) noted the same type of habitat, on a south-to-southwest exposure. Warren *et al.* (1991, p. 7) observed that *A. hypoxylus* is found in open, rocky clearings in woodlands comprised of *Quercus emoryi* (Emory oak), *Q. oblongifolia* (Mexican blue oak), *Juniperus deppeana* (alligator juniper), and *Pinus cembroides* (Mexican pinyon). The ground is characterized by loosely consolidated, gravelly soil composed of limestone and weathered rock. The plants are found at an elevation of approximately 1,676 m (5,500 ft) (Warren *et al.* 1991, p. 7). This habitat type is referred to as oak-savannah and is relatively common in the mountains of southeastern Arizona between elevations of 1,370 to 1,830 m (4,494 to 6,000 ft) (Brown 1982, p. 59).

Astragalus hypoxylus produces flowers in the spring (April-May), with fruits maturing approximately 3 weeks after the onset of flowering (Johnson *et al.* 1992, p. 5). Pollination studies on different species of *Astragalus* (Karron 1988, p. 332; Sugden 1985, pp. 303–304; Green and Bohart 1975, pp. 383–384; Geer *et al.* 1995, p. 23) reported that several bee species in the genera *Bombus, Osmia,* and *Anthophora* were the primary pollinators. However, there have been no studies on the pollinators for *A. hypoxylus.*

The pods of *Astragalus hypoxylus* do not split open when ripe and usually fall to the ground near the parent plant. However, the pods are light and may be blown to other locations by the wind (Johnson *et al.* 1992, p. 6). Seedlings are often detected in open places away from the parent plants; however, nothing is known regarding seed dispersal of this species (Falk, 2011, pers. obs.).

Germination studies of *Astragalus hypoxylus* were carried out by the Desert Botanical Garden (Garden) as part of the Center for Plant Conservation National Collection program for conserving rare plants and their germplasm. Seeds were collected from the Harshaw and Bear Canyon populations in 1991 and 1992. During the seed collection trips, the biologists noted that ''plants were frequent along disturbed areas (erosion cuts, dirt roads)'' (Pritchett-Kozak and Ecker 1992, p. 20). Two germination tests were done in 1992, with germination rates of 66 and 76 percent (Pritchett-Kozak and Ecker 1992, p. 20). Tests done in 1991 with fresh seed and previously frozen seed were used, and the germination rates were high for both sets of seeds, indicating that freezing does not interfere with seed viability. Germination took place during an average daytime temperature range of 73 to 86 °F (23 to 30 °C) (Ecker 1991, p. 1). These warm daytime temperatures may indicate that the seeds germinate in the summer, in response to summer rainfall, rather than in the winter. Also, the seeds readily germinated in August, indicating that there is no summer dormancy for these seeds (Ecker 1991, p. 1). Currently, there are approximately 14,000 seeds in frozen storage at the Garden and the National Seed Storage Lab in Ft. Collins, Colorado (*http://www.centerforplantconservation.org*). These seeds are available for re-introduction efforts or augmentation of existing populations.

In 1993, plants produced from collected seed were initiating floral buds in the greenhouse by February 20. These were plants that were produced from previous seedling experiments. On March 16, the plants were placed outside on the grounds of the Garden, underneath native trees. The plants began flowering profusely by early April. Open pollination (plants were left in the open and pollination occurred naturally) was successful, and the plants were producing numerous fruits by April 20. There was no indication of pollinators in the area. Plants that had been previously left in the greenhouse had not produced seed, probably due to a lack of pollinators in the greenhouse. Controlled cross-pollination of two plants (two flowers per plant) was conducted on April 13, which resulted in two fruits per plant (Pritchett-Kozak 1993, p. 20). Earlier attempts at self-pollination failed, but the technique (use of a small paintbrush to transfer the pollen) may not have been optimal (Pritchett-Kozak and Ecker 1992, p. 21). The results of the open pollination and the controlled cross-pollination experiment likely indicate that *Astragalus hypoxylus* is an obligate outcrosser (Pritchett-Kozak 1993, p. 20).

In conclusion, there is not a great deal of information on the biology and ecology of this species. The pollinators of the species are unknown; it is surmised that the plants are obligate outcrossers, and that pollination takes place in the field because fruit and seeds are produced. It is not known how seed is dispersed. Based on the germination experiments conducted by the Desert Botanical Garden, the best available information suggests that plants germinate in response to summer rainfall. Also, there is some anecdotal information that these plants occupy disturbed areas and may be tolerant of moderate disturbance.

Distribution, Abundance, and Trends

Astragalus hypoxylus was first collected by J. G. Lemmon in 1882 in Cochise County, Arizona, at a location described as ''Mahoney's Ranch, near Ft. Huachuca.'' (Johnson *et al.* 1992, p. 4). This site description proved to be so vague that this area was never able to be located again (Johnson *et al.* 1992, p. 4). The species was not detected again until 1986, when it was collected in the Patagonia Mountains, approximately 4.5 kilometers (km) (2.8 miles (mi)) south of Harshaw on the road to Washington Camp, in the Coronado National Forest (Levin 1987, pp. 170–171). Later in 1986, botanists visited this same location and counted approximately 107 plants in the area, again noting that the plants were ''common in grassy openings in oak woodland on relatively steep slopes with coarse sandy soils'' (Van Devender 1986, pers. comm.; Kennedy 1986, pers. comm.). In 1991, Malusa *et al.* (1992, p. 25) found two additional populations in the Patagonia

Mountains, near the Harshaw site. Approximately 180 plants were found in adjacent canyons. These populations are within a couple of miles of the Harshaw site and, for the purposes of this finding, will be referred to as the Harshaw2 populations.

In addition, many surveys were undertaken by staff at the Nature Conservancy and other botanical contractors to the Coronado National Forest, and populations of *Astragalus hypoxylus* were found in the Huachuca Mountains in Scotia, Bear, and Sycamore canyons, and in Collins Canyon in the Canelo Hills (Warren *et al.* 1989, p 30; Gori *et al.* 1990, p. 36; Gori *et al.* 1991, p. 45; Fishbein and Warren 1994, pp. 6–7). Populations in Bear, Sycamore, and Scotia canyons are dispersed over a wide area and composed of several sub-populations, but, for the purposes of this finding, will be referred to as individual populations. All of these locations are on the Sierra Vista Ranger District of the Coronado National Forest. In addition, suitable habitat on Ft. Huachuca and in Sonora, Mexico was searched, but plants were not found (Warren *et al.* 1991, pp. 5–6; Johnson *et al.* 1992, pp. 4–5; Warren and Reichenbacher 1991, p. 26; Fishbein and Warren 1994, pp. 6–7; Malusa 1995, p. 1). Therefore, the current distribution encompasses only plants that occur along Harshaw Road in the Patagonia Mountains, in Bear, Scotia, and Sycamore canyons in the Huachuca Mountains, and in Collins Canyon in the Canelo Hills.

The Nature Conservancy established monitoring plots for *Astragalus hypoxylus* in several of the populations (Warren *et al.* 1991, p. 8). Two plots were established to monitor growth, reproduction, and mortality of individual plants in the Harshaw population. These plots were established in 1988, but one plot was abandoned in 1989 because the site was steep and the survey was causing damage to the plants within the monitoring plot. The remaining plot was monitored annually, from 1989–1991 and in 1993. Another plot was established at the Bear Creek population in 1989, and data were collected from this plot in the same years as the Harshaw plot. All plots were monitored in late April or May, when the plants flower and set fruit. Neither monitoring plot has been evaluated since 1993. However, some occupied sites were visited in 1995, in 2010, and in 2011, and population estimates were made, although no other data were collected in the monitoring plots. Table 1 presents population estimates for the known locations.

TABLE 1—POPULATION COUNTS AND ESTIMATES FOR ASTRAGALUS HYPOXYLUS

Population (year of discovery)	Estimated number of individuals (year)
Harshaw (1986)	100–200 (1986)
** plants in both monitoring plots	109 (1988) **
* plants in remaining monitoring plot	112 (1989) *
	70 (1990) *
	139 (1991) *
	114 (1993) *
	22 (2011)
Bear Canyon (1988)	110 (1989) *
* plants in the monitoring plot	60 (1990) *
	85 (1991) *
	61 (1993) *
	154 (1995) *
	0 (2010) *
Bear Canyon (1990)	50 (1990)
(plants found outside the monitoring plot and in other areas of Bear Canyon).	346 (1995)
	100 (2010)
Scotia Canyon (1990)	600–700 (1990)
	1058 (1995)
	500–600 (2010)
Harshaw2 (1991)	180 (1991)
	0 (2011)
Sycamore Canyon (1993)	320 (1993)
	70–80 (1994) (not all sub-populations visited)
	65–80 (1994) (not all sub-populations visited)
	12 (1995) (not all sub-populations visited)
Canelo Hills (1993)	No estimate given in 1993; presence of ''small population'' was noted.

Based on the surveys and monitoring data, there have been some declines in the numbers of individuals found in the monitoring plots and in additional occupied locations. The Harshaw population appeared relatively stable throughout the monitoring period, with some fluctuations in the overall numbers. For the period 1991–1993, survivorship was 40 percent, with 64 recruits in 1993, which represented 56 percent of the population in the plot. It is unfortunate that the Harshaw site as not visited again until May 2011 (Service 2011b, pp. 1–4). During this visit, 5 healthy plants, which had flowered, were found in the cutbank of the road, and 14 additional plants were found nearby, slightly north of the road. The area where the original Harshaw monitoring plot was thought to have been was searched thoroughly and only three plants were found. These plants were very small compared to those near and in the cutbank of the road. The entire site was described as very dry, and the native grasses ''crunched beneath our feet'' (Service 2011b, p. 2). It is possible that the plants near the road were getting additional moisture due to their downslope location and their proximity to the road. Additional searches were conducted near the described locations for the Harshaw2 populations, but no plants were found. Given the 18-year gap in monitoring or visiting this site, we are unable to determine the long-term trend for this population.

The situation is similar for the Bear Canyon monitoring plot. Overall numbers fluctuated, but as of 1995,

there were more plants in the plot than there had been when the plot was established. Fifteen years passed before the next visit, which occurred in October 2010 (Service 2010, p. 1). This is not the ideal time of year for a visit, but the plants are usually visible if there has been summer rainfall. In this case, based on the growth of the perennial grasses in the surrounding area, it seemed as if there had been summer precipitation (Falk 2011, pers. obs.). No plants were found in the monitoring plot, but there were plants to the east and south of the plot. The plants were widely scattered over the area. There was no evidence of flowering or fruits.

Additional surveys were conducted that day (Service 2010, p. 1) along Forest Service Road 61, near Sycamore Canyon. Plants were scattered in several different locations adjacent to the road, including some areas that had been recently disturbed by vehicle traffic. The majority of the plants observed were healthy. Many of these plants looked like juveniles produced during the summer of 2010. The last site visited was Scotia Canyon (Service 2010, p. 1). Many plants were observed below the uppermost pond on the former Peterson ranch property (now part of the Coronado National Forest) and immediately downslope of that. Some of the largest plants were in the roadbed, associated with eroded portions of the road. The observations of these plants growing in disturbed areas (road cuts and eroded banks) may indicate that this species is adapted to and may tolerate moderate disturbance. We were unable to determine long-term trends for these populations based on inconsistent monitoring efforts.

Another type of disturbance to the plant's habitat is fire. There is no information on the plant's adaptation to fire, but the habitat where the species grows is subject to fire on a periodic basis (Kaib *et al.* 1996, p. 261). The observation that *Astragalus hypoxylus* is tolerant of moderate disturbance may indicate that the species is fire adapted, and may need periodic fire to reduce competition from grasses and remove overstory vegetation that may increase understory competition and shading.

Some of the fluctuation in population size may be attributable to variation in climate. During dry years, there was increased mortality of plants, and larger plants died in association with consecutive dry years (Johnson *et al.* 1992, p. 7). Recruitment and survival may also be correlated with winter precipitation as evidenced by the number of recruits that were counted in 1993 in the Bear Canyon plot; more than 72 percent of the individuals counted that year were seedlings (Falk and Warren 1994, p. 36). Coincidentally, 1992 was an El Niño year, with above-average precipitation for southern Arizona.

There are some observations from the monitoring efforts that may shed light on the ecology of this species. Population size and flower production appear to fluctuate greatly from year to year. There seems to be a correlation with winter rainfall. That is, when winter precipitation is good, the plants are larger and they produce more flowers and fruit (Warren *et al.* 1991, p. 9; Johnson *et al.* 1992, pp. 7–8). *Astragalus hypoxylus* has a taproot, and individual plants may be dormant (no above-ground biomass visible) during dry years, but produce growth again when there is rain (Falk 2011, pers. obs.). Consequently, the reduction in numbers across almost all of the populations may be in response to the on-going drought in southern Arizona. Winter rainfall has been declining steadily for the last 34 years, and most noticeably in the period from 1998 to the present (McPhee *et al.* 2004, p. 2). Although the correlation between population size and climate is not a formal test of this hypothesis, the sharp decline noted for most of these populations may be the result of prolonged drought.

Five-Factor Evaluation for *Astragalus hypoxylus*

In making this finding, information pertaining to *Astragalus hypoxylus* in relation to the five factors provided in section 4(a)(1) of the Act is discussed below.

Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Potential factors that may affect the habitat or range of *Astragalus hypoxylus* are discussed in this section, including: (1) Recreation; (2) watershed degradation resulting from improper livestock grazing; (3) nonnative invasive species; (4) fuel wood harvesting; (5) fire; (6) road maintenance; (7) drought; and (8) climate change.

Recreation

All known populations of this species occur on the Sierra Vista Ranger District, on the Coronado National Forest. There is no special management for the populations on Forest Service lands. The populations at Harshaw do not appear to be affected by any recreational activities (Johnson *et al.* 1992, p. 12). There was no sign of recreational activity or impacts during the 2011 site visit (Service 2011b, entire). The same is true for the populations scattered along Forest Service Road 61, near Sycamore Canyon and in Scotia Canyon. In 2010, neither of these populations showed evidence of trampling or associated effects from recreational activities.

The only population that has been identified as being impacted by recreational activity has been the upper Bear Canyon population. This population has been impacted by an informal parking lot near the turnoff to Wakefield Camp, which allows for access to Bear Creek, and is a very popular area for dispersed camping and hiking (Warren *et al.* 1991, p. 10; Gori *et al.* 1991, p. 45). In 2000, the Forest Service blocked off the informal parking area, created a formal parking in a less sensitive area, and restricted access to the Bear Creek riparian area (Frederick 2011, pers. comm.). This site has not been evaluated to determine if these changes reduced the impacts from recreational activity on *Astragalus hypoxylus.* At any rate, this population is relatively small (50 plants were estimated at the time of discovery in 1990) (Gori *et al.* 1991, p. 45) and represents less than 10 percent of the current population. In conclusion, recreational impacts may have affected only one of the sub-populations in the entire range of the species, and corrective actions were taken to reduce the impacts. Review of the best available scientific information revealed no further evidence that recreation is negatively affecting other *A. hypoxylus* populations; therefore, we determined that recreation is not a threat to the continued existence of the species, nor is it likely to become so.

Livestock Grazing

All of the *Astragalus hypoxylus* populations occur with Forest Service grazing allotments. The Harshaw populations are within the Bender allotment, and all of the other populations are located within the Lone Mountain allotment. The following information is from the Service's biological opinion on the Continuation of Livestock Grazing on the Coronado National Forest (2–21–98–F–399–R1) and additional details can be found in that document. The Bender allotment is 1,287 hectares (ha) (3,180 acres (ac)) and supports a 14-cow-and-calf operation. Grazing is allowed year-round and there is only one pasture. The allotment is reported to be in moderately good condition. The Lone Mountain allotment is 15,435 ha (38,140 ac), divided into 27 pastures. It supports a 1,346-cow-and-calf operation. The allotment is reported to be on an

upward trend, with 75 percent of the allotment classified as being in moderately high range condition. Both the Bender and Lone Mountain allotments are reported to be in moderately high range condition, and watershed degradation is not likely to be a problem in allotments that are maintained in good to high range conditions.

The Coronado National Forest has a drought policy which directs grazing permittees to work with the Forest when rainfall for the water year (beginning October 1) is less than 75 percent of normal by March 1 and the long-range forecast is for less than normal precipitation. In addition, critical habitat for *Liliaeopsis schaffneriana* var. *recurva* (Huachuca water umbel) is within the Lone Mountain allotment. As such, there are additional restrictions placed on the grazing practices in this allotment to protect occupied areas and critical habitat. Several areas within this allotment receive special protections, such as the Peterson pasture, which contains Scotia, Sycamore and Bear canyons. The pastures are grazed in winter (November–March) and only when winter rains are sufficient to provide adequate water throughout the pasture to encourage livestock dispersal away from the canyon bottom. Utilization of upland browse is not permitted to exceed 35–45 percent. These restrictions benefit *Astragalus hypoxylus* because they reduce impacts from livestock grazing and limit use of the upland areas during drought periods, when overgrazing and trampling of habitat are more likely to occur.

There were a few observations of trampling on *Astragalus hypoxylus* habitat in the Bear Creek population (Johnson *et al.* 1992, p. 12). Warren *et al.* (1991, p. 10) notes that livestock grazing, although present in the area, does not seem to pose a direct threat. Livestock trampling may disturb the soil and disrupt seedling establishment. Population visits in 2001 and 2011 (Service 2010, p. 1; Service 2011b, p. 2) did not note the presence of livestock or trailing through the populations.

Livestock have not been observed to eat *Astragalus hypoxylus.* Many species of *Astragalus* contain poisonous compounds, known as nitro-toxins, which are highly toxic to livestock (Williams and Barneby 1977, p. 310). *A. nothoxys,* which sometimes grows near and in proximity to *A. hypoxylus* populations, has been tested and does contain nitro-toxins (Johnson *et al.* 1992, p. 3). Livestock have been observed to graze on *A. nothoxys,* primarily when forage is lacking (Schmutz *et. al.* 1968, pp. 26–27). The Forest Service has not indicated that this species has caused any problems with livestock in the Forest. Any eradication program to eliminate *A. nothoxys* could possibly harm adjacent *A. hypoxylus;* however, there is no evidence of any efforts to eradicate *A. nothoxys. A. hypoxylus* has not been tested for nitro-toxins, but many species in the Leptocarpa section of *Astragalus* (*A. hypoxylus* is classified in this section) contain these chemicals. At any rate, the limited distribution of *A. hypoxylus* and the lack of observation of cattle eating this plant indicates that the potential poisoning of livestock is unlikely.

In summary, all populations of *Astragalus hypoxylus* occur in grazing allotments. Those grazing allotments are being managed in ways that promote healthy watershed and good range condition. The Lone Mountain allotment has additional grazing practices that protect riparian and upland habitat, resulting in improved watershed health, which benefits upland species, including *A. hypoxylus.* The best available information does not provide further evidence that livestock grazing is negatively affecting populations of *A. hypoxylus;* therefore, we have determined that livestock grazing is not a threat to the continued existence of the species now, nor is it likely to become so.

Nonnative, Invasive Species

Nonnative species can have negative effects on the ecology of native plant communities, as well as individual species (Brooks *et al.* 2004, p. 677; Alvarez and Cushman 2002, p. 1434; Mooney and Cleland 2001, p. 5446). However, there are no nonnative species that have been detected in the populations of *Astragalus hypoxylus.* The only nonnative grass that occurs in the vicinity of these populations is *Eragrostis lehmanniana* (Lehmann lovegrass), but this grass has not been seen in the monitoring plots or growing in the populations (Falk 2011, pers. obs.). *Eragrostis lehmanniana* can form dense stands, increasing fine fuels and fire danger (Anable *et al.* 1992, pp. 186–187), but there are no continuous stands near any of the *A. hypoxylus* populations (Falk 2011, pers. obs.). The best available scientific information does not suggest that nonnative invasive species are a threat to the continued existence of *A. hypoxylus,* nor are they likely to become so.

Fuel Wood Harvesting

The Coronado National Forest did allow fuel wood harvesting in the past near the known populations. It is unknown if these past activities affected *Astragalus hypoxylus* populations. The collection of dead and down wood was also allowed, with a permit, but this practice was stopped in 1990 (Johnson *et al.* 1992, p. 12). Fuel wood harvesting is no longer allowed in these areas (Frederick 2011, pers. comm.). The best available information does not provide evidence that fuel wood harvesting is currently affecting *A. hypoxylus* populations; therefore, we have determined that fuel wood harvesting is not a threat to *A. hypoxylus,* nor is it likely to become so.

Fire

As mentioned under *Habitat and Biology,* there is no information on *Astragalus hypoxylus* and fire effects. The Forest Service's Fire Effects Information System (*http://www.fs.fed.us/database/feis/*) contains information on 7 species of *Astragalus* in the United States, some of which are adapted to fire, and may even require fire, to complete one of their life cycles (*i.e.,* seeds need to be scarified by fire before germinating). It is unknown if this is the case for *A. hypoxylus,* but we hypothesize that this species may be tolerant of fire because of the plant community where it grows and its tolerance for moderate disturbance, including fire. Also, fire may be important in maintaining habitat for *A. hypoxylus* by removing the overstory, thus reducing competition and shading. In summary, given the limited available information about the effect of fire on *A. hypoxylus,* we determine that fire, or lack thereof, is most likely not a threat to the continued existence of *A. hypoxylus.*

Road Maintenance

Portions of a few of the *Astragalus hypoxylus* populations are near roads, and may be threatened by road maintenance activities, such as blading (clearing and smoothing the road with a large piece of equipment). However, the species appears to be tolerant of moderate disturbance. In 2010, *A. hypoxylus* were observed near the road going through Scotia Canyon. Portions of the road were well eroded, resulting in rills (portions of the road that are washed out, forming small gullies). There were 10–20 plants growing in the roadbed, on top of the erosion rills. These were some of the largest and healthiest plants observed in Scotia Canyon (Service 2010, p. 1). As mentioned previously, in 2011, Service biologists found 19 plants at Harshaw that were growing in the cutbank of the road, and these plants were larger and

healthier than the plants upslope in the area of the monitoring plot (Service 2011b, p. 1). This may indicate that plants are receiving supplemental water due to the proximity of the road and concentrated rainwater runoff, which may be why the plants are larger in the road cuts.

Disturbed areas often afford the plants which grow on them reduced competition for physical resources, such as water, and reduced competition from other plants. However, these potential positive effects of disturbance on *Astragalus hypoxylus* are unknown because there have been no such studies. Regardless, there are only a few portions of the populations that may be subject to Forest road maintenance activities, and they represent a very small portion of the total amount of occupied habitat. In addition, road maintenance activities take place on a periodic basis, so the effects are likely to be short-term and widely spaced over time. In conclusion, *A. hypoxylus* seems to tolerate moderate disturbance, and the best available information does not provide evidence that road maintenance activities are a threat to the continued existence of the species, nor are they likely to become so.

Drought

Data collected from the monitoring plots indicates that there is a likely correlation between rainfall and the population dynamics of *Astragalus hypoxylus.* As stated earlier, results from the Bear Canyon monitoring effort indicate that seedling recruitment and establishment was high when rainfall was high. We believe, based on data from the monitoring plots, that winter rainfall affects the survivorship of the seedlings. Summer rainfall may be important for germination, but without winter rainfall, the seedlings would not survive. The information provided in the following section was derived from data accessed on the National Oceanic and Atmospheric Administration (NOAA) National Climatic Data Center Web site (*http://www.ncdc.noaa.gov*). Rainfall totals for Arizona (Division 7), which includes all of the *A. hypoxylus* populations, for the months November through March, indicates a severe decline over the past 34 years. Another way to illustrate the decline is to use the Palmer Drought Severity Index (PDSI). The PDSI ''attempts to measure the duration and intensity of the long-term drought-inducing circulation patterns.'' It is an index used to gauge the severity of drought conditions by using a water balance equation to track water supply and demand. When the historical PDSI values are displayed for the years 1996–2011, 12 out of the 16 years were classified as moderate to severe drought. In comparison, the PDSI values for the same months during 1950–1960 (which is a well-documented drought period in Arizona) classified 8 out of 10 years as moderate to severe drought. There are significant differences between the two drought periods; mainly that the current drought is much warmer than the 1950s drought. On average, temperatures in the Four Corners region of the Southwest were about 2 to 7 °F (1 to 4 °C) warmer than in the 1950s (Weiss 2009, pp. 5920–5921). Drought with higher temperatures creates tough growing conditions for plants because warmer temperatures make the air drier, and drier air absorbs more moisture from the soils, vegetation, and reservoirs. Thus, not only is there less precipitation, but there is less moisture available in the soil for plant growth.

It is difficult to predict how *Astragalus hypoxylus* populations will fare with these drought conditions. The species apparently persisted and survived the 1950s drought; however, this information is of limited value as we evaluate potential conditions. The long-term trend for these populations is unknown; it is possible that the populations that are currently in decline will rebound when there is sufficient moisture. Despite drought conditions, *A. hypoxylus* populations in Scotia and Bear canyons seem stable, relative to the previous population estimates presented in Table 1. The largely circumstantial evidence available indicates that rainfall influences population dynamics for *A. hypoxylus,* and drought likely contributes to population declines. However, it is not known how the magnitude and intensity of drought will affect the long-term status of this species. Loss of individual plants, especially young plants, will likely occur during drought years. Dry conditions will likely reduce seed germination and survival. Population numbers of *A. hypoxylus* will fluctuate as observed during the period of data collection in the monitoring plots. However, this species is likely adapted to arid conditions. The ability to remain dormant during dry periods, and regrow when rainfall starts, is an adaptation for coping with arid conditions. Further, *A. hypoxylus* populations survived the 1950s drought, indicating the species has developed traits to survive during dry periods. Therefore, based on the best available information, we determine that drought is most likely not a threat to the continued existence of *A. hypoxylus.*

Climate Change

No further specific information is available regarding the effects of climate change on *A. hypoxylus;* therefore, please refer to the ''Climate Change'' discussion under Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range in the Five-Factor Evaluation for *Amoreuxia gonzalezii* Section.

As discussed in the previous sections above, *Astragalus hypoxylus* seedling establishment is likely correlated with rainfall; therefore, reduced precipitation may reduce seedling establishment. Additionally, the localized distribution of *A. hypoxylus* may make this species more susceptible to landscape-level stochastic events, such as regional drought. Despite these potential vulnerabilities, *A. hypoxylus* appears well-adapted to a dry climate and tolerates moderate disturbance. Plants growing in high-stress landscapes are adapted to stress, and drought-adapted species may experience lower mortality during severe droughts (Gitlin *et al.* 2006, pp. 1477, 1484).

In summary, climate change is affecting and will affect temperature and precipitation events. We expect that *Astragalus hypoxylus,* like other narrow endemics, may be negatively affected by drought associated with climate change. However, *A. hypoxylus* appears to be adapted to arid conditions, and has survived a previous long-term drought in the 1950s. Although climate change will likely affect plants in the future, the limited available information does not suggest that the effect on the status of the species will be significant. Therefore, based on the best available information, we have determined that climate change is not a threat to the continued existence of *A. hypoxylus.*

Summary of Factor A

In conclusion, based on the best available information, we have determined that recreation; livestock grazing; nonnative, invasive species; fuel wood harvesting; fire; road maintenance; or drought do not threaten the continued existence of *Astragalus hypoxylus.* Recreational impacts were associated with one population, and the Forest Service has taken corrective action to reduce those effects. The remaining populations are not affected by recreational activities. The best available information does not provide evidence that livestock grazing is a threat to this species. The plant is not eaten by livestock, both of the grazing allotments are in good range condition, and measures are in place to ensure

protection of upland and riparian areas. Nonnative, invasive species are not present in or near *A. hypoxylus* populations; therefore, we have determined that they are not a threat to the species. Fuel wood harvesting is not allowed in the areas where *A. hypoxylus* is located; therefore, we determined that this activity is not a threat to the species. Given the limited available information, we have determined that presence or absence of fire is most likely not a threat to the species. Road maintenance activities may affect small portions of *A. hypoxylus* populations, but we determined that these activities are not a threat to the continued existence of the species because the effects are short-term and the plants appear tolerant of moderate disturbance. Drought influences the population structure of *A. hypoxylus,* but the species has survived a previous long-term drought and appears to have adaptations for dealing with drought, therefore, we have determined that drought is not a threat to the continued existence of the species. We acknowledge that climate change, particularly the predictions of reduced precipitation and increasing temperatures in the Southwest, will affect individuals and populations of *A. hypoxylus.* However, the plant is adapted to arid conditions, and the limited available that can be applied at a local scale does not suggest that climate change is likely to threaten *A. hypoxylus.* Thus, the present or threatened destruction, modification, or curtailment of its habitat or range is not a threat to the continued existence of *A. hypoxylus,* nor is it likely to become so.

Factor B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Astragalus hypoxylus is not a plant of horticultural interest. There is no evidence of any instances where *A. hypoxylus* was collected from the wild other than as voucher specimens to document occurrences (*http://ag.arizona.edu/herbarium*) or seed collection for the purposes of banking seed for future conservation efforts. Therefore, we have determined that overutilization is not a threat to the continued existence of the species, nor is it likely to become so.

Factor C. Disease or Predation

There is no information indicating that disease affects *Astragalus hypoxylus.* There are no observations or evidence that *A. hypoxylus* is browsed by livestock (see Factor A, Livestock grazing). Data were collected on *A. hypoxylus* seed predation by small wasps in 1988, but it is unknown how this predation affected the *A. hypoxylus* population or how often seed predation occurs (Johnson *et al.* 1992, p. 13). Based on the best available information, we have determined that *A. hypoxylus* is not threatened by disease or predation, nor is it likely to become so.

Factor D. The Inadequacy of Existing Regulatory Mechanisms

The Act requires us to examine the adequacy of existing regulatory mechanisms with respect to threats that may place *Astragalus hypoxylus* in danger of extinction or likely to become so in the future. Existing regulatory mechanisms that could have an effect on potential threats to *A. hypoxylus* include (1) Local land use laws, processes, and ordinances; (2) State laws and regulations; and (3) Federal laws and regulations. *A. hypoxylus* occurs entirely on Federal land under the jurisdiction of the Coronado National Forest; therefore, the discussion below focuses on Federal laws.

Astragalus hypoxylus is listed as a sensitive species in the Coronado National Forest. The management of sensitive species is described in Forest Service Manual (FSM) 2670, and the management objectives are to develop and implement management practices to ensure that species do not become endangered or threatened because of Forest Service actions; maintain viable populations of all native and desired nonnative wildlife, fish, and plant species in habitats distributed throughout their geographic range on National Forest System lands; and develop and implement management objectives for populations or habitat of sensitive species or both. In addition, the Forest has to consider the effects of their actions on the viability of sensitive species through the NEPA process. As defined by Forest Service policy, actions must not result in loss of species viability or create significant trends toward the need for Federal listing. *A. hypoxylus* receives these protective measures in the Coronado National Forest, and the designation has resulted in measures to reduce impacts from recreation on the Bear Canyon *A. hypoxylus* population, and the consideration of the species' needs in the NEPA planning process for the Bender and Lone Mountain grazing allotments.

Summary of Factor D

We examined the existing regulatory mechanisms that protect *Astragalus hypoxylus.* We have determined that the Forest Service sensitive species designation adequately protects *A. hypoxylus* and its habitat, and, thus, there is no evidence of impacts to *A. hypoxylus* from inadequate existing regulatory mechanisms. We conclude that the best available information indicates that *A. hypoxylus* is not threatened by inadequate existing regulatory mechanisms.

Factor E. Other Natural or Manmade Factors Affecting Its Continued Existence

A threat identified by the petition was indirect effects to pollinators, mainly bees. Johnson *et al.* (1992, p. 13) noted that the use of pesticides to control insects, such as grasshoppers, may be harmful to bees. The Coronado National Forest has not sprayed pesticides for grasshopper control, and has no plans to do so. As mentioned previously, the pollinators for *Astragalus hypoxylus* have not been identified. As such, there is no evidence of activities that may harm the potential pollinators of this species; therefore, we have determined that the loss of pollinators from pesticide spraying is not a threat to the species.

We are not aware of any other potential threats related to this factor, such as small population size and overall rarity. Therefore, we find that *Astragalus hypoxylus* is not threatened by small population size and overall rarity, or is likely to become so.

Finding for *Astragalus hypoxylus*

As required by the Act, we evaluated the five factors in assessing whether *Astragalus hypoxylus* is endangered or threatened throughout all or a significant portion of its range. We examined the best scientific and commercial information available regarding the past, present, and future threats faced by *A. hypoxylus.* We reviewed the petition, information available in our files, other available published and unpublished information, and we consulted with recognized plant experts and Forest Service biologists.

Astragalus hypoxylus populations are primarily affected by drought; however, we determined that drought is not a threat to this species. The plants are tolerant of moderate disturbance, and are adapted to arid conditions, as evidenced by their survival during the 1950s drought. Climate change will likely impact the status of *A. hypoxylus* in the future; however, the limited available information suggests that climate change will not threaten the continued existence of the species. Other factors potentially affecting *A. hypoxylus*—including recreation;

livestock grazing; nonnative, invasive species; fuel wood harvesting; fire; and effects to potential pollinators—are either limited in scope, or available evidence is lacking to indicate that they adversely impact the species. There is no evidence that overutilization, disease, or predation is affecting this species. In addition, we find that the existing regulatory mechanisms are not a threat to the species.

Based on our review of the best available scientific and commercial information pertaining to the five factors, we find that the threats are not of sufficient imminence, intensity, or magnitude to indicate that *Astragalus hypoxylus* is in danger of extinction (endangered), or likely to become endangered within the foreseeable future (threatened), throughout all of its range.

Significant Portion of the Range

Having determined that *Astragalus hypoxylus* is not in danger of extinction, or likely to become so, throughout all of its range, we must next consider whether there are any significant portions of the range where *A. hypoxylus* is in danger of extinction or is likely to become endangered in the foreseeable future. We also considered the historical range of the species, and have determined that the current range is no different from the historical range. Therefore, there has been no loss of the historical range, and no further analysis of the historical range is required.

The Act defines an endangered species as one ''in danger of extinction throughout all or a significant portion of its range,'' and a threatened species as one ''likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' The term ''significant portion of its range'' is not defined by the statute. For the purposes of this finding, a portion of a species' range is ''significant'' if it is part of the current range of the species, and it provides a crucial contribution to the representation, resiliency, or redundancy of the species. For the contribution to be crucial it must be at a level such that, without that portion, the species would be in danger of extinction.

In determining whether *Astragalus hypoxylus* is endangered or threatened in a significant portion of its range, we considered status first to determine if any threats or potential threats acting individually or collectively threaten or endanger the species in a portion of its range. We evaluated the current range of *A. hypoxylus* to determine if there is any apparent geographic concentration of the primary stressors potentially affecting the species including recreation; livestock grazing; nonnative, invasive plants; fuel wood harvesting; fire; road maintenance; and drought. We have analyzed the stressors to the degree possible, and determined that they are essentially uniform throughout the species' range. We also found the stressors are not of sufficient imminence, intensity, magnitude, or geographically concentrated such that it warrants evaluating whether a portion of the range is significant under the Act. We do not find that *A. hypoxylus* is in danger of extinction now, nor is likely to become endangered within the foreseeable future, throughout all or a significant portion of its range. Therefore, listing *A. hypoxylus* as an endangered or threatened species under the Act is not warranted at this time.

We request that you submit any new information concerning the distribution and status of, or threats to, *Astragalus hypoxylus* to our U.S. Fish and Wildlife Service Office (see **ADDRESSES** section) whenever it becomes available. New information will help us monitor *A. hypoxylus* and encourage its conservation. If an emergency situation develops for *A. hypoxylus,* or any other species, we will act to provide immediate protection.

Species Information for *Erigeron piscaticus*

Species Description

Erigeron piscaticus is a herbaceous annual (a plant that completes its life-cycle in one year) in the Asteraceae (Sunflower) family. The plant is typically 15 to 40 cm (6 to 16 in) in height, multi-branched, procumbent or ascending—decumbent (trailing or lying on the ground), and densely pubescent (covered with hair) with coarse, stiff hair. One to 4 flower heads are produced per plant, each 5 to 7 mm (0.2 to 0.3 in) across with a white corolla (ray and disk flowers), and producing tan-colored achenes (fruit) to 1 mm (0.04 in) in length. The very small flower heads, coupled with entire (toothless) leaves are key factors distinguishing this species from close relatives (Nesom 1989, p. 306).

Habitat and Biology

Oak Grove Canyon, where the plant has been most recently located, is a narrow slot canyon with intermittent stream flow and a riparian gallery forest of sycamore, alder, and black walnut (Gori 1992, p. 2). Occurring at 1,000-m (3,300-ft) elevation, its steep (91 to 122 m) (300 to 400 ft)) canyon walls and northeast aspect provide for significantly cooler temperatures than the semidesert grasslands in the adjacent uplands (Haberstich 2011, pers. comm.). The plants are found on sandy terraces just above the floodplain and are subject to larger flood events; there is little associated understory (Gori 1992, p. 2). A single collection from Turkey Creek refers to a ''riparian woodland'' habitat, while the specimen from Fish Creek has no habitat information recorded. The collection from near Tucson refers to the plant being found ''in rock adjacent to stream.'' (Southwest Environmental Information Network 2011)

Erigeron piscaticus germinates following either winter or summer rains (Arizona Game and Fish Department (AZGD) Heritage Data Management 2001, p. 2), grows quickly, and has a long flowering period from May through October (Gori 1992, p. 2) or possibly through December (Southwest Environmental Information Network, 2011). Pollination has not been studied in this species, though other *Erigeron* species are typically pollinated by bees and wasps (Tepedino 2011, pers. comm.). Seed is dispersed by both wind and water; this species may also depend on flooding events to create suitable early-successional habitat (Gori 1992, p. 2). Seed bank longevity has not been studied in *E. piscaticus.*

Soil moisture is necessary for most annual plants to germinate and flower; therefore, seed production in most annuals is equally limited by soil moisture. Following this theory, Gori (1992, p. 3) suggested that *Erigeron piscaticus* populations would increase or decrease in sequential years of above- or below-average moisture. In the case of data collected at Oak Grove Canyon, this theory held in 1993, a wet year, when both 1994 and 1995 had high population numbers (79 and 68 respectively). However, the theory did not hold in 2002, a dry year, when 23 plants were found in 2003 followed by 64 plants in 2004. It is likely that this species instead responded to flooding that occurred in 1993 and not to precipitation. There is not sufficient data available to determine the ecological factors that influence the germination of this species.

Distribution, Abundance, and Trends

Erigeron piscaticus is ranked by NatureServe as G1S1 (Global and State Critically Imperiled). The species is known from two confirmed areas: Fish Creek Canyon and the Aravaipa Canyon Preserve of south-central Arizona. There are three populations in the Aravaipa Canyon Preserve; one is located in Turkey Creek Canyon, and the

remaining two populations are in Oak Grove Canyon. An additional site is currently under investigation in the mountains near Tucson. The herbarium specimen location for this third site states ''Box Canyon southwestern corner of Santa Catalina Mountains;'' the specimen was verified by Guy Nesom, the botanist who described the species (Southwest Environmental Information Network 2011). There have been discussions among botanists, however, that this location may be incorrect and Box Canyon could refer to either the Rincon or Santa Rita Mountains. It is also possible that the specimen was misidentified and the location is correct. The specimen currently resides at the New York Botanic Garden Herbarium and a loan has been requested by Shelley McMahon of the University of Arizona Herbarium for reverification. Surveys for the species are planned in 2012 (Crawford 2011, pers. comm.).

The species was first collected on the Tonto National Forest in Fish Creek Canyon in October 1929 by Eastwood, then again in 1931 by Peebles and Eaton (Nesom 1989, p. 305). *Erigeron piscaticus* was not collected again until 1976 in Turkey Creek then in 1979 in Oak Grove Canyon by Anderson and Warren (Southwest Environmental Information Network 2011). In 2002, a second group of plants was located in Oak Grove Canyon and those plants are counted as part of an annual census for the canyon as a whole (Haberstich and Killeen 2002, p. 1). Both Turkey Creek and Oak Grove Canyon are within the Aravaipa Canyon Preserve on Bureau of Land Management land managed jointly with The Nature Conservancy. The two locations within Oak Grove Canyon are approximately 0.8 km (0.5 mi) apart by air and the Oak Grove populations are approximately 3.7 air km (2.3 air mi) from the collection site in Turkey Creek. The Fish Creek locations are approximately 129 air km (80 air mi) from those in Aravaipa Preserve. There are many canyons supporting what seems to be suitable habitat between the known locations in Fish Creek and the Aravaipa Canyon Preserve. Several surveys have been completed, and no additional populations have been located (Gori 1991, p. 2).

Attempts were made in 1990 to locate the populations in both Fish Creek and Turkey Creek again, but none were found (Gori and Malusa 1991, p. 2). The Arizona Game and Fish Department reports 11 plants were located in Turkey Creek in 1992, although no other records indicate the plant has been found in Turkey Creek since its first collection in 1976. A letter in the files from Dave Gori to Dan Godec of the Arizona Game and Fish Department dated June 12, 1998 stated that *E. piscaticus* has not been relocated in Fish Creek Canyon or Turkey Creek Canyon. He related that, to his knowledge, there were ''no other extant locations for this plant except Oak Grove Canyon.'' It is unknown how many plants originally occurred at collection sites in Fish Creek or Turkey Creek Canyons. As these populations have not been detected again, it is unknown if they are extant or what the current population sizes are. Annual monitoring of plants in Oak Grove Canyon took place between 1992 and 2008 and is scheduled to occur in the summer of 2011 (Haberstich 2011, pers. comm.). These efforts show plant numbers fluctuating annually, ranging from 87 individuals in 1992, to 4 individuals in 2002, and back to 81 individuals in 2008.

To summarize, there is very little biological and ecological information known about this species. There are three known locations, but plants have not been seen in the original location, Fish Creek, since the 1930s. Today, plants are known from two locations, Oak Creek Canyon and Turkey Creek on the Aravaipa Canyon Preserve. There may be another location in the Santa Catalina Mountains, near Tucson, but it has not been verified. The species seem to be associated with floodplain terraces in riparian areas, but that is based on their current locations in the Aravaipa Canyon Preserve. The species may respond to rainfall, or germination may be triggered by flooding, or the apt combination of rainfall and flooding.

Five-Factor Evaluation for *Erigeron piscaticus*

In making this finding, information pertaining to *Erigeron piscaticus* in relation to the five factors provided in section 4(a)(1) of the Act is discussed below.

Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Potential factors that may affect the habitat or range of *Erigeron piscaticus* are discussed in this section, including: (1) Flooding; (2) recreation; (3) watershed degradation; and (4) climate change.

Flooding

Many annual and short-lived perennial plant species have a high rate of seed production and the ability to thrive following disturbance. Annual plants in the southwestern United States often increase in richness and cover following the disturbance of large flood events (Bagstad *et al.* 2005, p. 219). These events reduce competition with perennial plants, increase understory light, remove litter accumulation from overstory tree species, redistribute seed banks, and create nutrient-rich sediment beds for seed germination. Plants found above the inundation zones on high flood-plain surfaces respond most to the increased rainfall that led to flooding, while those in inundation zones respond most to the physical disturbance of flooding (Bagstad *et al.* 2005, p. 219, 221). *Erigeron piscaticus* is an annual riparian species that occurs above the inundation zone on shallow terraces that are subject to larger flooding events.

Census data for this species were collected on a nearly annual basis between 1992 and 2008, in one of two locations within the Aravaipa Canyon Preserve, in southeastern Arizona. Plant census data were compared against regional precipitation data during this time period, and no correlation was observed. In other words, population peaks varied between wet (1991 through 1995) and dry (2004 and 2008) years (NOAA 2011; Haberstich and Walker 2008, p. 1; Haberstich 2005, p. 1; Haberstich and Killeen 2004, p. 1; 2003, p. 1; 2002, p. 1; Haberstich 2011, pers. comm.). Aravaipa Creek has experienced significant flooding on four occasions (1979, 1984, 1993, and 2006) since stream flow gage records were first kept in 1932 (USGS, 2011). *Erigeron piscaticus* may be more closely associated with the physical scouring from flooding than with precipitation. *E. piscaticus* populations peaked following both the 1993 and 2006 floods.

Although periodic flooding events remove individual plants and seeds, total *Erigeron piscaticus* population numbers were very similar during the 2008 monitoring (81) to numbers the first time the species was monitored in 1992 (87). There is, however, great year-to-year variability in the census data, both in terms of population numbers (as low as 4 plants in 2002, and as high as 87 plants in 1992) and population locations (lower, middle, and upper sections of the canyon). The species seems to establish, increase and decrease; disperse via water or wind; and move to different locations within the canyon, which may explain the new location discovered downstream from known sites in 2002. In addition, in particularly dry years, plants may not germinate. This may explain why certain populations, like Fish Creek, have never been found again. If the populations are not present every year, and the location may move within the canyon based on flooding, it is easy to

understand why populations need regular and consistent monitoring.

Erigeron piscaticus seems to be well adapted to its environment and may require periodic flooding for survival. Too many large floods, however, could deplete the seed bank; too few large floods could lead to competition with perennial plants and litter accumulation (Gori 1992, p 3). We are making this conclusion based on the behavior of one population; however, this population may not be representative of the species. We conclude that *E. piscaticus* is tolerant of moderate disturbance and may need periodic flooding for successful seed germination. Therefore, based on the best available information, we determined that flooding is not a threat to the continued existence of *E. piscaticus,* nor is it likely to become so.

Recreation

Erigeron piscaticus plants are located near hiking and game trails in Oak Grove Canyon. Hiking and other forms of recreation, including all-terrain vehicle (ATV) use, occur frequently in the Aravaipa Canyon Preserve (Haberstich 2005, p. 1; Haberstich and Killeen 2004, p. 1). As stated above, this species seems to tolerate moderate levels of disturbance. The populations in Oak Grove Canyon seem to be persisting despite the levels of traffic, both human and ATV, that occur adjacent to and through the populations. There are also observations (Haberstich 2005, p. 1; Haberstich and Killeen 2004, p. 1) that *E. piscaticus* plants were found in various stages of germination and growth on an actively eroding site, another indication that the species tolerates disturbance. Impacts from recreation may have contributed to the loss of the Turkey Creek population in the Aravaipa Canyon Preserve, as the site was used as a casual camping site (AZGF Heritage Data Management 2001, p. 3). However, there is no documentary evidence that that is the case, and because no one has surveyed that area since the 1990s, there is no conclusive evidence that the population has been extirpated. In summary, *E. piscaticus* seems to tolerate disturbance, and, based on the best available information, we find that recreation is not a threat to the continued existence of this species, nor is it likely to become so.

Watershed Degradation

The Aravaipa Canyon watershed has a history of intense grazing by cattle, horses, and goats. This grazing occurred from the 1850s until the 1980s when grazing was removed from portions of the area and a pasture rotation system was initiated in other areas (Gori 1992, p. 4). By 1997, the entire area, including Oak Grove and Turkey Creek Canyons, was free of domestic grazing activity (Haberstich 2011, pers. comm.). The years of intense grazing, coupled with fire suppression, significantly altered plant species composition and abundance, and led to a degraded condition of the upland vegetation of the area (Gori 1992, pp. 3–4). By the 1980s, this upland semidesert grassland was described as being largely comprised of shrubs and annual grasses, an unnatural condition that reduces water infiltration and can cause more intense sheet flow during storm events (Gori 1999, pp. 41–42). Great strides have been made in recent decades to correct this problem. Preserve Manager Mark Haberstich reports that the uplands are fairly healthy with increases in native perennial grasses, thus reducing runoff and erosion (Haberstich 2011, pers. comm.). There is no evidence that watershed degradation is affecting *E. piscaticus* populations in the Aravaipa Canyon Preserve. Therefore, based on our review of the best available information, we conclude that watershed degradation is not a threat to the continued existence of this species, nor is it likely to become so.

Climate Change

For general background information on climate change, please refer to the first paragraphs of ''Climate Change'' under Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range in the Five-Factor Evaluation for *Amoreuxia gonzalezii* section.

It has been suggested that this species may be a relict of the last ice age due to its very restricted habitat of cool, shady, narrow, and steep slot canyons in perennial stream bottoms (Haberstich 2011, pers. comm.). If this is the case, recent and projected increases in regional daily temperatures and decreases in winter precipitation could negatively impact *Erigeron piscaticus.* Direct impacts due to rising temperature are unknown for this plant, although heat stress in plants in general is known to impact germination, photosynthesis, respiration, and a myriad of other functions (Wahid *et al.* 2007, p. 199). A reduction in precipitation or increase in temperature-related stress could preclude recruitment and therefore seed set in this annual species. Seed bank longevity for *E. piscaticus* has not been determined, although Bagstad *et al.* (2005, p. 219) state that ''many of the annual plant species found in southwestern riparian areas have long-lived seeds that are widely distributed in soil seed banks across the flood plain, enabling them to establish opportunistically when suitable germination sites develop.'' Similarly, other *Erigeron* seeds have been reported to last roughly 10 years with no refrigeration (Murray 2011, pers. comm.).

The information related to the effects of climate change on *Erigeron piscaticus* at a local scale is limited. Predicted changes in rainfall, temperature, and flooding frequency may all affect *E. piscaticus.* However, based on the species' life history and observed tolerances, it appears that the effects of climate change may be limited. In conclusion, based on the best available information, we have determined that climate change is not a threat to the continued existence of *E. piscaticus.*

Summary of Factor A

Based on the best available information, we have determined that flooding, recreation, watershed degradation, and climate change do not threaten *Erigeron piscaticus,* nor are they likely to do so. Flooding seems to play an important role in the germination and survival of *E. piscaticus* populations. As such, the species seems to tolerate moderate levels of disturbance, making the populations less vulnerable to impacts from recreation, such as hiking and ATV use. The watershed condition of Aravaipa Canyon has recovered from past grazing, and there is no evidence that *E. piscaticus* populations have been affected by watershed degradation. We acknowledge that climate change, particularly the predictions of reduced precipitation and increasing temperatures in the Southwest, may affect populations of *E. piscaticus;* however, the limited available information at the local scale suggests that a climate change will likely not be a threat to the continued existence of the species. Thus, the present or threatened destruction, modification, or curtailment of the habitat or range is not a threat to the continued existence of *E. piscaticus,* nor is it likely to become so.

Factor B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Erigeron piscaticus is not a plant of horticultural interest. There is no evidence of any instances in which *E. piscaticus* was collected from the wild other than as voucher specimens to document occurrences (*http://ag.arizona.edu/herbarium*). Therefore, we conclude, based on the best available information, that overutilization is not a threat to the continued existence of the species, nor is it likely to become so.

Factor C. Disease or Predation

There is no indication that any disease affects *Erigeron piscaticus.* There is no livestock grazing in Oak Grove Canyon and Turkey Creek on the Aravaipa Canyon Preserve, and there is no information about any other source of predation on the species. Therefore, we have determined that disease or predation is not a threat to this species' continued existence, nor is it likely to become so.

Factor D. The Inadequacy of Existing Regulatory Mechanisms

The Act requires us to examine the adequacy of existing regulatory mechanisms with respect to threats that may place *Erigeron piscaticus* in danger of extinction or likely to become so in the future. Existing regulatory mechanisms that could have an effect on potential threats to *E. piscaticus* include (1) Local land use laws, processes, and ordinances; (2) State laws and regulations; and (3) Federal laws and regulations. *E. piscaticus* occurs entirely on Federal land under the jurisdiction of the Bureau of Land Management (BLM) and the Tonto National Forest; therefore, the discussion below focuses on Federal laws.

Erigeron piscaticus is listed as a BLM sensitive species (BLM, 2010). The management of sensitive species is described in the BLM Manual Section 6840, which states that the BLM will focus sensitive species management on maintaining species habitat in functional ecosystems, ensuring the species is considered in land management decisions, and prioritizing conservation that emphasizes habitat needs for the species, thereby preventing the need to list the species under the Act.

Erigeron piscaticus is also listed as a sensitive species in the Tonto National Forest (Tonto National Forest 2004, entire). The management of sensitive species is described in U.S. Forest Service Manual (FSM) 2670, and the management objectives are to develop and implement management practices to ensure that species do not become endangered or threatened because of Forest Service actions; maintain viable populations of all native and desired nonnative wildlife, fish, and plant species in habitats distributed throughout their geographic range on National Forest System lands; and develop and implement management objectives for populations or habitat of sensitive species, or both. In addition, the Forest has to consider the effects of their actions on the viability of sensitive species through the NEPA process. As defined by Forest Service policy, actions must not result in loss of species viability or create significant trends toward the need for Federal listing. *E. piscaticus* receives these protective measures in the Tonto National Forest.

Summary of Factor D

We examined the existing regulatory mechanisms that protect *Erigeron piscaticus.* We have determined that the BLM and Forest Service sensitive species designation adequately protects *E. piscaticus* and its habitat and, thus, there is no evidence of impacts to *E. piscaticus* from inadequate existing regulatory mechanisms. We conclude that the best available information indicates that *E. piscaticus* is not threatened by inadequate existing regulatory mechanisms.

Factor E. Other Natural or Manmade Factors Affecting Its Continued Existence

Small Population Size

Small populations can be especially vulnerable to environmental disturbances such as habitat loss, nonnative species, grazing, and climate change (Barrett and Kohn 1991, p. 7; Oostermeijer 2003, p. 21; O'Grady 2004, pp. 513–514). However, plants that are historically rare may have certain adaptations to rarity (*e.g.,* early blooming, extended flowering, or mixed-mating systems) that enable them to persist (Brigham 2003, p. 61). For more information on species rarity and its effects on the conservation status of a species, see the discussion under Factor E. Other Natural or Manmade Factors Affecting Its Continued Existence in the Five-Factor Evaluation for *Amoreuxia gonzalezii.*

There is no indication that *Erigeron piscaticus* was ever present on the landscape over a more extensive range than it is today. Existing sites are monitored, and surveys have located no new occurrences. There is no information indicating that random demographic or environmental events are a threat to the continued existence of the species because of its small population size.

Genetic Diversity

Small population size can decrease genetic diversity due to genetic drift (the random change in genetic variation each generation), and inbreeding (mating of related individuals) (Antonovics 1976, p. 238; Ellstrand and Elam 1993, pp. 218–219). Genetic drift can decrease genetic variation within a population by favoring certain characteristics and, thereby, increasing differences between populations (Ellstrand and Elam 1993, pp. 218–219). Self-fertilization and low dispersal rates can cause low genetic diversity due to inbreeding (Antonovics 1976, p. 238; Barrett and Kohn 1991, p. 21). This decreased genetic diversity diminishes a species' ability to adapt to the selective pressures of a changing environment (Newman and Pilson 1997, p. 360; Ellstrand 1992, p. 77).

Limited information is available regarding the genetic diversity of the *Erigeron* genus. No information is available regarding the genetic diversity exhibited by *E. piscaticus.* Therefore, we have determined that a lack of genetic diversity is not a threat to the continued existence of the species.

Summary of Factor E

Erigeron piscaticus is a rare species known from two locations, Fish Creek Canyon and the Aravaipa Canyon Preserve. Currently, there are two known populations in Oak Creek Canyon, within the Aravaipa Canyon Preserve. The other populations of *E. piscaticus* in Fish Creek Canyon and Turkey Creek Canyon, in the Aravaipa Canyon Preserve, have not been seen in quite some time. There is no evidence that this species was at one time more widespread than its current distribution. There is no information that *E. piscaticus* populations are subject to threats resulting from small population size. The same conclusion is drawn for the lack of genetic diversity that may affect small populations. Therefore, based on the best available information, we have determined that small population size and lack of genetic diversity are not threats to the continued existence of *E. piscaticus,* nor are they likely to become so.

Finding for *Erigeron piscaticus*

As required by the Act, we considered the five factors in assessing whether *Erigeron piscaticus* is endangered or threatened throughout all or a significant portion of its range. We examined the best scientific and commercial information available regarding the past, present, and future threats faced by *E. piscaticus.* We reviewed the petition, information available in our files, other available published and unpublished information, and we consulted with recognized plant experts and land managers.

Erigeron piscaticus populations do not seem to face any obvious threats. The species is an annual, which means that there is less certainty about the size, location, and permanence of any given site. In addition, the species tolerates,

and may possibly require, disturbance in order to complete its life cycle. The only available information is monitoring data from one location, and two of the other locations have not been seen in quite some time, although attempts to find these populations again have not occurred. As such, there is an incomplete set of information about this species, which makes it difficult to assess threats and make valid predictions on how potential threats may affect *E. piscaticus.* For instance, climate change will affect temperature and precipitation in the Southwest, but it is not known what that means for changes in flooding, and how that will affect *E. piscaticus.*

Other factors potentially affecting *Erigeron piscaticus*—including recreation and watershed degradation—are either limited in scope, or lacking evidence indicating that they adversely impact the species. There is no evidence that overutilization, disease, or predation are affecting this species. Although the existing populations are small, there is no evidence that the populations are subject to a lack of genetic diversity or are more vulnerable to stochastic events. In addition, we conclude that the inadequacy of existing regulatory mechanisms is not a threat to the species.

Based on our review of the best available scientific and commercial information pertaining to the five factors, we find that the threats are not of sufficient imminence, intensity, or magnitude to indicate that *Erigeron piscaticus* is in danger of extinction (endangered) or likely to become endangered within the foreseeable future (threatened), throughout all of its range.

Significant Portion of the Range

Having determined that *Erigeron piscaticus* is not in danger of extinction, or likely to become so, throughout all of its range, we must next consider whether there are any significant portions of the range where *E. piscaticus* is in danger of extinction or is likely to become endangered in the foreseeable future. We also considered the historical range of the species, and have determined that the current range is no different from the historical range. Therefore, there has been no loss of the historical range, and no further analysis of the historical range is required.

The Act defines an endangered species as one ''in danger of extinction throughout all or a significant portion of its range,'' and a threatened species as one ''likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' The term ''significant portion of its range'' is not defined by the statute. For the purposes of this finding, a portion of a species' range is ''significant'' if it is part of the current range of the species, and it provides a crucial contribution to the representation, resiliency, or redundancy of the species. For the contribution to be crucial it must be at a level such that, without that portion, the species would be in danger of extinction.

In determining whether *Erigeron piscaticus* is endangered or threatened in a significant portion of its range, we considered status first to determine if any threats or potential threats acting individually or collectively threaten or endanger the species in a portion of its range. We evaluated the current range of *E. piscaticus* to determine if there is any apparent geographic concentration of the primary stressors potentially affecting the species including flooding, recreation, and watershed degradation. We have analyzed the stressors to the degree possible, and determined that they are essentially uniform throughout the species' range. We also found the stressors are not of sufficient imminence, intensity, magnitude, or geographically concentrated such that it warrants evaluating whether a portion of the range is significant under the Act. We do not find that *E. piscaticus* is in danger of extinction now, nor is likely to become endangered within the foreseeable future, throughout all or a significant portion of its range. Therefore, listing *E. piscaticus* as an endangered or threatened species under the Act is not warranted at this time.

Conclusion of 12-Month Finding

We find that *Amoreuxia gonzalezii* (Santa Rita yellowshow), *Astragalus hypoxylus* (Huachuca milk-vetch), and *Erigeron piscaticus* (Fish Creek fleabane) are not in danger of extinction now, nor is any of these three species likely to become endangered within the foreseeable future throughout all or a significant portion of their ranges. Therefore, listing any of these three species as endangered or threatened under the Act is not warranted at this time.

We request that you submit any new information concerning the distribution and status of, or threats to, *Erigeron piscaticus* to our U.S. Fish and Wildlife Service Office (see **ADDRESSES** section) whenever it becomes available. New information will help us monitor *E. piscaticus* and encourage its conservation. If an emergency situation develops for *E. piscaticus* or any other species, we will act to provide immediate protection.

References Cited

A complete list of references cited is available on the Internet at *http://www.regulations.gov* and upon request from the U.S. Fish and Wildlife Service, Arizona Ecological Services Field Office (see **ADDRESSES** section).

Authors

The primary authors of this finding are the staff members of the Arizona Ecological Services Field Office.

Authority

The authority for this action is section 4 of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: September 22, 2011.

Gregory E. Siekaniec,

Acting Director, Fish and Wildlife Service.

[FR Doc. 2011–25470 Filed 10–7–11; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AY28

[FWS–R9–ES–2011–0075; MO 92210–0–0010 B6]

Endangered and Threatened Wildlife and Plants; 12-Month Finding on a Petition and Proposed Rule To List the Yellow-Billed Parrot

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; 12-month finding.

SUMMARY: We, the U.S. Fish and Wildlife Service, propose to list as threatened the yellow-billed parrot *(Amazona collaria)* under the Endangered Species Act of 1973, as amended (Act). We are taking this action in response to a petition to list this species as endangered or threatened under the Act. This document, which also serves as the completion of the status review and as the 12-month finding on the petition, announces our finding that listing is warranted for the yellow-billed parrot. If we finalize this rule as proposed, it would extend the Act's protections to this species. We also propose a special rule for the yellow-billed parrot in conjunction with our proposed listing as threatened for this species. We seek information from the public on this proposed rule and status review for this species.

DATES: We will consider comments and information received or postmarked on or before December 12, 2011.

ADDRESSES: You may submit comments by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–R9–ES–2011–0075.
- *U.S. mail or hand-delivery*: Public Comments Processing, *Attn:* FWS–R9–ES–2011–0075, Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042–PDM; Arlington, VA 22203.

We will not accept comments by e-mail or fax. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Information Requested section below for more information).

FOR FURTHER INFORMATION CONTACT: Janine Van Norman, Chief, Branch of Foreign Species, Endangered Species Program, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 420, Arlington, VA 22203; telephone 703–358–2171. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Background

Section 4(b)(3)(B) of the Endangered Species Act (Act) (16 U.S.C. 1531 *et seq.*) requires that, for any petition to revise the Federal Lists of Endangered and Threatened Wildlife and Plants that contains substantial scientific or commercial information that listing the species may be warranted, we make a finding within 12 months of the date of receipt of the petition (''12-month finding''). In this finding, we determine whether the petitioned action is: (a) Not warranted, (b) warranted, or (c) warranted, but immediate proposal of a regulation implementing the petitioned action is precluded by other pending proposals to determine whether species are endangered or threatened, and expeditious progress is being made to add or remove qualified species from the Federal Lists of Endangered and Threatened Wildlife and Plants. Section 4(b)(3)(C) of the Act requires that we treat a petition for which the requested action is found to be warranted but precluded as though resubmitted on the date of such finding, that is, requiring a subsequent finding to be made within 12 months. We must publish these 12-month findings in the **Federal Register.**

The U.S. Fish and Wildlife Service (Service) publishes an annual notice of resubmitted petition findings (annual notice) for all foreign species for which listings were previously found to be warranted but precluded.

In this document, we announce that listing the yellow-billed parrot as threatened is warranted, and we are issuing a proposed rule to add that species as threatened under the Federal Lists of Endangered and Threatened Wildlife and Plants.

Prior to issuing a final rule on this proposed action, we will take into consideration all comments and any additional information we receive. Such information may lead to a final rule that differs from this proposal. All comments and recommendations, including names and addresses of commenters, will become part of the administrative record.

Previous Federal Actions

Petition History

On January 31, 2008, the Service received a petition dated January 29, 2008, from Friends of Animals, as represented by the Environmental Law Clinic, University of Denver, Sturm College of Law, requesting that we list 14 parrot species under the Act. The petition clearly identified itself as a petition and included the requisite information required in the Code of Federal Regulations (50 CFR 424.14(a)). On July 14, 2009 (74 FR 33957), we published a 90-day finding in which we determined that the petition presented substantial scientific and commercial information to indicate that listing may be warranted for 12 of the 14 parrot species. In our 90-day finding on this petition, we announced the initiation of a status review to list as threatened or endangered under the Endangered Species Act of 1973, as amended (Act), the following 12 parrot species: blue-headed macaw *(Primolius couloni),* crimson shining parrot *(Prosopeia splendens),* great green macaw *(Ara ambiguus),* grey-cheeked parakeet *(Brotogeris pyrrhoptera),* hyacinth macaw *(Anodorhynchus hyacinthinus),* military macaw *(Ara militaris),* Philippine cockatoo *(Cacatua haematuropygia),* red-crowned parrot *(Amazona viridigenalis),* scarlet macaw *(Ara macao),* white cockatoo *(C. alba),* yellow-billed parrot *(Amazona collaria),* and yellow-crested cockatoo *(C. sulphurea).* We initiated this status review to determine if listing each of the 12 species is warranted, and initiated a 60-day information collection period to allow all interested parties an opportunity to provide information on the status of these 12 species of parrots. The public comment period closed on September 14, 2009.

On October 24, 2009, and December 2, 2009, the Service received a 60-day notice of intent to sue from Friends of Animals and WildEarth Guardians, for failure to issue 12-month findings on the petition. On March 2, 2010, Friends of Animals and WildEarth Guardians filed suit against the Service for failure to make timely 12-month findings within the statutory deadline of the Act on the petition to list the 14 species *(Friends of Animals, et al* . v. *Salazar,* Case No. 10 CV 00357 D.D.C.).

On July 21, 2010, a settlement agreement was approved by the Court (CV–10–357, D. D.C.), in which the Service agreed to submit to the **Federal Register** by July 29, 2011, September 30, 2011, and November 30, 2011, determinations whether the petitioned action is warranted, not warranted, or warranted but precluded by other listing actions for no less than 4 of the petitioned species on each date. On August 9, 2011, the Service published in the **Federal Register** a 12-month status review finding and proposed rule for the following four parrot species: crimson shining parrot, Philippine cockatoo, white cockatoo, and yellow-crested cockatoo (76 FR 49202).

In this status review we make a determination whether the petitioned action is warranted, not warranted, or warranted but precluded by other listing actions for one of the remaining species, the yellow-billed parrot. This **Federal Register** document complies, in part, with the second deadline in the court-ordered settlement agreement.

Information Requested

We intend that any final actions resulting from this proposed rule will be based on the best scientific and commercial data available. Therefore, we request comments or information from other concerned governmental agencies, the scientific community, or any other interested parties concerning this proposed rule. We particularly seek clarifying information concerning:

(1) Information on taxonomy, distribution, habitat selection and trends (especially breeding and foraging habitats), diet, and population abundance and trends (especially current recruitment data) of this species.

(2) Information on the effects of habitat loss and changing land uses on the distribution and abundance of this species.

(3) Information on the effects of other potential threat factors, including live capture and hunting, domestic and international trade, predation by other animals, and any diseases that are known to affect this species or its principal food sources.

(4) Information on management programs for parrot conservation, including mitigation measures related to conservation programs, and any other private, nongovernmental, or governmental conservation programs that benefit this species.

(5) The potential effects of climate change on this species and its habitat.

Please include sufficient information with your submission (such as full references) to allow us to verify any scientific or commercial information you include. Submissions merely stating support for or opposition to the action under consideration without providing supporting information, although noted, will not be considered in making a determination. Section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered or threatened species must be made ''solely on the basis of the best scientific and commercial data available.''

Public Hearing

At this time, we do not have a public hearing scheduled for this proposed rule. The main purpose of most public hearings is to obtain public testimony or comment. In most cases, it is sufficient to submit comments through the Federal eRulemaking Portal, described above in the **ADDRESSES** section. If you would like to request a public hearing for this proposed rule, you must submit your request, in writing, to the person listed in the **FOR FURTHER INFORMATION CONTACT** section by November 25, 2011.

Species Information and Factors Affecting the Species

Section 4 of the Act (16 U.S.C. 1533) and implementing regulations (50 CFR part 424) set forth procedures for adding species to, removing species from, or reclassifying species on the Federal Lists of Endangered and Threatened Wildlife and Plants. Under section 4(a)(1) of the Act, a species may be determined to be endangered or threatened based on any of the following five factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

In considering whether a species may warrant listing under any of the five factors, we look beyond the species' exposure to a potential threat or aggregation of threats under any of the factors, and evaluate whether the species responds to those potential threats in a way that causes actual impact to the species. The identification of threats that might impact a species negatively may not be sufficient to compel a finding that the species warrants listing. The information must include evidence indicating that the threats are operative and, either singly or in aggregation, affect the status of the species. Threats are significant if they drive, or contribute to, the risk of extinction of the species, such that the species warrants listing as endangered or threatened, as those terms are defined in the Act.

Species Description

The yellow-billed parrot belongs to the family Psittacidae and is one of only two *Amazona* species endemic to Jamaica (Koenig 2001, p. 205; Snyder *et al.* 2000, p. 106). It measures approximately 28 centimeters (cm) (11 inches (in)) in length. This species is generally characterized as a green parrot with white lores (between the eye and bill) and frontal bar (forehead), a blue crown, pink throat and upper breast, bluish primary feathers, and a yellow bill (BLI 2011a, unpaginated; Forshaw and Knight 2010, p. 278).

This species occurs in mid-level (up to 1,200 meters (m) (3,937 feet (ft)), wet limestone and lower montane, mature forests of Jamaica. The late successional forest canopy height ranges from 15–20 m (49–66 ft), with occasional emergence of *Terminalia* and *Cedrela* tree species at 25–30 m (82–98 ft) (BLI 2011a, unpaginated; World Parrot Trust, 2009, unpaginated; Tole 2006, p. 790; Koenig 2001, pp. 205–206; Koenig 1999, p. 9; Wiley 1991, pp. 203–204). Undergrowth is thin, but mosses, vines, lianas, and epiphytes are abundant (Tole 2006, p. 790; Koenig 2001, p. 206). They may also be found near cultivated areas with trees at forest edge (World Parrot Trust, 2009, unpaginated; Tole 2006, p. 790); however, compared to the other endemic parrot species, the black-billed parrot *(Amazona agilis),* the yellow-billed parrot appears to prefer interior forests, rather than edge habitat (Koenig 2001, pp. 207–208, 220).

In the latter part of the 20th Century, the overall range and population of the yellow-billed parrot decreased (Juniper and Parr 1998 in BLI 2011a, unpaginated). The range of the yellow-billed parrot is estimated to be 5,400 square kilometers (km^2) (2,085 square miles (mi^2)) (approximately half the total area of Jamaica) (BLI 2011a, unpaginated). However, this species occurs in fragments within this range. The greatest occurrences are concentrated in extant mid-level wet limestone forests in the Blue Mountains, Cockpit Country, John Crow Mountains, and Mount Diablo (BLI 2011a, unpaginated; Koenig 2001, p. 205; Snyder *et al.* 2000, p. 106; Koenig 1999, pp. 9–10; Wiley 1991, pp. 203–204). Preliminary studies estimated 5,000 individuals in Cockpit Country, John Crow Mountains, and Mount Diablo (Snyder *et al.* 2000, p. 107). Today the yellow-billed parrot population is estimated to number 10,000–20,000 mature individuals, although the data quality is poor (BLI 2011a, unpaginated; World Parrot Trust, 2009, unpaginated). Cockpit Country is considered the stronghold of the species with an estimated 5,000–8,000 territorial pairs, at least 80 percent of the island's entire population (BLI 2011a, unpaginated; BLI 2011b, unpaginated; Koenig 2001, p. 205; Snyder *et al.* 2000, p. 107). Flocks of 50–60 individuals are observed year round and this species remains common in suitable habitat (BLI 2011a, unpaginated; Snyder *et al.* 2000, p. 106; Wiley 1991, p. 204); however, the yellow-billed parrot has declined, and is declining, in numbers and range based on habitat loss and degradation and trapping (BLI 2011a, unpaginated; Snyder *et al.* 2000, p. 106; Koenig 1999, p. 9; Wiley 1991, pp. 187, 204).

Like most parrot species, the yellow-billed parrot is a frugivore, and feeds on catkins, nuts, berries, fruits, blossoms, figs, and seeds (Jamaica Observer 2010, unpaginated; World Parrot Trust, 2009, unpaginated). Parrots, including this species, generally fly considerable distances in search of food (BLI 2011a, unpaginated; Lee 2010, p. 8) and disperse seeds over large areas, contributing to forest regeneration (NEPA 2010b, unpaginated). Because parrots feed primarily on fruits and flowers, they are linked to the fruiting and flowering patterns of trees; fluctuations in abundance and availability of these food sources may change diets, result in movements to areas with greater food availability, and influence local seasonal patterns of bird abundance (BLI 2011a, unpaginated; Lee 2010, p. 7; Tobias and Brightsmith 2007, p. 132; Brightsmith 2006, p. 2; Renton 2002, p. 17; Cowen n.d., pp. 5, 23).

The breeding season begins in March with yellow-billed parrots looking for and defending nest sites and ends in late July, the end of the fledgling period (BLI 2011a, unpaginated; Koenig 2001, p. 208). Mated pairs of yellow-billed parrots appear to be monogamous (Koenig 1998, unpaginated). Nesting areas, including the distance from the nest tree where pairs perch and engage in territorial vocalizations, the location

where males roost, and distance where pairs make their initial perch after arriving from foraging areas, is 50 m (164 ft) (Koenig 2001, p. 208). Yellow-billed parrots are believed to require larger, mature trees for nesting; these parrots do not excavate holes, but make use of existing ones found in old growth forests. This may explain why this species is more common, especially when nesting, in interior forests; although they have been found in other habitat types, including disturbed plantations (NEPA 2010b, unpaginated; Snyder *et al.* 2000, p. 107; Koenig 2001, p.220). Clutch size is typically 3 eggs measuring 36.0 x 29.0 mm (1.4 x 1.1 in) (World Parrot Trust, 2009, unpaginated; Koenig 2001, p. 212). *Amazona* species tend to lay one egg every other day and the female alone incubates (Koenig 2001, p. 209). Nesting success has been low, with studies showing 70 percent of breeding pairs in Cockpit Country exploring and defending nest sites, but failing to lay eggs (Snyder *et al.* 2000, p. 107). Outside of the breeding season, yellow-billed parrots have been seen in large communal roosts (World Parrot Trust, 2009, unpaginated).

Conservation Status

The yellow-billed parrot is currently classified as ''vulnerable,'' which means this species is facing a high risk of extinction in the wild, by the International Union for the Conservation of Nature due to the small, fragmented and declining range of this species, a decline in extent, area, and quality of suitable habitat due to logging and mining, and trapping (BLI 2011a, unpaginated; Snyder *et al.* 2000, p. 106). This species is also listed in Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) Appendix II, which includes species that although not necessarily now threatened with extinction may become so unless trade is strictly regulated. The yellow-billed parrot is also listed under the Second Schedule of Jamaica's Endangered Species (Protection, Conservation and Regulation of Trade) Act.

A. Present or Threatened Destruction, Modification, or Curtailment of Habitat or Range

Historically, 97 percent of Jamaica was a closed-forest ecosystem. After centuries of improper land use and a high rate of deforestation, the island has lost much of its original forest (Berglund and Johansson 2004, pp. 2, 5; Evelyn and Camirand 2003, p. 354; Koenig 2001, p. 206; Koenig 1999, p. 9). Some of the most important parrot habitat was protected from human activities by its inaccessibility, but today, even these areas are being encroached upon and degraded. Natural forests are being replaced with pine plantations and other fast-growing species (Wiley 1991, p. 201). Conversion of forest land to agriculture and pasture has accounted for a majority of deforested land and has resulted in the removal of valuable timber species as a byproduct, with natural regrowth removed as soon as it approaches marketable size (Eyre 1987, p. 342).

Today, Jamaica's forested area is estimated at 337,000 hectares (ha) (832,745 acres (ac)), or 31 percent (FAO 2011, p. 116). Of this remaining forested area, only 8 percent is classified as minimally disturbed or closed broadleaf forest, and these only occur on the steepest or most remote, inaccessible parts of the island (WWF 2001, unpaginated; Levy and Koenig 2009, p. 262; Koenig 1991, p. 9). This loss in forested habitat has resulted in a small and fragmented range for the yellow-billed parrot; a decline in the extent, area, and quality of suitable habitat; and a decline in the yellow-billed parrot population (BLI 2011a, unpaginated; World Parrot Trust 2009, unpaginated; Koenig 1999, p. 9). The greatest long-term threats to Jamaica's remaining population of yellow-billed parrot is deforestation via logging, agriculture, mining, road construction, and encroachment of nonnative species (BLI 2011a, unpaginated; NEPA 2010b, unpaginated; Levy and Koenig 2009, pp. 263–264; World Parrot Trust 2009, unpaginated; JEAN 2007, p. 4; John and Newman 2006, pp. 7, 15; Tole 2006, p. 799; Snyder *et al.* 2000, p. 106; Koenig 1999, p. 10; Varty 1991, pp. 135, 145; Wiley 1991, p. 190; Windsor Research Center n.d., unpaginated).

Cockpit Country is characterized by yellow and white limestone karst topography with rounded peaks and steep-sided, bowl-shaped depressions, known as cockpits (John and Newman 2006, p. 3; Tole 2006, p. 789). Historically, the edge forests of Cockpit Country experienced extensive clear-cutting for timber, but the rugged terrain and inaccessibility of Cockpit Country have prevented extensive resource exploitation in its interior forests (Koenig 2001, pp. 206–207; Wiley 1991, p. 201). This area has retained nearly all of its primary forest and is an important remaining tract of extensive primary forest in Jamaica; 81 percent of the region is under forest (John and Newman 2006, p. 3; Tole 2006, pp. 790, 795, 798). However, gaps indicate the beginning of a decline in contiguity and connectivity and the periphery and surrounding plains are already badly degraded (Tole 2006, pp. 790, 797; Koenig 2001, pp. 201–207). The greatest threat to the wet limestone forest habitat of Cockpit Country is deforestation due to bauxite mining. Additional threats include deforestation from road construction, conversion of forests for agriculture, poor agricultural practices, and logging, (BLI 2011b, unpaginated; Levy and Koenig 2009, p. 267; JEAN 2007, p. 4; BLI 2006, unpaginated; John and Newman 2006, p. 15; Wiley 1991, p. 201; Windsor Research Centre n.d., unpaginated).

The Blue Mountains and John Crow Mountains are located on the eastern side of Jamaica and are separated by the Rio Grande. Almost all of the two ranges were designated forest reserves and contain important remaining tracts of closed-canopy, broadleaf forest (TNC 2008b, unpaginated). In 1989, 78,200 ha (193,236 ac) were designated as the Blue and John Crow Mountains National Park (BLI 2011d, unpaginated; BLI 2011e, unpaginated; Dunkley and Barrett 2001, p. 1). The most significant threat to the Blue and John Crow Mountains is deforestation due to subsistence farming, commercial farming, and illegal logging and encroachment of invasive species (BLI 2011e, unpaginated; IUCN 2011, unpaginated; Chai *et al.* 2009, p. 2489; Dunkley and Barrett 2001, p. 2; WWF 2001, unpaginated; TNC 2008b, unpaginated).

Mount Diablo is located in the center of Jamaica and makes up part of the ''spinal forest,'' the forests along the main mountain ridges that extend along the center of the island. Conversion of forest for agriculture land, forestry plantations, expanding settlements, and bauxite mining has left the spinal forest severely fragmented (BLI 2011c, unpaginated).

Logging and Agriculture

In the Cockpit Country Conservation Action Plan, threats to the limestone forests from conversion of forest, incompatible agriculture practices, and timber extraction are ranked high (John and Newman 2006, p. 15). The immediate vicinity of Cockpit Country has a population of around 10,000 people who exploit the area (Day 2004, p. 34). Illegal logging and farming have extended into the forest reserve within Cockpit Country (Day 2004, p. 34; Chenoweth *et al.* 2001, p. 651). Loggers, legal and illegal, are removing unsustainable amounts of trees for furniture factories and other industries (TNC 2008a, unpaginated). Illegal logging opens new pathways into the forest for squatters who usually clear a patch for growing food, then move on after one season to clear additional land

(Tole 2006, p. 799). Farmers remove natural forests from cockpits, glades, and other accessible areas to plant yams, corn, dasheen, banana, plantain, and sugar cane, and graze cattle and goats (TNC 2008a, unpaginated; Day 2004, p. 35; Chenoweth *et al.* 2001, p. 652).

One of the greatest causes of deforestation and fragmentation in Cockpit Country is the illegal removal of wood for yam crops and yam sticks (JEAN 2007, p. 4; Tole 2006, p. 790; Chenoweth *et al.* 2001, p. 653). Farmers clear hillsides to plant yam crops, reducing forest cover and nesting trees. Yam plants require a support stake that is typically a sapling approximately 8–10 cm (3–4 in) in diameter. With suitable trees dwindling elsewhere, Cockpit Country is quickly becoming a source of supply. Forty percent of the total demand for yam sticks is supplied by Cockpit Country; this translates to 5 to 9 million saplings harvested annually from Cockpit Country alone (Tole 2006, pp. 790, 799). Yam stick harvesting is ranked as a medium threat to the limestone forests of Cockpit Country (John and Newman 2006, p. 15).

Adjacent to the Blue and John Crow Mountains National Park are isolated communities that rely on the park's resources for various economic activities; with almost unchecked access to the park, encroachment of these communities across the park boundary is cause for concern (IUCN 2011, unpaginated; Dunkley and Barrett 2001, pp. 2–3). Much of the area has been altered from its natural state and is used for forestry, coffee production, or subsistence farming (BLI 2011d, unpaginated). The adjacent communities have a tradition of small farming and, despite the steep slopes, hillsides are cleared and used by small subsistence farmers for carrots, peas, bananas, plantains, coconuts, pineapples, apples, cabbages, and tomatoes; coffee is also grown by small and large farmers for the well-known brand Blue Mountain Coffee (Dunkley and Barrett 2001, pp. 1, 3). Farmers use slash-and-burn techniques to clear forests for agricultural land; however, because of poor agricultural practices, the soil quality begins to deteriorate after one or two seasons, and farmers abandon their plots and clear additional land for new crops (Chai *et al.* 2009, p. 2489; TNC 2008b, unpaginated).

The human population surrounding Mount Diablo is steadily growing. Native vegetation is removed for housing, crop cultivation, and lumber. In this area, farming is the main livelihood after bauxite mining. Slash-and-burn practices are used on hillsides to clear land for cash crops, such as banana, plantain, yams, cabbage, okra, peppers, and tomatoes. Various tree species are cut for lumber and add to the deforestation and poor condition of the soils (Global Environmental Facility, Small Grants Programme (GEF SGP) 2006, unpaginated). Native forests are also removed for forestry plantations, including Pine *(Pinus caribaea),* blue Mahoe *(Hibiscus elatus),* Honduran Mahogany *(Swietenia macrophylla),* and Cedar *(Cedrela odorata).* These activities have left the mountain without any native vegetation and the central spinal forest severely fragmented.

Bauxite Mining

Bauxite is the raw material used to make aluminum and is Jamaica's principle export, accounting for over half of Jamaica's annual exports. Bauxite deposits occur in pockets of limestone and can be found under 25 percent of the island's surface (BLI 2006, unpaginated). It is removed through open pit mining (soil is removed, stored, and then replaced following completion of the mine) and is considered the most significant cause of deforestation in Jamaica (Berglund and Johansson 2004, p. 2). Bauxite mining is driving habitat destruction across the center of the island, including Mount Diablo, and has the potential to permanently destroy forests, including the wet limestone habitat found in Cockpit Country, resulting in irreversible effects on the yellow-billed parrot (Levy and Koenig 2009, p. 267; BLI 2006, unpaginated; John and Newman 2006, p. 7; Berglund and Johansson 2004, p. 6; Wiley 1991, p. 201; Windsor Research Centre n.d., unpaginated).

Within the past 50 years, bauxite mining has severely fragmented the spinal forests of Jamaica (BLI 2011c, unpaginated). In the past 40 years, Mount Diablo has been subjected to bauxite mining, which has destroyed much of the area beyond repair and is presumed to have contributed to the decline of populations of forest-dependent species, such as the yellow-billed parrot (BLI 2008, unpaginated; Koenig 2008, p. 145; Varty 2007, pp. 34, 93). In 2009, several bauxite/alumina mining companies closed their refineries due to a drop in demand; however, in July 2010 an alumina plant in Ewarton, a town located at the foot of Mount Diablo, reopened due to a return in demand, and two other plants are expected to reopen as well (RJR News 2010, unpaginated; Jamaica Observer 2010, unpaginated). One of these plants was expected to reopen in July 2011 (The Gleaner 2011, unpaginated). Where mining has occurred, it has resulted in severe impacts to the environment. For example, mining sites within Mount Diablo that were completed 10–15 years ago typically have only herbaceous groundcover, including nonnative ferns, and no regeneration of native woody tree species (BLI 2011c, unpaginated).

Bauxite mining is currently the most significant threat to Cockpit Country. It is ranked high in threats to the limestone forests in Cockpit Country (John and Newman 2006, p. 15). Bauxite deposits can be found throughout 70 percent of Cockpit Country and mining companies have already drilled for bauxite samples (BLI 2006, unpaginated; John and Newman 2006, p. 7; Walker 2006, unpaginated; Windsor Research Centre, n.d., unpaginated). In 2006, ALCOA Minerals of Jamaica and Clarendon Alumina Production were granted a renewal on two bauxite prospecting licenses, which encompassed more than 60 percent of the Cockpit Country Conservation Area and more than 42,000 ha (103,784 ac) of near-contiguous primary forest. After public outcry these licenses were suspended. The Jamaican Government has stated that it does not intend to allow mining in the Cockpit Country; however, the area remains open to future prospecting and mining interests are granted over other land uses, such as timber, agriculture, and conservation (Koenig 2008, pp. 135–137; TNC 2008a, unpaginated; JEAN 2007, p. 4; Walker 2006, unpaginated).

Few lands are excluded from mining or prospecting under the Mining Act, including 22,000 ha (54,363 ac) of Cockpit Country designated as forest reserves, which could be subject to prospecting or mining if a license or lease is obtained (JEAN 2007, p. 6). Additionally, in some, if not all, mining agreements, the Jamaican Government provides mining companies with entitlements to specific amounts of bauxite and guarantees them additional land for mining if the original land does not contain sufficient levels, further contributing to deforestation (JEAN 2007, p. 8). Although bauxite extraction is not currently occurring in Cockpit Country, mining remains a significant impending threat to the area. The amount of deposits found throughout the area, and the facts that the area remains open to future prospecting and bauxite is Jamaica's principle export, leaves open the possibility that mining may occur in the future (JEAN 2007, p. 4; Windsor Research Centre n.d., unpaginated).

If mining were to occur in Cockpit Country, the impacts to the wet limestone forest habitat and wildlife

would be irreversible (Varty 2007, p. 93; Windsor Research Centre n.d., unpaginated). During the prospecting phase, a company or individual is required to obtain a prospecting right from the Jamaican government; however, this does not require an environmental permit which requires an environmental impact assessment be conducted before being granted (Jamaica Ministry of Energy and Mining 2006a, unpaginated). Forests are cleared during this phase using heavy machinery to create roads for transporting drilling equipment. Once the area of interest has been identified and the existence of a commercially exploitable mineral exists, a mining lease must be obtained to mine and sell the product. A mining lease requires an environmental permit, and therefore, an environmental impact assessment (Jamaica Ministry of Energy and Mining 2006b, unpaginated); however, one of the problems with conservation in Jamaica is incomplete and improper environmental impact assessments (Levy and Koenig 2009, p. 263). The mining phase requires a more extensive road network and all the vegetation covering bauxite deposits are removed. Mining in a karst region can lead to altered flow regimes and changes in drainage patterns, and can reduce the soil's water retention capability, making it difficult to restore the area to its original state (JEAN 2007, pp. 4–5; Berglund and Johansson 2004, p. 6). After mining is completed, companies are required to restore lands destroyed by mining. However, a typical restored site consists of a thin layer of topsoil bulldozed over densely packed limestone gravel and planted with nonnative grasses, preventing the regeneration of native forests (Koenig 2008, p. 141; BLI 2006, unpaginated). Penalties for failing to meet the reclamation requirements are often not enforced (BLI 2006, unpaginated).

Bauxite mining has been shown to significantly impact native species and habitat. The forests of Mount Diablo have already suffered significant damage from bauxite mining, leading to the conclusion that mining cannot be allowed in Cockpit Country or it would destroy the area beyond repair (Varty 2007, p. 93). Because of the potential damage to the nesting environment, bauxite mining could drive the yellow-billed parrot population to the level of barely surviving (Koenig 2008, p. 147).

Roads

Access roads associated with bauxite mining is another significant cause of deforestation and a serious threat to the forest cover of Jamaica. Once established, either in the prospecting or mining phase, loggers use mining roads to gain access to additional forests and illegally remove trees in and around the mining area (BLI 2011a, unpaginated; JEAN 2007, pp. 4–5; Berglund and Johansson 2004, p. 6). If mining were to occur in Cockpit Country, roads established to access the cockpit bottoms would fragment the habitat, isolate forested hillsides, and increase the amount of edge habitat (Koenig 2008, pp. 141, 144). Improved human access via mining roads and the subsequent alteration in habitat and predator-prey dynamics (See Factor C) are predicted to hasten the decline of the yellow-billed parrot.

In addition to mining access roads, road construction and extensive trail systems have the potential to contribute to further deforestation or alter environmental conditions. Roads provide access to previously undisturbed forests. In Cockpit Country, forest clearance has occurred along the edge where roads have provided easy access (JEAN 2007, p. 4). Interior forests were once inaccessible; however, continued road construction into these areas will lead to increased deforestation and logging (WWF 2001, unpaginated). Construction of Highway 2000 along the southern boundary of Cockpit Country may threaten the area through subsequent logging and the need for limestone fill, which could be quarried from Cockpit Country (Day 2004, p. 35; Windsor Research Centre no date, unpaginated). Roads and trails are ranked high in threats to the limestone forest of Cockpit Country (John and Newman 2006, p. 15). Additionally, roads and trails create openings in the forest, exposing it to new environmental conditions that alter the high-humidity conditions in which species of wet limestone habitat are adapted and facilitate the spread of invasive species (JEAN 2007, p. 4; Windsor Research Centre no date, unpaginated).

Nonnative Species

Forest clearance, whether through mining, road/trail development, logging, or agriculture, not only reduces the size of continuous forests and opens them up to further deforestation, it also alters the natural environment and facilitates the spread of harmful nonnative plants and animals (JEAN 2007, p. 4; Windsor Research Centre n.d., unpaginated). Nonnative invasive plant species have the ability to outcompete and dominate native plant communities and are ranked high in threats to the limestone forests of Cockpit Country (John and Newman, 2006, p. 15). The many years of land clearance experienced by the Blue and John Crow Mountains National Park has led to the expansion of invasive species, including wild coffee *(Pittosporum undulatum)* and ginger lily *(Hydicum spicatum),* which are invading and quickly spreading in closed-canopy forests (BLI 2011d, unpaginated; TNC 2008b, unpaginated; JEAN 2007, p. 4; Windsor Research Centre no date, unpaginated). Nonnative species prevents the regeneration of native forests so that rare, late-successional species typical of old growth forests are replaced by common secondary species or nonnative species (Chai *et al.* 2009, p. 2490; Koenig 2008, p. 142; TNC 2008b, unpaginated).

Impacts of Deforestation

Deforestation through mining, road construction, logging, and agriculture contributes to the loss of Jamaica's remaining primary forest, habitat for the yellow-billed parrot, and essential resources for the life functions of the yellow-billed parrot. The removal of trees reduces food sources, shelter from inclement weather, and most importantly, nesting sites, which are reported to be limited (NEPA 2010b, unpaginated; Tole 2006, pp. 790–791; Koenig 2001, p. 206; Koenig 1999, p. 10; Wiley 1991, p. 190). The removal of saplings for yam sticks eliminates the source of regeneration for mature trees in which nesting cavities will form. Deforestation also changes the quality of remaining resources (Koenig 2001, p. 206; Koenig 1999, p. 10) and prevents the regeneration of native forests. The agricultural practices of farmers leave the land unfertile and unstable, especially on hillsides. Cash crops do not have a sufficient root system to hold soil, and the loss of the forest canopy leaves the soil vulnerable to impacts from rainfall, resulting in massive soil erosion (GEF SGP 2006, unpaginated). This decrease in the quality of the land prevents native forests from regenerating (Dunkley and Barrett 2001, p. 2; WWF 2001, unpaginated). Furthermore, deforestation also allows human disturbance to extend further into the interior of the forest, contributing to further deforestation, altering the habitat, and affecting the predator/prey balance (See Factor C) (Tole 2006, pp. 790–791; Koenig 1999, pp. 11–12). Threats to the limestone forest of Cockpit Country overall are considered very high (John and Newman 2006, p. 15).

Deforestation can also change the species composition and structure of a forest, rendering it unsuitable for the yellow-billed parrot. Openings in the forest expose the forest edge to new environmental conditions, such as increased sunlight and airflow, altering

the microclimate from the highly humid conditions of the interior forest, to which species such as the yellow-billed parrot are adapted (JEAN 2007, p. 4; Tole 2006, p. 798; Windsor Research Centre no date, unpaginated). The new environmental conditions facilitate the establishment of nonnative species and prevent the regeneration of native forests; rare, late-successional species typical of old growth forests are replaced by common secondary species or nonnative species (Chai *et al.* 2009, p. 2490; Koenig 2008, p. 142; TNC 2008b, unpaginated). This resulting ''edge habitat'' can exert a strong effect on species; birds have been shown to be affected from 50 m (164 ft) to 250 m (820 ft) from the cleared edges (Chai *et al.* 2009, p. 2489). Studies on the black-billed parrot found that boa abundance and accessibility of parrot nests to boas were higher in forest edge than in the interior (See Factor C) (Koenig *et al.* 2007, p. 87). Only 26 percent of black-billed parrot nests located in regenerating edge habitat successfully fledged at least one chick, whereas 60 percent of nests in moderately disturbed interior forests successfully fledged at least one nestling (Koenig *et al.* 2007, p. 86). Of 35 nests that failed, 50 percent experienced predation in regenerating edge, compared to none in the interior forest (Koenig *et al.* 2007, p. 86). Fecundity was found to decline in edge habitat; over 60 percent lower than that of the interior, a level inadequate for population persistence (Koenig 2008, pp. 143, 145; Koenig *et al.* 2007, p. 86).

Conservation Programs

Conservation International, South Trelawny Environmental Agency, the Windsor Research Centre, and Jamaica's Forestry Department are working together to produce a long-term protection strategy for Cockpit Country. Part of the strategy involves the use of plastic yam sticks, incentive programs to encourage farmers to set aside 40 ha (99 ac) of forest as a reserve, training members of the community as enforcement officers, and restoring abandoned land with native species (Tole 2006, p. 800). We do not know the status of this program or what goals have been achieved.

Within the Blue and John Crow Mountains National Park, there are programs aimed at controlling nonnative species. Parks in Peril and the Jamaica Conservation and Development Trust established a nursery as a forest restoration project; timber and fruit trees are distributed to adjacent communities for planting (TNC 2008b, unpaginated). The success of this program is unknown.

Summary of Factor A

The yellow-billed parrot is restricted to the island of Jamaica. Past deforestation has resulted in a small and fragmented range on the island, a decline in the extent and quality of suitable habitat, and a declining yellow-billed parrot population. Deforestation remains a significant threat to Jamaica's forests. Mining, road and trail construction, logging, agriculture, and encroachment of nonnative species continue to threaten the remaining primary forests where this species exists. Removal of these forests without adequate regeneration permanently eliminates trees vital for foraging and nesting activities. Without these essential resources, the population of the yellow-billed parrot will likely continue to decline. Therefore, based on the best available scientific and commercial information, we find that the present or threatened destruction, modification, or curtailment of habitat or range is a threat to the yellow-billed parrot throughout its range now and in the foreseeable future.

B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Harvesting of parrot chicks for pets has seriously affected most of the parrot species in the West Indies (Wiley 1991, p. 191). In Jamaica, illegal poaching for the pet trade and farmers who shoot them to protect their crops have contributed to the decline of the yellow-billed parrot (BLI 2011a, unpaginated; Sylvester 2011, unpaginated; Jamaica Observer 2010, unpaginated; Koenig 2008, p. 145; JEAN 2007, p. 4; Snyder *et al.* 2000, p. 107; Windsor Research Center no date, unpaginated).

In 1981, the yellow-billed parrot was listed in Appendix II of CITES. CITES is an international agreement between governments to ensure that the international trade of CITES-listed plant and animal species does not threaten species' survival in the wild. There are currently 175 CITES Parties (member countries or signatories to the Convention). Under this treaty, CITES Parties regulate the import, export, and reexport of specimens, parts, and products of CITES-listed plants and animal species (also see Factor D). Trade must be authorized through a system of permits and certificates that are provided by the designated CITES Scientific and Management Authorities of each CITES Party (CITES 2010a, unpaginated).

For species listed in Appendix II of CITES, commercial trade is allowed. However, CITES requires that before an export of Appendix-II specimens can occur, a determination must be made that the specimens were legally obtained (in accordance with national laws) and that the export will not be detrimental to the survival of the species in the wild, and a CITES export document must be issued by the designated CITES Management Authority of the country of export and must accompany the export of the specimens.

According to worldwide trade data obtained from UNEP–WCMC CITES Trade Database, from 1981, when the species was listed in CITES, through 2009, 210 yellow-billed parrot specimens were reported in international trade, including 208 live birds, 1 scientific specimen, and 1 body. In analyzing these reported data, several records appear to be overcounts due to slight differences in the manner in which the importing and exporting countries reported their trade, and it is likely that the actual number of specimens of yellow-billed parrots reported to UNEP–WCMC in international trade from 1981 through 2009 was 195; including 193 live birds, 1 scientific specimen, and 1 body. Of these specimens, 11 (5.6 percent) were reportedly exported from Jamaica (UNEP–WCMC 2011, unpaginated). With the information given in the UNEP–WCMC database, from 1981 through 2009 only 1 wild specimen of yellow-billed parrot was reported in trade, and this was a nonliving body traded for scientific purposes. One live specimen with the source recorded as unknown was also reported in trade. All other specimens reported in trade were captive-bred or captive-born specimens.

Because the majority of the specimens of this species reported in international trade (99 percent) are captive-bred or captive-born, and the one wild specimen reported in trade was a scientific specimen traded for scientific purposes, we believe that international trade controlled via valid CITES permits is not a threat to the species.

Most yellow-billed parrot nestlings are poached for the local market and are not highly desirable in the international pet trade (Koenig 2001, p. 206). They are popular on Jamaica as pets because of their colorful plumage and ability to mimic human sounds; the yellow-billed parrot appears to be in higher demand than black-billed parrot because of their brighter coloration (Snyder *et al.* 2000, p. 107; Windsor Research Center no date, unpaginated). Most poaching operations are small-scale, although larger-scale operations exist (Sylvester 2011, unpaginated). Poachers may use sticks baited with fruit and covered in

glue to trap birds (Sylvester 2011, unpaginated). Additionally, poachers will cut down nesting trees to obtain nestlings (BLI 2011a, unpaginated; NEPA 2010b, unpaginated; Koenig 2008, p. 145). In March 2010, Jamaica's National Environment and Planning Agency (NEPA) published a news release reminding residents that it is illegal to buy and/or sell Jamaican parrots locally or trade in them internationally (NEPA 2010b, unpaginated). In Cockpit Country, threats to the yellow-billed parrot from collection are ranked as medium (John and Newman 2006, p. 15).

Poaching for use as a cage-bird places a strong pressure on the population of yellow-billed parrots and is the primary cause of nest failures and reduces the number of parrots in the wild (BLI 2011a, unpaginated; Snyder *et al.* 2000, p. 106). The cutting of trees to obtain parrots destroys nest cavities and reduces the number of available nesting sites for future generations. This has a significant negative impact on the yellow-billed parrot as it does not excavate its own holes for nesting, but relies on existing holes that often form in old-growth trees (BLI 2011a, unpaginated; Sylvester 2011, unpaginated; NEPA 2010b, unpaginated; Wiley 1991, p. 191). Mining access roads create accessibility to forests, and illegal timber extraction in bauxite mining areas facilitates the poaching of both nestlings and adults and exacerbates the effects of poaching on nest failures (BLI 2011a, unpaginated; Koenig 2008, p.136). Although we don't have detailed information on the numbers of yellow-billed parrots taken for the pet trade, when combined with habitat loss from deforestation, the impact to the survival of this species is severe (Sylvester 2011, unpaginated).

As described under Factor A, parrot habitat is threatened by the conversion of forests to agriculture. As agriculture spreads into parrot habitat, farmers and birds came into conflict over crops (Wiley 1991, p. 191). Some persecution for crop and garden damage, especially citrus, has been reported for the yellow-billed parrot (Snyder *et al.* 2000, p. 107).

Summary of Factor B

Since the CITES Appendix-II listing, legal international commercial trade has been very limited. However, the yellow-billed parrot appears to be popular in Jamaica's domestic market and has contributed to the decline of the species. In addition to removing individuals from the wild population, poachers cut trees to trap nestlings, removing limited essential nesting cavities and reducing the availability of nesting cavities for future generations. Ongoing deforestation in Jamaica may increase the likelihood of birds and farmers coming into conflict and yellow-billed parrots being killed to protect crops. Combined with the ongoing deforestation in Jamaica, poaching and further loss of nesting trees is a significant threat to the survival of this species. Therefore, we find that overutilization for commercial, recreational, scientific, or educational purposes is a threat to the yellow-billed parrot throughout its range now and in the foreseeable future.

C. Disease or Predation

Nonnative psittacines imported for the pet trade pose a high threat to the yellow-billed parrot through the introduction of disease, the potential for hybridization, and competitive exclusion of nesting activities (See also Factor E) (Levy and Koenig 2009, p. 264; Wiley 1991, p. 191). However, in Cockpit Country, threats from introduced diseases are ranked low (John and Newman 2006, p. 15). A temporary ban on importation of nonnative parrot species was put in place based on concerns for the introduction of highly pathogenic strains of avian influenza (Levy and Koenig 2009, p. 264).

Avian influenza is an infection caused by flu viruses, which occur in birds worldwide, especially waterfowl and shorebirds. Most strains of the avian influenza virus have low pathogenicity and cause few clinical signs in infected birds, but it is highly contagious among birds (CDC 2010, 2005, unpaginated). Pathogenicity is the ability of a pathogen to produce an infectious disease in an organism. However, strains can mutate into highly pathogenic forms, which is what happened in 1997, when the highly pathogenic avian influenza virus (called H5N1) first appeared in Hong Kong (USDA *et al.* 2006, pp. 1–2). Signs of low pathogenic avian influenza include decreased food consumption, coughing and sneezing, and decreased egg production. Birds infected with highly pathogenic influenza may exhibit these same symptoms plus a lack of energy, soft-shelled eggs, swelling, purple discoloration, nasal discharge, lack of coordination, diarrhea, or sudden death (USDA 2007, unpaginated).

Jamaica's ban on importation of nonnative psittacines is still in effect and efforts have been made to make the ban permanent (Levy and Koenig 2009, p. 264). Additionally, importation of caged birds from Trinidad and Tobago or any country of South America is prohibited under the Animal Disease and Importation Act (The Animal Diseases (Importation) Control Regulations 1948, p. 76). Most of the information regarding avian influenza is on domesticated bird species, especially poultry. We do not have information on the extent that introduced parrot species and the spread of avian influenza has impacted the yellow-billed parrot.

The Jamaican boa, or yellow boa *(Epicrates subflavus),* is the only native predator to be of potential consequence for roosting parrots (Koenig 2008, p. 144). The yellow boa is also an endemic species listed as vulnerable. Edge habitats appear to provide an optimal habitat for the boa due to the proximity to human settlements and the subsequent increased number of pests, such as rats (Tole 2006, p. 799). Also, edge habitats are exposed to more sunlight than the interior forest; this exposure likely results in an increase in the abundance of vines, which enhances the connectivity between neighboring trees and facilitates the movement of boas (Koenig *et al.* 2007, p. 86). Habitat loss has contributed to the decline and isolation of yellow boas, although it is common in Cockpit Country, and nestling parrots represent one important prey item (Koenig *et al.* 2007, p. 87; Koenig 2001, p. 221). Although yellow-billed parrots appear to prefer interior forests and are less common in edge habitat than the black-billed parrot, there is direct evidence of yellow boas preying on yellow-billed nestlings and predation by yellow boas has been identified as a major cause of dwindling numbers (Koenig *et al.* 2007, p. 82; Tole 2006, p. 799; Koenig 2001, p. 217; Koenig 1999, p. 10). As deforestation continues and more edge habitat is created, the yellow-billed parrot may become more vulnerable to predation by boas. Any decline in recruitment due to predation of nestlings will have a negative impact on the ability of the yellow-billed parrot population to stabilize or increase.

Red-tailed hawks *(Buteo jamaicensis),* are another important predator of fledgling and juvenile parrots. They occur in low densities across the closed canopy of Cockpit Country, however, it is commonly observed in peripheral habitat. Mining in Cockpit Country would create additional suitable habitat for these birds and increase the risk of predation on parrots (Koenig 2008, p. 144).

Summary of Factor C

Although imported nonnative psittacines were identified as a high threat to the yellow-billed parrot, in part, due to concerns for the introduction of highly pathogenic

strains of avian influenza, we have no information that the yellow-billed parrot has been impacted by this disease at a level which may affect the status of the species as a whole and to the extent that it is considered a threat to the species. Furthermore, we believe that the ban on importation on nonnative parrot species, although still currently temporary, and the prohibition on the importation of caged birds from Trinidad and Tobago and South America, play a vital role in preventing the spread of this disease. Therefore, we find that disease is not a threat to this species throughout its range now or in the foreseeable future.

There is direct evidence of boas preying on yellow-billed parrot nestlings. Edge habitat provides an optimal habitat for the yellow boa. As primary forests diminish and edge habitat increases, predation by boas on parrots may also increase. We do not have any information on actual predation by red-tailed hawks on the yellow-billed parrot. However, if mining occurs in Cockpit Country, habitat may be altered to conditions suitable for the hawk and increase the risk of predation. Based on the direct evidence of predation by boas and the continuing threat of deforestation and conversion of primary forests to edge habitat, and the associated increased risk of predation, we find that predation is a threat to the yellow-billed parrot throughout its range now and in the foreseeable future.

D. Inadequacy of Existing Regulatory Mechanisms

National Laws

The yellow-billed parrot is listed under the Second Schedule of Jamaica's Endangered Species (Protection, Conservation and Regulation of Trade) Act (JESA). The Second Schedule includes those species that could become extinct or which have to be effectively controlled (JESA 2000, pp. 72, 80). It is illegal to buy and/or sell Jamaican parrots locally or trade them internationally (NEPA 2010b, unpaginated; JESA 2000, p. 14; Snyder *et al.* 2000, p. 107; Wiley 1991, p. 202). CITES permits or certificates are required to import animals under JESA (Williams-Raynor 2010, unpaginated). Offenses can result in a fine of 2,000,000 Jamaican dollars (approximately 23,500 U.S. dollars), imprisonment up to 2 years, or both. If convicted in a Circuit Court, the offender is subject to a fine, prison term up to 10 years, or both (JESA 2000, p. 39).

Parrots have full protection under section six of the Jamaican Wildlife Protection Act (1974) (WPA) (Wiley 1991, p. 202). The WPA was originally passed in 1945 to regulate sport hunting and fishing, but since that time has undergone changes to address protection of animals. It does not, however, address habitat protection or the conservation of flora (Levy and Koenig 2009, p. 263). Possession is regulated by the WPA (Koenig 1999, p. 10). Under this Act it is illegal for any person to hunt or possess a protected bird, including the yellow-billed parrot, take, or have in possession the nest or egg of any protected bird (WPA 1945, pp. 4–5). Under section 20 of the legislation, anyone found in possession of a live Jamaican parrot or any of its parts can face a maximum fine of 100,000 Jamaican dollars (1,200 U.S. dollars) or 12 months in prison (WPA 1945, p. 11). However, fines levied are often much less. For example, one offender was charged a fine of only 5,000 Jamaican dollars (55 U.S. dollars) (Sylvester 2011, unpaginated).

As described under Factor B, the poaching of adult and nestling yellow-billed parrots for the local pet bird trade has contributed to the decline of the species and remains a threat; therefore, the JESA and WPA do not appear to adequately protect this species.

Forestry Acts of 1937 and 1973 provide certain protections to some habitat (e.g., Cockpit Country Forestry Reserve) and other areas have been established as sanctuaries (Snyder *et al.* 2000, p. 107; Wiley 1991, p. 202). There are more than 150 forest reserves, which provide for the preservation of forests, watershed protection, and ecotourism (Levy and Koenig 2009, p. 263). After Hurricane Gilbert in 1988, a new Forest Act (1996) was implemented. This Act provides for the conservation and sustainable management of forests and covers such activities as protection of the forest for ecosystem services and biodiversity (Levy and Koenig 2009, p. 263). The Act provides for the declaration of forest reserves and forest management areas for purposes such as conservation of natural forests, development of forest resources, generation of forest products, conservation of soil and water resources, and protection of flora and fauna. The lease of any parcel of land in a forest reserve is also regulated. Management plans are required every 5 years which include a determination of an allowable annual cut, forest plantations to be established, a conservation and protection program, and portions of the land to be leased and for what purposes. Clearing of land for cultivation, cattle grazing, and the burning of vegetation are regulated. Permits are also required for harvesting of timber on Crown land, the processing of timber, or sale of timber; no person shall cut a tree in a forest reserve without a license. As described under Factor A, deforestation is the main threat to Jamaica's forests. Forests originally covered 97 percent of the island; they now cover only 30 percent. The remaining forests continue to be threatened by deforestation from logging, agriculture, and mining; therefore, it appears that this regulation does not adequately protect the forest resources of Jamaica.

Under the Natural Resources Conservation Authority Act, an environmental permit is required for the first-time introduction of species of flora and fauna and genetic material (Williams-Raynor 2010, unpaginated). Mining is also regulated by this Act. Before any physical development or construction can take place, a permit must be obtained from the Natural Resources Conservation Authority (NRCA). If the activity is likely to be harmful to public health or natural resources, NRCA can refuse a permit or order the immediate cessation of the activity or even closure of the plant (Berglund and Johansson 2004, p. 8). This Act also addresses habitat protection by providing a framework for a system of protected areas, such as the Blue and John Crow Mountains National Park (Levy and Koenig 2009, p. 263). We do not have information to completely analyze the adequacy of this regulation; however, one of the problems with conservation in Jamaica is incomplete and improper environmental impact assessments which are required to obtain an environmental permit (Levy and Koenig 2009, p. 263). Therefore, it appears that this regulation may not be adequate to ameliorate threats to the forest resources of Jamaica.

Under the Mining Act (1947), bauxite deposits are owned by the government, not by the owner of the land. The government may issue licenses to anyone to explore the land or mining leases to exploit it; therefore, in order to prospect and search for minerals, companies do not need to purchase the land. The Act gives the lessee or the license holder the right to enter government land or privately owned land to search for minerals or to mine minerals. Compensation is payable to the landowner for damages to land and property. The Act also stipulates that the mining companies must restore every mined area of land to the level of productivity that existed prior to the mining. Restoration must take place within 6 months following the end of mining activity. Failure to do so results in a penalty of 4,500 U.S. dollars per

acre. The average cost for mined-out bauxite restoration is 4,000 U.S. dollars per acre; therefore, companies are more encouraged to restore. According to the Jamaican Bauxite Institute (the government agency responsible for monitoring the bauxite industry), failure of restoration is very unusual (Berglund and Johansson 2004, p. 7). However, there are reports that penalties for failing to meet reclamation requirements are rarely enforced. Furthermore, when restoration is done, it is often planted with nonnative grasses and is not the same habitat that existed before mining (See Bauxite Mining section above) (BLI 2011c, unpaginated; Koenig 2008, p. 141; BLI 2006, unpaginated). Given the resulting habitat following bauxite mining on Mount Diablo, it appears that this regulation is not adequate to ameliorate threats to the forest resources of Jamaica.

An import permit is also required from the Veterinary Services Division under the Animal Disease and Importation Act (Williams-Raynor 2010, unpaginated). Additionally, no caged bird shall be imported into Jamaica from Trinidad and Tobago or any country of South America. Based on an increase in illegal importation of animals into Jamaica (See Factor E), it appears that this law may not adequately protect the yellow-billed parrots from potential disease, hybridization, or competition with non-native species.

There are at least 34 pieces of Jamaican legislation that refer to the environment. However, there are problems with conservation in Jamaica that stem from poor communication between various government institutions, regulations insufficient at recognizing the value of biodiversity, insufficient funding, poor enforcement, and incomplete and improper environmental impact assessments (Levy and Koenig 2009, p. 263). In fact, due to the limitations of the Forestry Department and NRCA, management of the first national park was delegated to an NGO, Jamaica Conservation and Development Trust (JCDT) (Levy and Koenig 2009, p. 263). The Forestry Department currently manages the entire Cockpit Country region as a forest reserve; however, they lack adequate technical and enforcement staff to respond to the increasing deforestation problem (Tole 2006, p. 799).

Policies have led to a greater awareness of the legal status of parrots; however, they continue to be illegally harvested for local and, perhaps, some international trade (Snyder *et al.* 2000, p. 107). Stringent gun control has been instituted by the Jamaican Government, but a stricter policy on poaching of nests is needed (Snyder *et al.* 2000, p. 107; Wiley 1991, p. 202). At a meeting in February 2010, NEPA, along with others, decided to take actions to cut down on trade. These actions include a public awareness program, increased monitoring of ports and territorial waters, adding pet stores in the Natural Resources Conservation Authority's Permit and License System, and publicizing information on seizures and confiscations; to date the agency has undertaken the awareness campaign (Williams-Raynor 2010, unpaginated).

Protected Areas

Habitat in the Blue and John Crow Mountains was declared a national park in 1989 and is managed by the Jamaica Conservation and Development Trust, a local nongovernmental organization (NGO) (BLI 2011d, unpaginated; BLI 2011e, unpaginated; Dunkley and Barrett 2001, p. 1; Snyder *et al.* 2000, p. 107; Wiley 1991, p. 202). It protects one third of the approximately 30 percent of Jamaica that remains forested (TNC 2008b, unpaginated). The purpose of this national park is to ensure long-term conservation of biodiversity, ecosystem services, and other cultural heritage. The main conservation objective is to maintain and enhance the remaining area of closed broadleaf forest and the flora and fauna within it. The park is guided by a 5-year management plan (IUCN 2011, unpaginated).

Enforcement and management of the national park are weak. Laws that prohibit forest clearance inside National Parks are largely not enforced as park rangers fear reprisals from farmers (Chai *et al.* 2009, pp. 2489, 2491). One study found that even after designation as a protected area, the Blue and John Crow Mountains National Park continued to experience forest clearance and fragmentation, resulting in an increasing number of smaller, more vulnerable fragments, species shifts, and loss in biodiversity. However, forest regrowth increased, resulting in a 63 percent decline in deforestation (Chai *et al.* 2009, pp. 2487–2488, 2489). Because this park is managed by an NGO, funding is a continuing problem and restricts actions (BLI 2011d, unpaginated).

Fifteen important bird areas (IBAs) cover approximately 3,113 km^2 (1,202 mi^2), or 25 percent, of Jamaica's land area. The yellow-billed parrot is listed as occurring in 10 of these IBAs, although population estimates are not available for most. IBAs are international site priorities for bird conservation. These areas may overlap with forest reserves or Crown lands that offer protection, but designation as an IBA itself does not afford any protection to the area. In Jamaica, 44 percent of the area covered by IBAs is under formal protection, but active management is minimal in many areas (Levy and Koenig 2009, p. 265).

International Laws

The yellow-billed parrot is listed in Appendix II of CITES. CITES is an international treaty among 175 nations, including Jamaica and the United States, entered into force in 1975. In the United States, CITES is implemented through the U.S. Endangered Species Act of 1973, as amended. The Act designates the Secretary of the Interior as lead responsibility to implement CITES on behalf of the United States, with the functions of the Management and Scientific Authorities to be carried out by the Service. Under this treaty, member countries work together to ensure that international trade in animal and plant species is not detrimental to the survival of wild populations by regulating the import, export, and reexport of CITES-listed animal and plant species.

Through Resolution Conf. 8.4 (Rev. CoP15), the Parties to CITES adopted a process, termed the National Legislation Project, to evaluate whether Parties have adequate domestic legislation to successfully implement the Treaty (CITES 2010b, pp. 1–5). In reviewing a country's national legislation, the CITES Secretariat evaluates factors such as whether a Party's domestic laws designate the responsible Scientific and Management Authorities, prohibit trade contrary to the requirements of the Convention, have penalty provisions in place for illegal trade, and provide for seizure of specimens that are illegally traded or possessed. The Government of Jamaica was determined to be in Category 1, which means they meet all the requirements to implement CITES (*http://www.cites.org,* SC59 Document 11, Annex p. 1).

As discussed under Factor B, we do not consider international trade to be a threat impacting this species. Therefore, protection under this Treaty against unsustainable international trade is an adequate regulatory mechanism.

The import of yellow-billed parrots into the United States is also regulated by the Wild Bird Conservation Act (WBCA) (16 U.S.C. 4901 *et seq.*), which was enacted on October 23, 1992. The purpose of the WBCA is to promote the conservation of exotic birds by ensuring that all imports to the United States of exotic birds are biologically sustainable and not detrimental to the species. The WBCA generally restricts the importation of most CITES-listed live or

dead exotic birds except for certain limited purposes such as zoological display or cooperative breeding programs. Import of dead specimens is allowed for scientific specimens and museum specimens. The Service may approve cooperative breeding programs and subsequently issue import permits under such programs. Wild-caught birds may be imported into the United States if certain standards are met and they are subject to a management plan that provides for sustainable use. At this time, the yellow-billed parrot is not part of a Service-approved cooperative breeding program and has not been approved for importation of wild-caught birds.

International trade of parrots was significantly reduced during the 1990s as a result of tighter enforcement of CITES regulations, stricter measures under EU legislation, and adoption of the WBCA, along with adoption of national legislation in various countries (Snyder *et al.* 2000, p. 99). As discussed under Factor B, we found that commercial legal international trade has been very limited; however, yellow-billed parrots are taken for the local Jamaican market. We believe that regulations are adequately protecting the species from international trade, but national laws are inadequate to ameliorate threats from poaching for Jamaica's domestic pet bird trade.

Summary of Factor D

Although there are laws intended to protect the forests of Jamaica and the yellow-billed parrot, deforestation from mining, logging, and agriculture continues to be a threat, even within protected areas such as the Blue and John Crow Mountains National Park; predation increased by habitat alteration continues to be a threat, and yellow-billed parrots continue to be poached for the local pet bird market. Therefore, we find that inadequate regulatory mechanisms are a threat to the yellow-billed parrot throughout its range now and in the foreseeable future.

E. Other Natural or Manmade Factors Affecting the Species' Continued Existence

Hurricanes

Hurricanes are a constant threat to island populations of wildlife and are a frequent occurrence in the Caribbean (Wiley and Wunderle 1993, p. 320). In 1988, Hurricane Gilbert hit Jamaica causing widespread damage to the island's mid-level and montane forests; Cockpit Country, Blue Mountains, and John Crow Mountains all suffered severe and very extensive damage (Varty 1991, pp. 135, 138). Since 2004, Jamaica has been hit by 5 major storms, including 2 hurricanes and 3 tropical storms (Thompson 2011, unpaginated). The most vulnerable birds are frugivorous and birds that require large trees for foraging or nesting; require a closed canopy forest; have special microclimate requirements; or live in a habitat in which vegetation is slow to recover, like the yellow-billed parrot (Wiley and Wunderle 1992, pp. 319, 337). Survival of small populations within a fragmented habitat becomes more uncertain if the destructive potential of catastrophic events increases, as predicted for hurricanes with increased climate change (Wiley and Wunderle 1993, p. 319).

Frequent hurricanes can have direct and indirect effects on bird populations. Direct effects include mortality from winds, rain, and storm surges, and geographic displacement of individuals by the wind. Wet plumage may cause hypothermia and death in birds, with chicks being at greater risk than adults. Additionally, birds may be killed by falling trees or flying debris, thrown against objects, or high winds may blow them out to sea where they die from exhaustion and drowning (Wiley and Wunderle 1993, pp. 319, 321–322). However, the greatest impacts to birds are the indirect effects that come after the storm has passed and stem from the destruction of vegetation. These effects include loss of food sources, loss of nests and nesting sites, increased vulnerability to predation, microclimate changes, and increased conflict with humans (Wiley and Wunderle 1993, pp. 319, 321, 326, 337; Varty 1991, p. 148).

Defoliation is the most common type of damage caused by hurricanes. High winds remove flowers, fruit, and seeds, impacting frugivores like the yellow-billed parrot, the greatest. Larger trees, which are typically the best producers, are the ones most affected by hurricanes. Certain sections of Jamaica following Hurricane Gilbert regenerated quickly, while the destruction in some areas was so complete it was estimated to take many years to be reestablished. The majority of trees and shrubs were reported to have been mostly or totally defoliated; trees in flower or fruit lost their blooms and crops (Varty 1991, pp. 139, 148). In some cases, the production of flowers and fruits are less than 50 percent of pre-hurricane levels after 1 year (Wiley and Wunderle 1993, pp. 324–325). Seven months after Hurricane Gilbert, some areas had little or no apparent regrowth; although most trees showed signs of refoliation, and after 10 months some trees began to show signs of growth (Varty 1991, pp. 140–141). For frugivores, food supplies are likely to be reduced for several years following a destructive hurricane, and with limited resources birds may experience greater competition for food, leading to a decline in populations (Wiley and Wunderle 1993, p. 332; Varty 1991, pp. 144, 148).

Nesting sites can also be damaged by high winds, rain, or flooding. The larger, taller trees, like those needed by the yellow-billed parrot for nesting activities, are the most susceptible to snapping or uprooting (Wiley and Wunderle 1993, p. 327). During Hurricane Gilbert, many trees were toppled or had crowns or major limbs broken or snapped off. Others were damaged or knocked over by other windfall trees. In some places, landslides totally destroyed the forests (Varty 1991, p. 139). The loss of these nesting trees further reduces the already-limited nesting cavities available. Damaged trees that remain standing are more likely to be lost in future storms, increasing the risk to yellow-billed parrots using them. However, trees that suffer limb breakage but remain standing may create additional cavities for nesting (Wiley and Wunderle 1993, pp. 326–328). With the loss of suitable nesting sites, reproductive responses may vary following a storm. Hurricane Gilbert severely damaged or blew over 50 percent and 44 percent of the larger trees in John Crow Mountains and Cockpit Country, respectively; however, some yellow-billed parrots were observed successfully breeding in Cockpit Country within 10 months of the storm (Wiley and Wunderle 1993, p. 335; Varty 1991, pp. 143, 149).

Defoliated habitat may increase the risk of yellow-billed parrots to predators, including humans. For example, because of competition for limited food resources, forest dwellers may be forced to forage closer to the ground or wander more widely, exposing them to predators. Birds may be weakened after a storm and serve as an easy source of protein for predators and humans in need of food. Additionally, while in search of food and cover, birds may come into conflict with humans in agricultural regions, making them more vulnerable to poaching; farmers may shoot birds to protect any remaining crops (Wiley and Wunderle 1993, pp. 330–332). Hurricanes also create additional edge habitat by increasing the number and size of forest openings; this may enable predators to invade forest tracts they would otherwise avoid (Wiley and Wunderle 1993, p. 336).

Furthermore, where trees have been blown down, subsistence farmers may move in to exploit the land. Governments may also make subsidies available for timber removal and development of the land, including the use of chainsaws and heavy equipment to clear away debris and dead trees. The equipment may not be recalled following cleanup and may be used to clear healthy forests (Wiley and Wunderle 1993, p. 331). Following Hurricane Gilbert, chainsaws brought in for cleanup were later used to clear forests for timber (Varty 1991, p. 146). Additionally, farmers lost most or all of their cultivated land, increasing the demand for new land and, therefore, deforestation (Varty 1991, p. 145).

Hurricanes are a natural occurrence in the Caribbean, and birds have adapted to periodic storms. Parrots should be able to adapt to changes following hurricanes and healthy, wide-ranging populations should be able to, in the long term, survive hurricanes. However, hurricanes play a more important role in extinction when a species already has a restricted and fragmented range due to habitat loss and is reduced to fewer individuals (Wiley and Wunderle 1993, pp. 340–341; Varty 1991, p. 149; Wiley 1991, p. 191). After a population has declined due to deforestation activities, they may not be able to recover from the additional loss of forests from hurricanes (Varty 1991, p. 149). The yellow-billed parrot population has survived through hurricanes, but long-term survival is a concern given the impact of hurricanes on food and nesting sources, combined with the continuing habitat destruction by humans (Wiley 1991, p. 203).

Competition With Nonnative Species

NEPA has noticed an increase in the illegal importation of monkeys, birds, and snakes into the country. Jamaica is now believed to be a trans-shipment point for illegal trade in animals from Central and South America (NEPA 2010a, p. 1). Nonnative species not only introduce diseases to native wildlife (See Factor C), but escaped individuals also pose a threat through hybridization and competition for food and nesting sources (Levy and Koenig 2009, p. 264; Wiley 1991, p. 191). A temporary ban was placed on the importation of nonnative psittacines due to potential introduction of disease, hybridization, and competition with the two native parrot species. Other nonnative species known to have played a role in the decline and extinction of parrots include honeybees *(Apis mellifera)* and rats (especially *Rattus rattus);* these compete with parrots for nest cavities.

We have no information on the extent of non-native species being introduced to Jamaica or the extent of hybridization and competition. Therefore, we do not find that competition with non-native species is a threat to the yellow-billed parrot.

Summary of Factor E

We do not have any information on the actual impacts of nonnative species on the yellow-billed parrot on which to base an analysis of potential threats; therefore, we do not find that nonnative species pose a threat to the yellow-billed parrot.

Hurricanes frequently occur in the Caribbean. Healthy, widespread populations of birds should be able to adapt to changes following a hurricane. However, species like the yellow-billed parrot that are frugivores and rely on cavities in old growth trees, are particularly vulnerable to the impacts of hurricanes on forests. Food sources may be reduced for years following a storm and already-limited nesting cavities are further reduced; declines in these vital resources could result in competition with other species and a decline in the population. These impacts are further exacerbated due to deforestation activities that have caused a decline in the extent and quality of yellow-billed parrot habitat and declines in the yellow-billed parrot population. Because of the ongoing loss of habitat, yellow-billed parrots may not be able to recover from the impacts of a destructive hurricane; therefore, we find that hurricanes are a threat to the yellow-billed parrot now and in the foreseeable future.

Finding

As required by the Act, we conducted a review of the status of the species and considered the five factors in assessing whether the yellow-billed parrot is endangered or threatened throughout all or a significant portion of its range. We examined the best scientific and commercial information available regarding the past, present, and future threats faced by the yellow-billed parrot. We reviewed the petition, information available in our files, and other available published and unpublished information.

The yellow-billed parrot is only found on the island of Jamaica and occurs in fragments across its range; at least 80 percent of the yellow-billed parrot population occurs in one area of the island. The entire population of this species is reported as declining, and the extent and quality of habitat is also declining. This species faces immediate and significant threats, primarily from deforestation through logging, conversion of land to agriculture, road construction, and mining and the subsequent encroachment of nonnative species. Ongoing deforestation activities threaten to remove more of the limited mature trees the yellow-billed parrot needs for nesting. Cockpit Country is also threatened by potential future mining. If mining were to occur, the damage would be irreversible. Additionally, habitat alteration creates an optimal habitat for the yellow boa, which has already been reported to prey on yellow-billed parrot nestlings; continuing deforestation increases this risk of predation. Adults and nestling yellow-billed parrots are captured for the local pet bird trade. Poaching of birds for the pet bird trade removes vital individuals from the population and essential nesting cavities. There are regulatory mechanisms in place to protect the yellow-billed parrot and its habitat, but enforcement appears to be inadequate given the threats this species is currently facing. Hurricanes also pose a threat to the yellow-billed parrot because of the already ongoing deforestation and population decline. This species, in the long term, may not be able to recover from the additional impacts of hurricanes on foraging and nesting resources given the continuing loss of food and nesting resources by logging, agriculture, road development, and mining.

Section 3 of the Act defines an ''endangered species'' as ''any species which is in danger of extinction throughout all or a significant portion of its range,'' and a ''threatened species'' as ''any species which is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' The magnitude of the threats the yellow-billed parrot is facing is high. Nesting success is reported to be low for this species. Given the declining population, limited habitat and range, the ongoing and future threats to the remaining habitat, the associated increased risk of predation, and the loss of individuals from poaching, long-term survival of this species is a concern. Impacts from hurricanes are likely to be exacerbated by the ongoing deforestation and declining population. Any loss of individuals from the population or loss of vital nesting cavities from current or future threats further reduces the population and loss of already limited habitat and is likely to affect the reproductive success of this species. Because the population of this species is estimated at 10,000–20,000 individuals and mining is not currently occurring in

Cockpit Country, we do not believe that this species is currently in danger of extinction. However, we believe that if mining occurs in Cockpit Country, suitable habitat continues to be lost, or the effects of the current threats acting on the species are not sufficiently ameliorated within the foreseeable future, the species will continue to decline and likely become in danger of extinction; therefore on the basis of the best scientific and commercial information, we find that the yellow-billed parrot meets the definition of a ''threatened species'' under the Act, and we are proposing to list the yellow-billed parrot as threatened throughout its range.

Significant Portion of the Range

Having determined that the yellow-billed parrot meets the definition of threatened throughout its range, we must next consider whether the yellow-billed parrot is in danger of extinction within a significant portion of its range.

The Act defines an endangered species as one ''in danger of extinction throughout all or a significant portion of its range,'' and a threatened species as one ''likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' The term ''significant portion of its range'' is not defined by the statute. For the purposes of this finding, a portion of a species' range is ''significant'' if it is part of the current range of the species and it provides a crucial contribution to the representation, resiliency, or redundancy of the species. For the contribution to be crucial it must be at a level such that, without that portion, the species would be in danger of extinction.

In determining whether a species is threatened or endangered in a significant portion of its range, we first identify any portions of the range of the species that warrant further consideration. The range of a species can theoretically be divided into portions in an infinite number of ways. However, there is no purpose to analyzing portions of the range that are not reasonably likely to be significant and threatened or endangered. To identify only those portions that warrant further consideration, we determine whether there is substantial information indicating that: (1) The portions may be significant, and (2) the species may be in danger of extinction there or likely to become so within the foreseeable future. In practice, a key part of this analysis is whether the threats are geographically concentrated in some way. If the threats to the species are essentially uniform throughout its range, no portion is likely to warrant further consideration. Moreover, if any concentration of threats applies only to portions of the species' range that clearly would not meet the biologically based definition of ''significant'' (*i.e.,* the loss of that portion clearly would not reasonably be expected to increase the vulnerability to extinction of the entire species to the point that the species would then be in danger of extinction), such portions will not warrant further consideration.

If we identify portions that warrant further consideration, we then determine their status (*i.e.,* whether in fact the species is endangered or threatened in a significant portion of its range). Depending on the biology of the species, its range, and the threats it faces, it might be more efficient for us to address either the ''significant'' question first, or the status question first. Thus, if we determine that a portion of the range is not ''significant,'' we do not need to determine whether the species is endangered or threatened there; if we determine that the species is not endangered or threatened in a portion of its range, we do not need to determine if that portion is ''significant.''

Applying the process described above for determining whether this species is endangered in a significant portion of its range, we considered status first to determine if any threats or future threats acting individually or collectively endanger the species in a portion of its range. We have analyzed the threats to the degree possible, and determined they are essentially uniform throughout the species' range and no portion is being impacted to a significant degree more than any other.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness, and encourages and results in conservation actions by Federal and State governments, private agencies and interest groups, and individuals.

The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to all endangered and threatened wildlife. These prohibitions, at 50 CFR 17.21 and 17.31, in part, make it illegal for any person subject to the jurisdiction of the United States to ''take'' (includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or to attempt any of these) within the United States or upon the high seas; import or export; deliver, receive, carry, transport, or ship in interstate or foreign commerce in the course of commercial activity; or sell or offer for sale in interstate or foreign commerce any endangered wildlife species. It also is illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken in violation of the Act. Certain exceptions apply to agents of the Service and State conservation agencies.

Permits may be issued to carry out otherwise prohibited activities involving endangered and threatened wildlife species under certain circumstances. Regulations governing permits are codified at 50 CFR 17.22 for endangered species and 17.32 for threatened species. With regard to endangered wildlife, a permit may be issued for the following purposes: For scientific purposes, to enhance the propagation or survival of the species, and for incidental take in connection with otherwise lawful activities. For threatened species, a permit may be issued for the same activities, as well as zoological exhibition, education, and special purposes consistent with the Act.

Special Rule

Section 4(d) of the Act states that the Secretary of the Interior (Secretary) may, by regulation, extend to threatened species prohibitions provided for endangered species under section 9 of the Act. Our implementing regulations for threatened wildlife (50 CFR 17.31) incorporate the section 9 prohibitions for endangered wildlife, except when a special rule is promulgated. For threatened species, section 4(d) of the Act gives the Secretary discretion to specify the prohibitions and any exceptions to those prohibitions that are appropriate for the species, and provisions that are necessary and advisable to provide for the conservation of the species. A special rule allows us to include provisions that are tailored to the specific conservation needs of the threatened species and which may be more or less restrictive than the general provisions at 50 CFR 17.31.

If the proposed special rule is adopted, all prohibitions and provisions of 50 CFR 17.31 and 17.32 will apply to the yellow-billed parrot, except that import and export of certain yellow-billed parrots into and from the United States and certain acts in interstate commerce will be allowed without a permit under the Act, as explained below.

Import and Export

The proposed special rule will apply to all commercial and noncommercial international shipments of live and dead yellow-billed parrots and parts and products, including the import and export of personal pets and research samples. In most instances, the special rule will adopt the existing conservation regulatory requirements of CITES and the WBCA as the appropriate regulatory provisions for the import and export of certain yellow-billed parrots. The import and export of birds into and from the United States, taken from the wild after the date this species is listed under the Act; conducting an activity that could take or incidentally take yellow-billed parrots; and foreign commerce will need to meet the requirements of 50 CFR 17.31 and 17.32, including obtaining a permit under the Act. However, the special rule proposes to allow a person to import or export either: (1) A specimen held in captivity prior to the date this species is listed under the Act; or (2) a captive-bred specimen, without a permit issued under the Act, provided the export is authorized under CITES and the import is authorized under CITES and the WBCA. If a specimen was taken from the wild and held in captivity prior to the date this species is listed under the Act, the importer or exporter will need to provide documentation to support that status, such as a copy of the original CITES permit indicating when the bird was removed from the wild or museum specimen reports. For captive-bred birds, the importer would need to provide either a valid CITES export/reexport document issued by a foreign Management Authority that indicates that the specimen was captive-bred by using a source code on the face of the permit of either ''C,'' ''D,'' or ''F.'' For exporters of captive-bred birds, a signed and dated statement from the breeder of the bird, along with documentation on the source of their breeding stock, would document the captive-bred status of U.S. birds.

The proposed special rule will apply to birds captive-bred in the United States and abroad. The terms ''captive-bred'' and ''captivity'' used in the proposed special rule are defined in the regulations at 50 CFR 17.3 and refer to wildlife produced in a controlled environment that is intensively manipulated by man from parents that mated or otherwise transferred gametes in captivity. Although the proposed special rule requires a permit under the Act to ''take'' (including harm and harass) a yellow-billed parrot, ''take'' does not include generally accepted animal husbandry practices, breeding procedures, or provisions of veterinary care for confining, tranquilizing, or anesthetizing, when such practices, procedures, or provisions are not likely to result in injury to the wildlife when applied to captive wildlife.

We assessed the conservation needs of the yellow-billed parrot in light of the broad protections provided to the species under CITES and the WBCA. The yellow-billed parrot is listed in Appendix II under CITES, a treaty which contributes to the conservation of the species by monitoring international trade and ensuring that trade in Appendix II species is not detrimental to the survival of the species (see *Conservation Status).* The purpose of the WBCA is to promote the conservation of exotic birds and to ensure that imports of exotic birds into the United States do not harm them (See Factor D). The best available commercial data indicate that the current threat to the yellow-billed parrot stems mainly from illegal trade in the domestic markets of Jamaica. Thus, the general prohibitions on import and export contained in 50 CFR 17.31, which only extend within the jurisdiction of the United States, would not regulate such activities. Accordingly we find that the import and export requirements of the proposed special rule provide the necessary and advisable conservation measures that are needed for this species.

Interstate Commerce

Under the proposed special rule, a person may deliver, receive, carry, transport, or ship a yellow-billed parrot in interstate commerce in the course of a commercial activity, or sell or offer to sell in interstate commerce a yellow-billed parrot without a permit under the Act. At the same time, the prohibitions on take under 50 CFR 17.31 would apply under this special rule, and any interstate commerce activities that could incidentally take yellow-billed parrots or otherwise prohibited acts in foreign commerce would require a permit under 50 CFR 17.32.

Although we do not have current data, we believe there are few yellow-billed parrots in the United States. Current ISIS (International Species Information System) information shows no yellow-billed parrots held in U.S. zoos (ISIS 2011, p. 1). However, some zoos do not enter data into the ISIS database. Persons in the United States have imported and exported captive-bred yellow-billed parrots for commercial purposes and one body for scientific purposes, but trade has been very limited (UNEP–WCMC 2011, unpaginated). We have no information to suggest that interstate commerce activities are associated with threats to the yellow-billed parrot or would negatively affect any efforts aimed at the recovery of wild populations of the species. Therefore, because acts in interstate commerce within the United States has not been found to threaten the yellow-billed parrot, the species is otherwise protected in the course of interstate commercial activities under the incidental take provisions and foreign commerce provisions contained in 50 CFR 17.31, and international trade of this species is regulated under CITES, we find this special rule contains all the prohibitions and authorizations necessary and advisable for the conservation of the yellow-billed parrot.

Peer Review

In accordance with our policy, ''Notice of Interagency Cooperative Policy for Peer Review in Endangered Species Act Activities,'' that was published on July 1, 1994 (59 FR 34270), we will seek the expert opinion of at least three appropriate independent specialists regarding this proposed rule. The purpose of such review is to ensure listing decisions are based on scientifically sound data, assumptions, and analysis. We will send copies of this proposed rule to the peer reviewers immediately following publication in the **Federal Register.** We will invite these peer reviewers to comment, during the public comment period, on the specific assumptions and the data that are the basis for our conclusions regarding the proposal to list as as threatened the yellow-billed parrot, under the Act.

We will consider all comments and information we receive during the comment period on this proposed rule during preparation of a final rulemaking. Accordingly, our final decision may differ from this proposal.

Required Determinations

Clarity of Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(a) Be logically organized;

(b) Use the active voice to address readers directly;

(c) Use clear language rather than jargon;

(d) Be divided into short sections and sentences; and

(e) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the names of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, *etc.*

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

We have determined that we do not need to prepare an environmental assessment, as defined under the authority of the National Environmental Policy Act of 1969, in connection with regulations adopted under section 4(a) of the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

References Cited

A list of all references cited in this document is available at *http://www.regulations.gov,* Docket No. FWS–R9–ES–2011–0075, or upon request from the U.S. Fish and Wildlife Service, Endangered Species Program, Branch of Foreign Species (see **FOR FURTHER INFORMATION CONTACT** section).

Author

The primary authors of this notice are staff members of the Branch of Foreign Species, Endangered Species Program, U.S. Fish and Wildlife Service.

Authority

We are issuing this proposed rule under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

2. Amend § 17.11(h) by adding an entry for ''Parrot, yellow-billed'' in alphabetical order under BIRDS to the List of Endangered and Threatened Wildlife to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
*	*	*	*	*	*		*
BIRDS							
*	*	*	*	*	*		*
Parrot, yellow-billed	*Amazona collaria*	Jamaica	Entire	T		NA	17.41(c)
*	*	*	*	*	*		*

* * * * *

3. Amend § 17.41 by revising paragraph (c) to read as follows:

§ 17.41 Special rules—birds.

* * * * *

(c) The following species in the parrot family: Salmon-crested cockatoo *(Cacatua moluccensis)* and yellow-billed parrot *(Amazona collaria).*

(1) Except as noted in paragraphs (c)(2) and (c)(3) of this section, all prohibitions and provisions of §§ 17.31 and 17.32 of this part apply to these species.

(2) *Import and export.* You may import or export a specimen without a permit issued under § 17.32 of this part only when the provisions of parts 13, 14, 15, and 23 of this chapter have been met and you meet the following requirements:

(i) *Captive-bred specimens:* The source code on the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) document accompanying the specimen must be ''F'' (captive-bred), ''C'' (bred in captivity), or ''D'' (bred in captivity for commercial purposes) (see 50 CFR 23.24); or

(ii) *Specimens held in captivity prior to certain dates:* You must provide documentation to demonstrate that the specimen was held in captivity prior to the dates specified in paragraphs (c)(2)(ii)(A) and (B) of this section. Such documentation may include copies of receipts, accession or veterinary records, CITES documents, or wildlife declaration forms, which must be dated prior to the specified dates.

(A) *For salmon-crested cockatoos:* January 18, 1990 (the date this species was transferred to CITES Appendix I).

(B) *For yellow-billed parrots:* [Insert publication date for final rule] (the date this species was listed under the Endangered Species Act of 1973, as amended (Act) (16 U.S.C. 1531 *et seq.*)).

(3) *Interstate commerce.* Except where use after import is restricted under § 23.55 of this chapter, you may deliver, receive, carry, transport, or ship in interstate commerce and in the course of a commercial activity, or sell or offer to sell, in interstate commerce the species listed in paragraph (c) of this section.

* * * * *

Dated: September 20, 2011

Gregory E. Siekaniec

Director, Fish and Wildlife Service.

[FR Doc. 2011–25811 Filed 10–7–11; 8:45 am]

BILLING CODE 4310–55–P

Notices

Federal Register

Vol. 76, No. 196

Tuesday, October 11, 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.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

October 5, 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 and 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), Washington, DC, *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) 720–8681.

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.

Forest Service

Title: Overcoming Barriers to Wildland Fire Defensible Space.

OMB Control Number: 0596—New.

Summary of Collection: The Forest and Rangeland Renewable Resources Research Act of 1978 (Pub. L. 95–307) is the Department of Agriculture's primary authority to conduct research activities. The Secretary is authorized to conduct, support, and cooperate in investigations, experiments, tests, and other activities the Secretary deems necessary to obtain, analyze, develop, demonstrate, and disseminate scientific information about protecting, managing, and utilizing forest and rangeland renewable resources in rural, suburban, and urban areas. This study will provide information regarding barriers to participating in fire hazard reduction programs in the wildland urban interface and basic socio-demographics. The results of this study will assist efforts to decrease the cost to society from wildland fires and improve the efficiency of federal agencies in wildland fire management.

Need and Use of the Information: Information will be collected through a voluntary mail survey of wild land urban interface homeowners. The information collected will help wildland fire managers and researchers (1) Identify practical steps for reducing barriers to implementing defensible space behaviors at an individual and neighborhood level and (2) develop future risk reduction programs. The information will be used by local, county, state, and federal wildland fire managers in the development of educational information regarding defensible space and firewise construction. If the collection is not conducted, agencies will continue to operate their programs under assumptions about their effectiveness that may not be true or scientifically valid.

Description of Respondents: Individuals and households.

Number of Respondents: 4.509.

Frequency of Responses: Reporting: One time.

Total Burden Hours: 2,328.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. 2011–26203 Filed 10–7–11; 8:45 am]

BILLING CODE 3410–P

DEPARTMENT OF AGRICULTURE

Office of the Secretary

National Agricultural Research, Extension, Education, and Economics Advisory Board Meeting Notice

AGENCY: Research, Education, and Economics, United States Department of Agriculture (USDA).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, 5 U.S.C. App 2, the USDA announces a meeting of the National Agricultural Research, Extension, Education, and Economics Advisory Board.

DATES: The National Agricultural Research, Extension, Education, and Economics Advisory Board will meet November 7–9, 2011. The public may file written comments before or up to two weeks after the meeting with the contact person.

ADDRESSES: The meeting will take place at the Mandarin Oriental, 1330 Maryland Avenue, SW., Washington, DC 20024. Written comments from the public may be sent to the Contact Person identified in this notice at: The National Agricultural Research, Extension, Education, and Economics Advisory Board Office, Room 3901 South Building, United States Department of Agriculture, STOP 0321, 1400 Independence Avenue, SW., Washington, DC 20250–0321.

FOR FURTHER INFORMATION CONTACT: J. Robert Burk, Executive Director or Shirley Morgan-Jordan, Program Support Coordinator, National Agricultural Research, Extension, Education, and Economics Advisory Board; *telephone:* (202) 720–3684; *fax:* (202) 720–6199; or *e-mail: Robert.Burk@ars.usda.gov* or *Shirley.Morgan@ars.usda.gov.*

SUPPLEMENTARY INFORMATION: The Honorable Secretary of Agriculture Tom Vilsack, and the Under Secretary for Research, Education, and Economics Dr. Catherine Woteki have been invited to

provide brief remarks and welcome the new Board members during the meeting.

On Monday, November 7, 2011, an orientation session for new members and interested incumbent members will be held from 1 p.m.–5:30 p.m. Specific topics of discussion will include an introduction to the leadership and structure of the Agricultural Research Service, Economic Research Service, National Agricultural Statistics Service, and the National Institute of Food and Agriculture, and information on the core functions of those agencies as it relates to the impending budgets proposed by Congress.

On Tuesday, November 8, 2011 the full Advisory Board will convene at 8 a.m. with introductory remarks by the Chair of the Advisory Board. The morning session will include: brief introductions of new Board members, incumbents, and guests; comments from a variety of distinguished leaders, experts, and departmental personnel; and items of board business. Specific items on the agenda will include a discussion related to the Farm Bill and the relevant Research, Education, and Economics components of the Bill. The afternoon session will also include a discussion on the impact of National Agricultural Statistic Service reports on grain market volatility in 2011. The meeting will conclude with an evening reception that will be held from 6 p.m.–8 p.m.

On Wednesday November 9, 2011, the Board will reconvene at 8 a.m. to: elect the Executive Committee of the Advisory Board; discuss initial recommendations resulting from the meeting and future planning for the Board; to organize the memberships of the committees, sub-committees, and working groups of the Advisory Board; and to finalize Board business for the meeting. The Board Meeting will adjourn by 12 p.m. (noon).

Opportunity for public comment will be offered each day of the meeting. Written comments by attendees or other interested stakeholders will be welcomed for the public record before and up to two weeks following the Board meeting (by close of business Wednesday, November 23, 2011). All statements will become a part of the official record of the National Agricultural Research, Extension, Education, and Economics Advisory Board and will be kept on file for public review in the Research, Education, and Economics Advisory Board Office.

Done at Washington, DC, this 28 day of September 2011.

Catherine Woteki,

Under Secretary, Research, Education, and Economics.

[FR Doc. 2011–26129 Filed 10–7–11; 8:45 am]

BILLING CODE 3410–22–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Proposed Collection; Comment Request—People's Garden Initiative Evaluation of Healthy Gardens Healthy Youth Project

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on proposed information collections. This is a new information for the ''Healthy Gardens, Healthy Youth Study,'' part of the USDA's People's Garden program. This study will use the network of Cooperative Extension Educators to collect information from children in schools that have agreed to participate in the study in four states: Arkansas, Iowa, New York, and Washington. The information collected will build on existing knowledge by examining how school gardens affect children's fruit and vegetable consumption and other outcomes.

DATES: Written comments on this notice must be received on or before December 12, 2011.

ADDRESSES: Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to: Duke Storen, Director, Office of Strategic, Initiatives, Partnership and Outreach, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 1441, Alexandria, VA 22302. Comments may also be submitted via e-mail to *Duke.Storen@fns.usda.gov.* Be sure to include the title of the notice in the subject line of the message. Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically.

All written comments will be open for public inspection at the office of the Food and Nutrition Service during regular business hours (8:30 a.m. to 5 p.m., Monday through Friday) at 3101 Park Center Drive, Alexandria, Virginia 22302, Room 1441.

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

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection form and instructions should be directed to: Duke Storen, (703) 305–1431.

SUPPLEMENTARY INFORMATION:

Title: Healthy Gardens, Healthy Youth.

OMB Number: 0584–New.

Form Number: Not Yet Assigned.

Expiration Date: Not Yet Determined.

Type of Request: New collection.

Abstract: The People's Garden Initiative Evaluation of Healthy Gardens Healthy Youth Project is authorized under the Richard B. Russell National School Lunch Act (42 U.S.C. 1769(g)(3)) and section 14222(b) of the Food, Conservation, and Energy Act of 2008. The Healthy Gardens, Healthy Youth project, part of the USDA's People's Garden program, was funded by FNS in April, 2011. Prior research has suggested that school gardens may contribute to increased fruit and vegetable consumption among youth. This study will evaluate the impact of those gardens and examine how school gardens along with garden curricula to link classrooms to gardens will affect diet outcomes among youth in under-resourced communities. At all participating schools, at least 50% of children qualify for Free or Reduced Price Meals (FRPM). Up to seventy schools in four states (AK, IA, NY, WA) will be partners in this study and will be randomly assigned to one of two conditions: (1) A treatment group of no more than 34 schools will receive the garden intervention and curricula in year 1; and (2) a waitlist control group of approximately 34 schools will receive gardens near the end of the project. In

each school, 2nd and 4th and/or 5th grade classes will participate.

Affected Public: Individual/Household, State, Local and Tribal Government. The proposed data collection activities will require three types of respondent groups: individual students who participate in the study; parents or guardians who will be asked to complete some surveys; and school personnel including principals and teachers.

Estimated Number of Respondents: The total estimated number of sample members is 25,259 (*only a portion of these individual will be recruited*). This total includes 469 staff (approximately 7 staff members at each of the 67 schools (*i.e.,* principal, food service manager, physical education director, on average 268 teachers)); 5,360 youth (80 at each of the 67 schools); and 5,360 parents (80 at each of the 67 schools). Of the 5,360 youth, 2,680 will be in the intervention group; 2,680 in the control group. The total estimated number of children respondents to the survey is 4,824 (90% of 5360). The total of the estimated parent/guardian respondents is 3,216 (60% of 5360).

State Agencies (SA)

Number of Responses per Respondent: 469.

Estimated Frequency of Responses per Respondent: 1.57.

Estimated Total Annual Responses per Respondent: 737.

Estimated Time per Response: 0.82 minutes (*approximately 50 minutes*).

Estimated Total Annual Burden Hours (SA): 603.

Individual/Household

Number of Responses per Respondent: 10,720.

Estimated Frequency of Responses per Respondent: 2 .

Estimated Total Annual Responses per Respondent: 21,440.

Estimated Time per Response: 1.15 hour.

Estimated Total Annual Burden Hours for SA & I/H: 11,189.

See Table 1 below for the estimated total burden for each type of respondent by instrument type.

TABLE 1

Affected public	Respondent type	Instrument	Number of respondents	Avg. number of responses per respondent	Total annual responses	Hours per response	Total burden
Schools	School principals	Interview	67	1.00	67.00	.50	33.50
	Food Service Manager.	Interview	67	1.00	67.00	.25	16.75
	Physical Education Director.	Interview	67	1.00	67.00	.25	16.75
	Teacher	Questionnaire	268	2.00	536.00	1.00	536.00
Total SA Reporting burden.			469	1.57	737.00	.82	603.00
Individual/Household.	Children	Questionnaire	4,824	3.00	14,472.00	1.20	17,366.40
			536	0	0	0	0
	Nonrespondents [1]	Questionnaire	3216	1.00	3,216.00	1.00	3,216.00
	Parents/Guardians non-respondents.		2144	1.00	2,144.00	.05	107.20
Total I/H Burden.			10,720		19,832.00		20,689.60
Total Burden			11,189		20,569.00		21,292.60

[1] We anticipate that some students will be absent. For this reason we estimate 90% response rate among children.

Dated: October 3, 2011.

Audrey Rowe,

Administrator, Food and Nutrition Service.

[FR Doc. 2011–26145 Filed 10–7–11; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Proposed Collection; Comment Request—State Administrative Expense Funds Regulations

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection related to State administrative expense funds expended in the operation of the Child Nutrition Programs administered under the Child Nutrition Act of 1966. This collection is a revision of a currently approved collection.

DATES: Written comments must be received on or before December 12, 2011.

ADDRESSES: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to Lynn Rodgers-Kuperman, Branch Chief,

Program Analysis and Monitoring Branch, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 640, Alexandria, VA 22302. Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically.

All written comments will be open for public inspection at the office of the Food and Nutrition Service during regular business hours (8:30 a.m. to 5 p.m. Monday through Friday) at 3101 Park Center Drive, Room 640, Alexandria, Virginia 22302.

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

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Ms. Lynn Rodgers-Kuperman at (703) 305–2590.

SUPPLEMENTARY INFORMATION:

Title: 7 CFR part 235, State Administrative Expense Funds Regulations.

OMB Number: 0584–0067, Form Number(s) FNS–74, FNS–525, FNS–777, FNS 10.

Expiration Date: 12/31/2011.

Type of Request: Revision of a currently approved collection.

Abstract: Section 7 of the Child Nutrition Act of 1966 (Pub. L. 89–642), 42 U.S.C. 1776, authorizes the Department to provide Federal funds to State agencies (SAs) for administering the Child Nutrition Programs. State Administrative Expense Funds (SAE), 7 CFR part 235, sets forth procedures and recordkeeping requirements for use by SAs in reporting and maintaining records of their needs and uses of SAE funds.

Reporting Burden

Estimated Number of Respondents: 88.

Estimated Number of Responses per Respondent: 6.82.

Estimated Total Annual Responses: 601.

Estimated Time per Response: 1.32 hours.

Estimated Total Annual Burden on Respondents: 799.

Record Keeping Burden

Estimated Number of Respondents: 88.

Estimated Number of Responses per Respondent: 140.

Estimated Total Annual Responses: 12,354.

Estimated Time per Response: 1.03.

Estimated Total Annual Burden on Respondents: 12,726.

Total Burden Including Reporting and Recordkeeping

Affected Public: State Agencies.

Estimated Number of Respondents: 88.

Estimated Number of Responses per Respondent: 147.

Estimated Total Annual Responses: 12,936.

Estimated Time per Response: 1.04 hours.

Estimated Total Annual Burden on Respondents: 13,453.

Current OMB Inventory (part 235): 14,783.

Difference: 1,258.

Dated: October 3, 2011.

Audrey Rowe,

Administrator, Food and Nutrition Service.

[FR Doc. 2011–26150 Filed 10–7–11; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Forest Service

Wallowa-Whitman and Umatilla National Forests, Oregon Granite Creek Watershed Mining Plans

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The USDA, Forest Service will prepare an environmental impact statement to authorize the approval of mining Plans of Operation in the Granite Creek Watershed Mining Plans analysis area on the Whitman Ranger District of the Wallowa-Whitman National Forest, and the North Fork John Day Ranger District of the Umatilla National Forest.

Both forests had previously initiated environmental analyses for proposed mining Plans in the portions of the Granite Creek Watershed under their administration. As issues identified by each forest were similar, it became clear that combining the analysis into one EIS would be the most efficient way to complete the task.

DATES: Written comments concerning the scope of the analysis must be received by November 10, 2011. The draft environmental impact statement is expected July 2012 and the final environmental impact statement is expected November 2012.

ADDRESSES: Send written comments and suggestions to Jeff Tomac, Whitman District Ranger, Wallowa-Whitman National Forest, PO Box 947, Baker City, OR 97814. Comments may also be sent via e-mail to *comments-pacificnorthwest-wallowa-whitman-whitmanunit@fs.fed.us.*

FOR FURTHER INFORMATION CONTACT: Sophia Millar, Interdisciplinary Team Leader, Wallowa-Whitman National Forest, Wallowa Mountains Office, PO Box 905, Joseph, OR 97846, Phone: (541) 426–5540.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Purpose and Need

The purpose of and need for this action is to authorize the approval of proposed Plans of Operations (Plans) submitted by the operations, as specified in 36 CFR 228.4(a), pending receipt of 401 certifications as deemed necessary by the Oregon Department of Environmental Quality.

Proposed Action

The Granite Creek Watershed Mining Plans analysis area is located on the Whitman Ranger District of the Wallowa-Whitman National Forest, approximately 45 miles west of Baker City, Oregon, and on the North Fork John Day Ranger District of the Umatilla National Forest, approximately 45 miles south of Ukiah, Oregon. The decision area will cover 30 proposed mining Plans of Operation within the Granite Creek Watershed, an area of approximately 94,479 acres of National Forest System lands, in Baker and Grant Counties. Typically, each project will disturb and reclaim an area of approximately 1–2 acres annually.

This EIS will analyze and authorize the approval of 30 proposed mining Plans (17 on the Wallowa-Whitman National Forest, 11 on the Umatilla National Forest, and 2 overlapping both forests), and evaluate and propose additional operational requirements for some or all of these Plans. Authorization of Plan approvals will occur after receipt of 401 certification, as deemed necessary by the Oregon Department of Environmental Quality.

Responsible Official

The Whitman District Ranger, Jeff Tomac, will be the responsible official for making the decision and providing direction for the analysis.

Nature of Decision To Be Made

The responsible official will decide whether or not to authorize the approval

of mining Plans within the Granite Creek Watershed Mining Plans analsyis area. The responsible official will also decide whether or not to select the proposed action as stated or modified, or to select an alternative to it, any mitigation measures needed, and any monitoring that may be required.

Preliminary Issues

The interdisciplinary team has conducted field surveys and data research to identify preliminary issues of concern with this proposal. The primary concern is the potential for sediment or heavy metal discharges into streams from mining operations, potentially impacting water quality, fish and fish habitat (pools and temperature).

Within the Granite Creek Watershed, under section 303(d) of the Clean Water Act, the Oregon Department of Environmental Quality (DEQ) has listed Beaver Creek and Clear Creek as water quality limited for temperature, and Bull Run Creek and Granite Creek as water quality limited for temperature and sediment. Fish species listed as threatened under the Endangered Species Act occurring within the watershed include bull trout and middle Columbia River steelhead trout. Based on these preliminary issues and the level of activity proposed at some sites, there is the potential for significant impacts to some resources, therefore an EIS fits the scope of this analysis rather than an Environmental Assessment (EA).

Scoping Process

This notice of intent initiates the scoping process, which guides the development of the environmental impact statement. Public participation is especially important at several points during the development of the EIS. The Forest Service is seeking information, comments, and coordination with Federal, State, and local agencies, and tribal governments, individuals or organizations who may be interested in or affected by the proposed action. The most useful comments to developing or refining the proposed action would be site-specific concerns and those that pertain to authorizing mining activities within the Granite Creek Watershed Mining Plans analysis area that meets the Purpose of and Need for Action.

It is important that reviewers provide their comments at such times and in such manner that they are useful to the agency's preparation of the environmental impact statement. Therefore, comments should be provided prior to the close of the comment period and should clearly articulate the reviewer's concerns and contentions.

Comments received in response to this solicitation, including names and addresses of those who comment, will be part of the public record for this proposed action and will be available for public inspection.

Authority: 40 CFR 1501.7 and 1508.22; Forest Service Handbook 1909.15, Section 21. Comments submitted anonymously will be accepted and considered, however those who only submit anonymous comments will not have standing to appeal the subsequent decision under 36 CFR part 215.

Dated: October 2, 2011.

Jeff Tomac,

Whitman District Ranger Wallowa-Whitman National Forest.

[FR Doc. 2011–26220 Filed 10–7–11; 8:45 am]

BILLING CODE 3410–11–P

BROADCASTING BOARD OF GOVERNORS

Government in the Sunshine Act Meeting Notice

DATE AND TIME: Thursday, October 13, 2011, 3 p.m.

PLACE: Cohen Building, Room 3321, 330 Independence Ave., SW., Washington, DC 20237.

SUBJECT: Notice of Meeting of the Broadcasting Board of Governors.

SUMMARY: The Broadcasting Board of Governors (BBG) will be meeting at the time and location listed above. The BBG will receive and consider recommendations regarding the conclusion of the year-long strategic review and the BBG committee membership. The BBG will also consider revising its BBG meeting schedule for the remaining calendar year. The BBG will receive reports from: the International Broadcasting Bureau Director, the Voice of America Director, the Office of Cuba Broadcasting Director, the Technology, Services and Innovation Director, the Office of New Media, and the Presidents of Radio Free Europe/Radio Liberty, Radio Free Asia, and the Middle East Broadcasting Networks. The meeting is open to public observation via streamed webcast, both live and on-demand, on the BBG's public Web site at *http://www.bbg.gov.*

CONTACT PERSON FOR MORE INFORMATION: Persons interested in obtaining more information should contact Paul Kollmer-Dorsey at (202) 203–4545.

Paul Kollmer-Dorsey,

Deputy General Counsel.

[FR Doc. 2011–26253 Filed 10–6–11; 11:15 am]

BILLING CODE 8610–01–P

DEPARTMENT OF COMMERCE

Bureau of the Census

[Docket No. 110921595–1594–01]

2011 Company Organization Survey

AGENCY: Bureau of the Census, Commerce.

ACTION: Notice of determination.

SUMMARY: The Bureau of the Census (Census Bureau) is conducting the 2011 Company Organization Survey. The survey's data are needed, in part, to update the multilocation companies in the Business Register. The survey, which has been conducted annually since 1974, is designed to collect information on the number of employees, payroll, geographic location, current operational status, and kind of business for each establishment of companies with more than one location. We have determined that annual data collected from this survey are needed to aid the efficient performance of essential governmental functions, and that these data have significant application to the needs of the public and industry. The data derived from this survey are not available from any other source.

ADDRESSES: The Census Bureau will furnish report forms to organizations included in the survey, and additional copies are available by written request to the Director, U.S. Census Bureau, Washington, DC 20233–0101.

FOR FURTHER INFORMATION CONTACT: Joy P. Pierson, Economic Planning and Coordination Division, U.S. Census Bureau, Room 8K319, Washington, DC 20233–6100 or by e-mail at *joy.p.pierson@census.gov.*

SUPPLEMENTARY INFORMATION: Sections 182, 195, 224, and 225 of Title 13, United States Code (U.S.C.), authorize the Census Bureau to undertake surveys necessary to furnish current data on the subjects covered by the major censuses. Years that end in 2 and 7 are considered ''census years.'' In non-census years, companies report only on basic company affiliation and operations of establishments not within the scope of the economic censuses. In these non-census years, all multi-establishment companies with 250 or more employees report survey information. Also, groups of smaller companies that are divided into panels may be selected to report information for one of the non-census years. Smaller companies may be selected if an organizational change within the company is indicated, or if they have been selected through the probability sampling procedure. The

next economic census will be conducted for the year 2012. The data collected in the Company Organization Survey will be within the general scope, type, and character of those that are covered in the economic censuses. Forms NC–99001 (for multi-establishment companies) and NC–99007 (for single-location companies) will be used to collect the desired data.

Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid Office of Management and Budget (OMB) control number. In accordance with the Paperwork Reduction Act, 44 U.S.C., Chapter 35, the OMB approved Forms NC–99001 and NC–99007 under OMB Control Number 0607–0444. We will furnish report forms to organizations included in the survey, and additional copies are available upon written request to the Director, U.S. Census Bureau, Washington, DC 20233–0101.

I have, therefore, directed that the 2011 Company Organization Survey be conducted for the purpose of collecting these data.

Dated: October 3, 2011.

Robert M. Groves,

Director, Bureau of the Census.

[FR Doc. 2011–26197 Filed 10–7–11; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket T–5–2011]

Foreign-Trade Zone 277—Western Maricopa County, AZ; Application for Temporary/Interim Manufacturing Authority; Sub-Zero, Inc.; (Refrigerators); Goodyear, AZ

An application has been submitted to the Executive Secretary of the Foreign-Trade Zones Board (the Board) by the Greater Maricopa County Foreign Trade Zone, Inc., grantee of FTZ 277, requesting temporary/interim manufacturing (T/IM) authority within FTZ 277 at the Sub-Zero, Inc. (Sub-Zero), facility, located in Goodyear, Arizona. The application was filed on October 3, 2011.

The Sub-Zero facility (260 employees, 10 acres, 150,000 units/year) is located at 4295 N. Cotton Lane within the Palm Valley 303 Industrial Park in Goodyear, Arizona (Site 3). Under T/IM procedures, Sub-Zero has requested authority to produce refrigerators (HTSUS 8418.10 and 8418.21, duty rate: free). Foreign components that would be used in production (representing 45% of the value of the finished refrigerators) include: ABS resin (HTSUS 3903.30), fittings (3917.40), rubber gaskets (4016.93), articles of rubber (4016.99), fasteners (7318.14, 7318.15, 7318.29), hinges (8302.10), brackets (8302.50), plates (8310.00), compressors (8414.30, 8414.90), parts of refrigerators (8418.99), filters (8421.21), filter/dryer (8421.29), valves (8481.80), motors (8501.10, 8501.40), inverters (8504.40), wiring harnesses (8516.80), switches (8536.50), plugs and sockets (8536.61), controllers (8537.10), lamps (8539.22), and conductors (8544.42) (duty rate range: free–8.6%). T/IM authority could be granted for a period of up to two years.

FTZ procedures could exempt Sub-Zero from customs duty payments on the foreign components used in export production. The company anticipates that some 10 percent of the plant's shipments will be exported. On its domestic sales, Sub-Zero would be able to choose the duty rate during customs entry procedures that applies to refrigerators (duty rate: free) for the foreign inputs noted above.

In accordance with the Board's regulations, Pierre Duy 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 pursuant to Board Orders 1347 and 1480.

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the following address: Office of the Executive Secretary, Foreign-Trade Zones Board, U.S. Department of Commerce, Room 2111, 1401 Constitution Ave., NW., Washington, DC 20230. The closing period for their receipt is November 10, 2011.

Sub-Zero has also submitted a request to the FTZ Board for FTZ manufacturing authority beyond a two-year period, which may include additional products and components. It should be noted that the request for extended authority would be docketed separately and would be processed as a distinct proceeding. Any party wishing to submit comments for consideration regarding the request for extended authority would need to submit such comments pursuant to the separate notice that would be published for that request.

A copy of the application will be available for public inspection at the Office of the Foreign-Trade Zones Board's Executive Secretary at the address listed above, 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: Pierre Duy at *Pierre.Duy@trade.gov* or (202) 482–1378.

Dated: October 4, 2011.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2011–26217 Filed 10–7–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1784]

Grant of Authority for Subzone Status; LVMH Watch and Jewelry U.S.A., Inc.; (Watches, Jewelry Products and Leather Goods) Springfield, NJ

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a-81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Foreign-Trade Zones Act provides for ''* * * the establishment * * * of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes,'' and authorizes the Foreign-Trade Zones Board to grant to qualified corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs and Border Protection ports of entry;

Whereas, the Board's regulations (15 CFR part 400) provide for the establishment of special-purpose subzones when existing zone facilities cannot serve the specific use involved, and when the activity results in a significant public benefit and is in the public interest;

Whereas, the Port Authority of New York and New Jersey, grantee of Foreign-Trade Zone 49, has made application to the Board for authority to establish a special-purpose subzone at the warehouse and distribution facility of LVMH Watch and Jewelry U.S.A., Inc., located in Springfield, New Jersey (FTZ Docket 5–2011, filed 1–14–2011);

Whereas, notice inviting public comment has been given in the **Federal Register** (76 FR 4284, 1–25–2011) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the

requirements of the FTZ Act and Board's regulations are satisfied, and that the proposal is in the public interest;

Now, Therefore, the Board hereby grants authority for subzone status for activity related to watch, jewelry and leather goods warehousing and distribution at the facility of LVMH Watch and Jewelry U.S.A, Inc., located in Springfield, New Jersey (Subzone 49M), as described in the application and **Federal Register** notice, subject to the FTZ Act and the Board's regulations, including Section 400.28.

Signed at Washington, DC, this 30 day of September 2011.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

[FR Doc. 2011–26221 Filed 10–7–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–810]

Stainless Steel Bar From India: Extension of Time Limit for the Preliminary Results of the 2010–2011 Antidumping Duty Administrative Review

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

DATES: *Effective Date:* October 11, 2011.

FOR FURTHER INFORMATION CONTACT: Joseph Shuler or Yasmin Nair, AD/CVD Operations, Office 1, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–1293 and (202) 482–3813, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 31, 2011, the Department of Commerce (Department) published in the **Federal Register** its initiation of an administrative review of the antidumping duty order on stainless steel bar from India, covering the period February 1, 2010, through January 31, 2011. *See Initiation of Antidumping Duty Administrative Reviews, Requests for Revocation in Part, and Deferral of Administrative Review,* 76 FR 17825 (March 31, 2011) (*Initiation Notice*). The preliminary results for this review are currently due no later than October 31, 2011.

Extension of Time Limit for the Preliminary Results of Review

Section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), requires the Department to issue its preliminary results in an administrative review of an antidumping duty order within 245 days after the last day of the anniversary month of the order for which the administrative review was requested. However, if the Department determines that it is not practicable to complete the review within the aforementioned specified time limits, section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(2) allow 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. *See* section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(2).

The Department has determined that it requires additional time to complete the preliminary results for this review. After publishing the *Initiation Notice,* the Department sent a questionnaire response to Mukand, Ltd., a respondent in the instant review. We received responses to our questionnaire on May 18 and May 31, 2011, but we need additional time to issue supplemental questionnaires based on the responses we received. Further, the Department needs to allow time for parties to review and respond to our supplemental questionnaires. Thus, it is not practicable to complete the preliminary results by October 31, 2011, and the Department is extending the time limit for completion of the final results by an additional 90 days to January 29, 2012. However, January 29, 2012, falls on a Sunday and it is the Department's long-standing practice to issue a determination the next business day when the statutory deadline falls on a weekend, federal holiday, or any other day when the Department is closed. *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). Accordingly, the deadline for completion of the preliminary results is now no later than January 30, 2012.

This notice is published pursuant to sections 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(2).

Dated: October 4, 2011.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2011–26225 Filed 10–7–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–900]

Diamond Sawblades and Parts Thereof From the People's Republic of China: Extension of Time Limit for Final Results of the Antidumping Duty Changed Circumstances Review

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

DATES: *Effective Date:* October 11, 2011.

FOR FURTHER INFORMATION CONTACT: Alan Ray, AD/CVD Operations, Office 9, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–5403.

Background

On June 30, 2011, the Department of Commerce (''Department'') published in the **Federal Register** the *Preliminary Results* of the antidumping duty changed circumstances review of the antidumping duty order on diamond sawblades and parts thereof from the People's Republic of China. *See Diamond Sawblades and Parts Thereof From the People's Republic of China: Preliminary Results and Preliminary Intent To Terminate, in Part, Antidumping Duty Changed Circumstances Review and Extension of Time Limit for Final Results,* 76 FR 38357 (June 30, 2011) (''*Preliminary Results*''). Subsequent to the publication of the *Preliminary Results,* the Department received affirmative and rebuttal comments. On July 25, 2011, the Department held a hearing in which interested parties presented arguments from their affirmative and rebuttal comments. On August 15, 2011, the Department published a notice in the **Federal Register** that extended the time limit to issue the final results by 30 days, extending the deadline to September 19, 2011. *See Diamond Sawblades and Parts Thereof From the People's Republic of China: Extension of Time Limit for Final Results of the Antidumping Duty Changed Circumstances Review,* 76 FR 50455 (August 15, 2011). On September 23, 2011, the Department published a notice in the **Federal Register** that extended the time limit to issue the final results by an additional 15 days, making the current deadline to issue the final results October 4, 2011. *See Diamond Sawblades and Parts Thereof From the People's Republic of China: Extension of Time Limit for Final Results of the*

Antidumping Duty Changed Circumstances Review, 76 FR 59111 (September 23, 2011).

Extension of Time Limit for the Final Results

The Department finds that it is not practicable to complete this review by the current deadline. The Department has determined that it requires additional time to analyze the case and rebuttal briefs submitted by interested parties. Consequently, in accordance with 19 CFR 351.302(b), the Department is extending the time period for issuing the final results in this review by an additional 15 days. Therefore, the final results will be due no later than October 19, 2011.

We are issuing and publishing this notice in accordance with sections 751(b) and 777(i) of the Tariff Act of 1930, as amended.

Dated: October 3, 2011.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2011–26211 Filed 10–7–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–588–850, A–588–851, A–485–805]

Certain Large Diameter Carbon and Alloy Seamless Standard, Line and Pressure Pipe From Japan; Certain Small Diameter Carbon and Alloy Seamless Standard, Line and Pressure Pipe From Japan and Romania: Continuation of Antidumping Duty Orders

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

DATES: *Effective Date:* October 11, 2011.

SUMMARY: As a result of the determinations by the Department of Commerce (''Department'') and the International Trade Commission (''ITC'') that revocation of the antidumping duty orders on certain large diameter carbon and alloy seamless standard, line and pressure pipe (''large diameter pipe'') from Japan and certain small diameter carbon and alloy seamless standard, line and pressure pipe (''small diameter pipe'') from Japan and Romania would likely lead to a continuation or recurrence of dumping and material injury to an industry in the United States, the Department is publishing a notice of continuation of the antidumping duty orders.

FOR FURTHER INFORMATION CONTACT: Mary Kolberg, AD/CVD Operations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; *telephone:* (202) 482–1785.

SUPPLEMENTARY INFORMATION: On April 1, 2011, the Department published in the **Federal Register** the notice of initiation of the second sunset reviews of the antidumping duty orders on large diameter pipe from Japan and small diameter pipe from Japan and Romania, pursuant to section 751(c)(2) of the Tariff Act of 1930, as amended (''the Act''). *See Initiation of Five-Year (''Sunset'') Review,* 76 FR 18163 (April 1, 2011).

As a result of its review, the Department determined that revocation of the antidumping duty orders on large diameter pipe from Japan and small diameter pipe from Japan and Romania would likely lead to a continuation or recurrence of dumping and, therefore, notified the ITC of the magnitude of the margins likely to prevail should the order be revoked. *See Certain Large Diameter Carbon and Alloy Seamless Standard, Line and Pressure Pipe From Japan; Certain Small Diameter Carbon and Alloy Seamless Standard, Line and Pressure Pipe From Japan and Romania: Final Results of the Expedited Second Five-Year Sunset Reviews of the Antidumping Duty Orders,* 76 FR 47555 (August 5, 2011).

On September 28, 2011, the ITC determined, pursuant to section 751(c)(1) of the Act, that revocation of the antidumping duty orders on large diameter pipe from Japan and small diameter pipe from Japan and Romania would likely lead to a continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time. *See Carbon and Alloy Seamless Standard, Line, and Pressure Pipe From Japan and Romania,* 76 FR 60083 (September 28, 2011), and *USITC Publication 4262* (September 2011), Carbon and Alloy Seamless Standard, Line, and Pressure Pipe from Japan and Romania, Investigation Nos. 731–TA–847 and 849 (Second Review).

Scope of the Orders

Large Diameter Pipe From Japan

The products covered by this order are large diameter seamless carbon and alloy (other than stainless) steel standard, line, and pressure pipes produced, or equivalent, to the American Society for Testing and Materials (''ASTM'') A–53, ASTM A–106, ASTM A–333, ASTM A- 334, ASTM A–589, ASTM A–795, and the American Petroleum Institute (''API'') 5L specifications and meeting the physical parameters described below, regardless of application. The scope of this order also includes all other products used in standard, line, or pressure pipe applications and meeting the physical parameters described below, regardless of specification, with the exception of the exclusions discussed below. Specifically included within the scope of this order are seamless pipes greater than 4.5 inches (114.3 mm) up to and including 16 inches (406.4 mm) in outside diameter, regardless of wall-thickness, manufacturing process (hot finished or cold-drawn), end finish (plain end, beveled end, upset end, threaded, or threaded and coupled), or surface finish.

The seamless pipes subject to this order are currently classifiable under the subheadings 7304.10.10.30, 7304.10.10.45, 7304.10.10.60, 7304.10.50.50, 7304.19.10.30, 7304.19.10.45, 7304.19.10.60, 7304.19.50.50, 7304.31.60.10, 7304.31.60.50, 7304.39.00.04, 7304.39.00.06, 7304.39.00.08, 7304.39.00.36, 7304.39.00.40, 7304.39.00.44, 7304.39.00.48, 7304.39.00.52, 7304.39.00.56, 7304.39.00.62, 7304.39.00.68, 7304.39.00.72, 7304.51.50.15, 7304.51.50.45, 7304.51.50.60, 7304.59.20.30, 7304.59.20.55, 7304.59.20.60, 7304.59.20.70, 7304.59.60.00, 7304.59.80.30, 7304.59.80.35, 7304.59.80.40, 7304.59.80.45, 7304.59.80.50, 7304.59.80.55, 7304.59.80.60, 7304.59.80.65, and 7304.59.80.70 of the Harmonized Tariff Schedule of the United States (''HTSUS'').

Specifications, Characteristics, and Uses: Large diameter seamless pipe is used primarily for line applications such as oil, gas, or water pipeline, or utility distribution systems. Seamless pressure pipes are intended for the conveyance of water, steam, petrochemicals, chemicals, oil products, natural gas and other liquids and gasses in industrial piping systems. They may carry these substances at elevated pressures and temperatures and may be subject to the application of external heat. Seamless carbon steel pressure pipe meeting the ASTM A–106 standard may be used in temperatures of up to 1000 degrees Fahrenheit, at various American Society of Mechanical Engineers (''ASME'') code stress levels. Alloy pipes made to ASTM A–335 standard must be used if temperatures and stress levels exceed those allowed for ASTM A–106. Seamless pressure pipes sold in the United States are commonly produced to the ASTM A–

106 standard. Seamless standard pipes are most commonly produced to the ASTM A–53 specification and generally are not intended for high temperature service.

They are intended for the low temperature and pressure conveyance of water, steam, natural gas, air and other liquids and gasses in plumbing and heating systems, air conditioning units, automatic sprinkler systems, and other related uses. Standard pipes (depending on type and code) may carry liquids at elevated temperatures but must not exceed relevant ASME code requirements. If exceptionally low temperature uses or conditions are anticipated, standard pipe may be manufactured to ASTM A–333 or ASTM A–334 specifications.

Seamless line pipes are intended for the conveyance of oil and natural gas or other fluids in pipe lines. Seamless line pipes are produced to the API 5L specification. Seamless water well pipe (ASTM A–589) and seamless galvanized pipe for fire protection uses (ASTM A–795) are used for the conveyance of water.

Seamless pipes are commonly produced and certified to meet ASTM A–106, ASTM A–53, API 5L–B, and API 5L–X42 specifications. To avoid maintaining separate production runs and separate inventories, manufacturers typically triple or quadruple certify the pipes by meeting the metallurgical requirements and performing the required tests pursuant to the respective specifications. Since distributors sell the vast majority of this product, they can thereby maintain a single inventory to service all customers.

The primary application of ASTM A–106 pressure pipes and triple or quadruple certified pipes in large diameters is for use as oil and gas distribution lines for commercial applications. A more minor application for large diameter seamless pipes is for use in pressure piping systems by refineries, petrochemical plants, and chemical plants, as well as in power generation plants and in some oil field uses (on shore and off shore) such as for separator lines, gathering lines and metering runs. These applications constitute the majority of the market for the subject seamless pipes. However, ASTM A–106 pipes may be used in some boiler applications.

The scope of this order includes all seamless pipe meeting the physical parameters described above and produced to one of the specifications listed above, regardless of application, with the exception of the exclusions discussed below, whether or not also certified to a non-covered specification. Standard, line, and pressure applications and the above-listed specifications are defining characteristics of the scope of this review. Therefore, seamless pipes meeting the physical description above, but not produced to the ASTM A–53, ASTM A–106, ASTM A–333, ASTM A–334, ASTM A–589, ASTM A–795, and API 5L specifications shall be covered if used in a standard, line, or pressure application, with the exception of the specific exclusions discussed below.

For example, there are certain other ASTM specifications of pipe which, because of overlapping characteristics, could potentially be used in ASTM A–106 applications. These specifications generally include ASTM A–161, ASTM A–192, ASTM A–210, ASTM A–252, ASTM A–501, ASTM A–523, ASTM A–524, and ASTM A–618. When such pipes are used in a standard, line, or pressure pipe application, such products are covered by the scope of this order.

Specifically excluded from the scope of this order are: A. Boiler tubing and mechanical tubing, if such products are not produced to ASTM A–53, ASTM A–106, ASTM A–333, ASTM A–334, ASTM A–589, ASTM A–795, and API 5L specifications and are not used in standard, line, or pressure pipe applications. B. Finished and unfinished oil country tubular goods (''OCTG''), if covered by the scope of another antidumping duty order from the same country. If not covered by such an OCTG order, finished and unfinished OCTG are included in this scope when used in standard, line or pressure applications. C. Products produced to the A–335 specification unless they are used in an application that would normally utilize ASTM A–53, ASTM A–106, ASTM A–333, ASTM A–334, ASTM A–589, ASTM A–795, and API 5L specifications. D. Line and riser pipe for deepwater application, *i.e.,* line and riser pipe that is (1) Used in a deepwater application, which means for use in water depths of 1,500 feet or more; (2) intended for use in and is actually used for a specific deepwater project; (3) rated for a specified minimum yield strength of not less than 60,000 psi; and (4) not identified or certified through the use of a monogram, stencil, or otherwise marked with an API specification (*e.g.,* API 5L).

With regard to the excluded products listed above, the Department will not instruct U.S. Customs and Border Protection (''CBP'') to require end-use certification until such time as Petitioner or other interested parties provide to the Department a reasonable basis to believe or suspect that the products are being utilized in a covered application. If such information is provided, we will require end-use certification only for the product(s) (or specification(s)) for which evidence is provided that such products are being used in a covered application as described above. For example, if, based on evidence provided by Petitioner, the Department finds a reasonable basis to believe or suspect that seamless pipe produced to the A–335 specification is being used in an A–106 application, we will require end-use certifications for imports of that specification. Normally we will require only the importer of record to certify to the end use of the imported merchandise. If it later proves necessary for adequate implementation, we may also require producers who export such products to the United States to provide such certification on invoices accompanying shipments to the United States.

Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the merchandise subject to this scope is dispositive.

Small Diameter Pipe From Japan and Romania

The products covered by these orders include small diameter seamless carbon and alloy (other than stainless) steel standard, line, and pressure pipes and redraw hollows produced, or equivalent, to the ASTM A–53, ASTM A–106, ASTM A–333, ASTM A–334, ASTM A–335, ASTM A–589, ASTM A–795, and the API 5L specifications and meeting the physical parameters described below, regardless of application. The scope of these orders also includes all products used in standard, line, or pressure pipe applications and meeting the physical parameters described below, regardless of specification. Specifically included within the scope of these orders are seamless pipes and redraw hollows, less than or equal to 4.5 inches (114.3 mm) in outside diameter, regardless of wall-thickness, manufacturing process (hot finished or cold-drawn), end finish (plain end, beveled end, upset end, threaded, or threaded and coupled), or surface finish.

The seamless pipes subject to these orders are currently classifiable under the subheadings 7304.10.10.20, 7304.10.50.20, 7304.19.10.20, 7304.19.50.20, 7304.31.30.00, 7304.31.60.50, 7304.39.00.16, 7304.39.00.20, 7304.39.00.24, 7304.39.00.28, 7304.39.00.32, 7304.51.50.05, 7304.51.50.60, 7304.59.60.00, 7304.59.80.10,

7304.59.80.15, 7304.59.80.20, and 7304.59.80.25 of the HTSUS.

Specifications, Characteristics, and Uses: Seamless pressure pipes are intended for the conveyance of water, steam, petrochemicals, chemicals, oil products, natural gas and other liquids and gasses in industrial piping systems. They may carry these substances at elevated pressures and temperatures and may be subject to the application of external heat. Seamless carbon steel pressure pipe meeting the ASTM A–106 standard may be used in temperatures of up to 1000 degrees Fahrenheit, at various ASME code stress levels. Alloy pipes made to ASTM A–335 standard must be used if temperatures and stress levels exceed those allowed for ASTM A–106. Seamless pressure pipes sold in the United States are commonly produced to the ASTM A–106 standard.

Seamless standard pipes are most commonly produced to the ASTM A–53 specification and generally are not intended for high temperature service. They are intended for the low temperature and pressure conveyance of water, steam, natural gas, air and other liquids and gasses in plumbing and heating systems, air conditioning units, automatic sprinkler systems, and other related uses. Standard pipes (depending on type and code) may carry liquids at elevated temperatures but must not exceed relevant ASME code requirements. If exceptionally low temperature uses or conditions are anticipated, standard pipe may be manufactured to ASTM A–333 or ASTM A–334 specifications.

Seamless line pipes are intended for the conveyance of oil and natural gas or other fluids in pipe lines. Seamless line pipes are produced to the API 5L specification.

Seamless water well pipe (ASTM A–589) and seamless galvanized pipe for fire protection uses (ASTM A–795) are used for the conveyance of water.

Seamless pipes are commonly produced and certified to meet ASTM A–106, ASTM A–53, API 5L–B, and API 5L–X42 specifications. To avoid maintaining separate production runs and separate inventories, manufacturers typically triple or quadruple certify the pipes by meeting the metallurgical requirements and performing the required tests pursuant to the respective specifications. Since distributors sell the vast majority of this product, they can thereby maintain a single inventory to service all customers.

The primary application of ASTM A–106 pressure pipes and triple or quadruple certified pipes is in pressure piping systems by refineries, petrochemical plants, and chemical plants. Other applications are in power generation plants (electrical-fossil fuel or nuclear), and in some oil field uses (on shore and off shore) such as for separator lines, gathering lines and metering runs. A minor application of this product is for use as oil and gas distribution lines for commercial applications. These applications constitute the majority of the market for the subject seamless pipes. However, ASTM A–106 pipes may be used in some boiler applications.

Redraw hollows are any unfinished pipe or ''hollow profiles'' of carbon or alloy steel transformed by hot rolling or cold drawing/hydrostatic testing or other methods to enable the material to be sold under ASTM A–53, ASTM A–106, ASTM A–333, ASTM A–334, ASTM A–335, ASTM A–589, ASTM A–795, and API 5L specifications.

The scope of these orders includes all seamless pipe meeting the physical parameters described above and produced to one of the specifications listed above, regardless of application, with the exception of the specific exclusions discussed below, and whether or not also certified to a non-covered specification. Standard, line, and pressure applications and the above-listed specifications are defining characteristics of the scope of the orders. Therefore, seamless pipes meeting the physical description above, but not produced to the ASTM A–53, ASTM A–106, ASTM A–333, ASTM A–334, ASTM A–335, ASTM A–589, ASTM A–795, and API 5L specifications shall be covered if used in a standard, line, or pressure application, with the exception of the specific exclusions discussed below.

For example, there are certain other ASTM specifications of pipe which, because of overlapping characteristics, could potentially be used in ASTM A–106 applications. These specifications generally include ASTM A–161, ASTM A–192, ASTM A–210, ASTM A–252, ASTM A–501, ASTM A–523, ASTM A–524, and ASTM A–618. When such pipes are used in a standard, line, or pressure pipe application, such products are covered by the scope of these orders.

Specifically excluded from the scope of these orders are boiler tubing and mechanical tubing, if such products are not produced to ASTM A–53, ASTM A–106, ASTM A–333, ASTM A–334, ASTM A–335, ASTM A–589, ASTM A–795, and API 5L specifications and are not used in standard, line, or pressure pipe applications. In addition, finished and unfinished OCTG are excluded from the scope of these orders, if covered by the scope of another antidumping duty order from the same country. If not covered by such an OCTG order, finished and unfinished OCTG are included in these scopes when used in standard, line or pressure applications.

With regard to the excluded products listed above, the Department will not instruct CBP to require end-use certification until such time as Petitioner or other interested parties provide to the Department a reasonable basis to believe or suspect that the products are being used in a covered application. If such information is provided, we will require end-use certification only for the product(s) (or specification(s)) for which evidence is provided that such products are being used in covered applications as described above. For example, if, based on evidence provided by Petitioner, the Department finds a reasonable basis to believe or suspect that seamless pipe produced to the A–161 specification is being used in a standard, line or pressure application, we will require end-use certifications for imports of that specification. Normally we will require only the importer of record to certify to the end use of the imported merchandise. If it later proves necessary for adequate implementation, we may also require producers who export such products to the United States to provide such certification on invoices accompanying shipments to the United States.

Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the merchandise under these orders is dispositive.

Continuation of the Order

As a result of these determinations by the Department and the ITC that revocation of the antidumping duty orders would likely lead to a continuation or recurrence of dumping and material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act, the Department hereby orders the continuation of the antidumping orders on large diameter pipe from Japan and small diameter pipe from Japan and Romania. CBP will continue to collect antidumping duty cash deposits at the rates in effect at the time of entry for all imports of subject merchandise. The effective date of the continuation of these orders will be the date of publication in the **Federal Register** of this notice of continuation. Pursuant to section 751(c)(2) of the Act, the Department intends to initiate the next five-year review of the orders not later than 30 days prior to the fifth

anniversary of the effective date of continuation.

This five-year (sunset) review and this notice are in accordance with section 751(c) of the Act and published pursuant to section 777(i)(1) of the Act.

Dated: October 3, 2011.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 2011–26226 Filed 10–7–11; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–941]

Certain Kitchen Appliance Shelving and Racks From the People's Republic of China: Preliminary Results of the First Administrative Review, Preliminary Rescission, in Part, and Extension of Time Limits for the Final Results

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

DATES: *Effective Date:* October 11, 2011.

SUMMARY: The Department of Commerce (''Department'') is conducting an administrative review of the antidumping duty order on certain kitchen appliance shelving and racks from the People's Republic of China (''PRC''), covering the period of review (''POR'') of March 5, 2009, through August 31, 2010.[1] The Department has preliminarily determined that sales have been made below normal value (''NV'') by the respondents examined in this administrative review. If these preliminary results are adopted in our final results of this review, the Department will instruct U.S. Customs and Border Protection (''CBP'') to assess antidumping duties on all appropriate entries of subject merchandise during the period of review.

FOR FURTHER INFORMATION CONTACT: Katie Marksberry or Kabir Archuletta, 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) 482–7906 or (202) 482–2593, respectively.

SUPPLEMENTARY INFORMATION:

Background

On October 28, 2010, the Department initiated an administrative review of certain kitchen appliance shelving and racks from the PRC for the period March 5, 2009, through August 31, 2010. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 75 FR 66349 (October 28, 2010) (''*First Initiation*'').[2]

On December 1, 2010, the Department placed U.S. Customs and Border Protection (''CBP'') data for the Harmonized Tarrif Schedule (''HTS'') numbers listed in the scope of the *Order* on the record of the review and stated that because there were apparent anomalies in the data that, for respondent selection purposes, it would be issuing quantity and value (''Q&V'') questionnaires to all companies under review, which were also issued on December 1, 2010.[3] The Department received timely Q&V responses from four exporters that shipped subject merchandise to the United States during the POR: Jiangsu Weixi Group Co. (''Weixi''); Guangdong Wireking Housewares & Hardware Co., Ltd. (''Wireking''); New King Shan (Zhuhai) Wire Co., Ltd. (''NKS''); and Hangzhou Dunli Import & Export Co., Ltd., (''Dunli''). The Department also received a timely Q&V response from Hengtong Hardware Manufacturer (Huizhou) Co., Ltd. (''Hengtong Hardware'') indicating that it had no shipments of subject merchandise during the POR. On December 23, 2010, the Department received an untimely Q&V response from Leader Metal Industry Co., Ltd., (aka Marmon Retail Services Asia Company) (''Leader''). On January 20, 2011, the Department sent a letter to Leader rejecting its untimely filed Q&V response and stating that it would not be considered for the purposes of this review.

Respondent Selection

On January 20, 2011, the Department selected two mandatory respondents for this review, pursuant to section 777A(c)(2)(B) of the Tariff Act of 1930, as amended (''the Act''), Wireking and Weixi.[4] The Department sent its antidumping duty questionnaire to Weixi and Wireking on January 20, 2011.[5] In its questionnaire, the Department requested that each firm provide a response to Section A of the Department's non-market economy (''NME'') questionnaire by February 10, 2011, and Sections C and D of the NME questionnaire by February 28, 2011.

On February 2, 2011, eight days prior to the Department's February 10, 2011, deadline for Section A questionnaire responses, the Department received a request on behalf of NKS, a mandatory respondent in the *LTFV Investigation*[6] and a company for which an administrative review was requested, to be selected as a replacement mandatory respondent in the event of a non-responsive mandatory respondent. NKS also requested a 28-day extension to submit its questionnaire responses.[7] On February 4, 2011, Wireking filed a request for an extension of the deadline to submit its Section A response, which the Department extended to February 22, 2011, for Wireking and any potential voluntary respondents.[8] The

[1] *See* ''Period of Review'' section below for further explanation of the POR in this administrative review.

[2] Nashville Wire Products Inc. and SSW Holding Company, Inc. (collectively, ''Petitioners'') initially requested that the Department initiate an administrative review of ten companies; however, we required additional information concerning why, pursuant to 19 CFR 351.213(b)(1), Petitioners requested a review of five of these companies. *See First Initiation,* 75 FR at 66352. Accordingly, the Department postponed initiation of this administrative review with respect to five companies requested by Petitioners. *See id.* and *Initiation of Antidumping and Countervailing Duty Administrative Reviews; Correction,* 75 FR 69054 (November 10, 2010). After reviewing additional information placed on the record of this administrative review by Petitioners, we determined that, for three of the five companies, Petitioners did not provide any reason, other than alleged transshipment, for initiation; therefore, we declined to initiate a review for Asia Pacific CIS (Thailand) Co., Ltd., Taiwan Rail Company, and King Shan Wire Co., Ltd. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 75 FR 73036, 73039 (November 29, 2010). However, we did determine that it was appropriate to initiate this review with respect to two additional companies originally requested by Petitioners: Asia Pacific CIS (Wuxi) Co., Ltd.; and Hengtong Hardware Manufacturing (Huizhou) Co., Ltd. *See id.*

[3] *See* Memorandum to The File, from Katie Marksberry, International Trade Specialist, Office 9, regarding ''Release of Customs and Border Protection (''CBP'') Data'', dated December 1, 2010.

[4] *See* Memorandum to James C. Doyle, Office Director, Office 9, through Catherine Bertrand, Program Manager, Office 9, from Kabir Archuletta, International Trade Analyst, Office 9, regarding ''Selection of Respondents for the Antidumping Review of Certain Kitchen Appliance Shelving and Racks from the People's Republic of China,'' dated January 20, 2011.

[5] *See* Letters to Weixi and Wireking from Catherine Bertrand, Program Manager, AD/CVD Operations, Office 9, regarding ''Kitchen Appliance Shelving and Racks from the People's Republic of China,'' dated January 20, 2011.

[6] *See Certain Kitchen Appliance Shelving and Racks From the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 74 FR 36656 (July 24, 2009) (''*LTFV Investigation Final*''), amended by *Certain Kitchen Appliance Shelving and Racks from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value and Notice of Antidumping Duty Order,* 74 FR 46971 (September 14, 2009) (''*LTFV Investigation Amended Final*'').

[7] *See* Letter from NKS regarding ''Request for Extension of Time to File Voluntary Response and Request for Clarification of Reporting of Sales,'' dated February 2, 2011 (''NKS February 2 Submission'').

[8] *See* Memorandum to the File from Kabir Archuletta, International Trade Analyst, Office 9, regarding ''Guangdong Wireking Housewares &

Continued

Department did not receive an extension request from Weixi and did not receive its Section A response by the appointed deadline.

On February 23, 2011, the Department received a voluntary Section A questionnaire response from NKS.[9] On March 1, 2011, because Weixi did not cooperate with our request for information, the Department selected NKS as a replacement mandatory respondent because it was the the next largest exporter of subject merchandise.[10] We also determined that it was appropriate to use the voluntary Section A response already submitted by NKS as the basis for that company's response as a mandatory respondent.[11] On March 1, 2011, the Department sent its antidumping questionnaire to NKS and assigned a deadline of March 22, 2011, for its Sections C and D responses.[12]

Case Schedule

On April 14, 2011, in accordance with section 751(a)(3)(A) of the Act, we extended the time period for issuing the preliminary results by 120 days, until September 30, 2011.[13]

Period of Review

This review was intiated with a POR of March 5, 2009, through August 31, 2010. On February 2, 2011, the Department received a letter from NKS requesting clarification of the proper reporting periods for U.S. sales of subject merchandise.[14] In its letter, NKS noted that the U.S. International Trade Commission found that there was a threat of injury with regard to oven racks during the period of investigation.[15] As such, entries of oven racks prior to September 9, 2009, were liquidated without antidumping or countervailing duties. On February 9, 2011, the Department sent interested parties a letter stating that it would not be appropriate to include sales of merchandise that have been liquidated by the Department without the assessment of antidumping duties in the margin calculation for the current POR.[16] Accordingly, the Department instructed interested parties to adhere to an abbreviated reporting period for sales of oven racks, while sales of refrigerator and freezer shelves should continue to be reported in accordance with the POR for this review. The abbreviated POR for oven racks is September 9, 2009, through August 31, 2010. Additionally, the Department clarified that respondents should report their factors of production according to the reporting period specific to the type of merchandise they reported in their U.S. sales database.[17]

Scope of the Order

The scope of the order consists of shelving and racks for refrigerators, freezers, combined refrigerator-freezers, other refrigerating or freezing equipment, cooking stoves, ranges, and ovens (''certain kitchen appliance shelving and racks'' or ''the merchandise under order''). Certain kitchen appliance shelving and racks are defined as shelving, baskets, racks (with or without extension slides, which are carbon or stainless steel hardware devices that are connected to shelving, baskets, or racks to enable sliding), side racks (which are welded wire support structures for oven racks that attach to the interior walls of an oven cavity that does not include support ribs as a design feature), and subframes (which are welded wire support structures that interface with formed support ribs inside an oven cavity to support oven rack assemblies utilizing extension slides) with the following dimensions:

—Shelving and racks with dimensions ranging from 3 inches by 5 inches by 0.10 inch to 28 inches by 34 inches by 6 inches; or

—baskets with dimensions ranging from 2 inches by 4 inches by 3 inches to 28 inches by 34 inches by 16 inches; or

—side racks from 6 inches by 8 inches by 0.1 inch to 16 inches by 30 inches by 4 inches; or

—subframes from 6 inches by 10 inches by 0.1 inch to 28 inches by 34 inches by 6 inches.

The merchandise under the order is comprised of carbon or stainless steel wire ranging in thickness from 0.050 inch to 0.500 inch and may include sheet metal of either carbon or stainless steel ranging in thickness from 0.020 inch to 0.2 inch. The merchandise under this order may be coated or uncoated and may be formed and/or welded. Excluded from the scope of this order is shelving in which the support surface is glass.

The merchandise subject to the order is currently classifiable in the Harmonized Tariff Schedule of the United States (''HTSUS'') statistical reporting numbers 8418.99.8050, 8418.99.8060, 7321.90.5000, 7321.90.6090, 8516.90.8000 and 8419.90.9520. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.

NKS's Sales of Out of Scope Products

In its initial Section C Questionnaire Response, NKS provided information related to all of its POR production, including product codes of the subject merchandise it sold to the United States during the POR and also the product codes of certain products it claimed were out of the scope of this *Order* and, therefore, not reported in its U.S. Sales Database.[18] Petitioners subsequently argued that those products not reported by NKS have not been subject to a formal scope determination and therefore cannot be definitively excluded from reportable sales.[19] In response to the Department's request for more information regarding these products, NKS submitted detailed descriptions of the product codes it claims do not fall within the scope of this *Order,* justification as to why they should not be included in the scope of this *Order* and production drawings of the products in question.[20] NKS conceded that it would submit a request for a formal scope ruling if requested to do so by the Department but argued that

Hardware Co., Ltd. Section A Questionnaire Extension Request,'' dated February 10, 2011.

[9] *See* Letter from NKS regarding ''Voluntary Response to Section A by New King Shan (Zhuhai) Co., Ltd.,'' dated February 23, 2011.

[10] *See* Memorandum to James C. Doyle, Office Director, Office 9, through Catherine Bertrand, Program Manager, Office 9, from Kabir Archuletta, International Trade Analyst, Office 9, regarding ''Antidumping Review of Certain Kitchen Appliance Shelving and Racks from the People's Republic of China: Selection of an Additional Mandatory Respondent,'' dated March 1, 2011.

[11] *See id.*

[12] *See* Letter to NKS from Catherine Bertrand, Program Manager, Office 9, regarding ''Kitchen Appliance Shelving and Racks from the People's Republic of China,'' dated March 1, 2011.

[13] *See Certain Kitchen Appliance Shelving and Racks From the People's Republic of China: Extension of Time Limits for the Preliminary Results of the First Antidumping Duty Administrative Review,* 76 FR 20950 (April 14, 2011).

[14] *See* NKS February 2 Submission.

[15] *See id.* at 6 (citing *Certain Kitchen Appliance Shelving and Racks from China* (Investigation No. 731–TA–1154 (Final), USITC Publication 4098 (August 2009)).

[16] *See* Letter to All Interested Parties from Catherine Bertrand, Program Manager, Office 9, regarding ''Section C Reporting,'' dated February 9, 2011.

[17] *See* Letter to NKS from Catherine Bertrand, Program Manager, Office 9, regarding ''Section D and Appendix V Supplemental Questionnaire,'' dated May 5, 2011, at 4.

[18] *See* NKS Section C questionnaire response, dated April 6, 2011 (''NKS SCQR''), at 4–6.

[19] *See* Petitioners' Comments on NKS Supplemental Section A Response and Section C Response, dated April 15, 2011 (''Petitioners April 15 Comments''), at 8–10, and Petitioners' Comments on NKS Supplemental Section C Response and Additional Information Response, dated June 16, 2011 (''Petitioners June 16 Comments''), at 11–14.

[20] *See* NKS Second Supplemental Section A questionnaire response, dated April 26, 2011 (''NKS SSSAQR''), at Exhibit SSA–10, and NKS Supplemental Section D questionnaire response, dated June 7, 2011 (''NKS SSDQR''), at 22–23.

an examination of the products in question reveal that they are not racks and clearly fall outside of the dimensions specified by the scope of the *Order.*[21] Upon review of the documentation submitted by NKS, the Department preliminarily concludes that there is no evidence on the record of this review to indicate that the products in question fall within the scope of the *Order.* This conclusion is based on an examination of the dimensions of the products in question, as well as the factual information submitted by NKS indicating that these products do not appear to be shelving, baskets, racks, side racks, or subframes, as defined by the scope of the *Order.*[22] Therefore, the Department has not required NKS to report sales of these specific products made during the POR in its U.S. Sales Database for consideration in these preliminary results.

NKS Affiliation

In the *LTFV Investigation,* we found based on the evidence on the record that NKS was affiliated with certain related entities, pursuant to sections 771(33)(A), (E) and (F) of the Act, based on ownership and common control.[23] While NKS has stated in this review that its corporate structure has changed since the *LTFV Investigation* such that an owner with more than five percent ownership of a related entity has sold that interest,[24] we preliminarily determine that the changes reported by NKS do not significantly impact the affiliation analysis conducted in conjunction with the *LTFV Investigation.*[25] As such, we continue to find NKS affiliated with the same entities with which we found it affiliated in the *LTFV Investigation.*[26] However, we note that while we find NKS and its related entities affiliated, we are not finding that the facts warrant treatment as a single entity.

Dunli's Separate Rate Certification

On December 21, 2010, the Department received a timely filed separate rate certification from Dunli. Subsequently, the Department determined that there are two separate PORs applicable to this review. *See* ''Period of Review'' section above. On February 10, 2011, the Department sent a letter to Dunli asking that they clarify that they had made sales of subject merchandise within the amended PORs (*i.e.,* sales of subject refrigerator/freezer shelves during the period March 5, 2009–August 31, 2010, and/or sales of subject oven racks during the period September 9, 2009–August 31, 2010).[27] On February 16, 2011, Dunli submitted a response which stated that it had no sales of refrigerator/freezer shelves during the period of March 5, 2009 through August 31, 2010, and no sales of oven/baking racks during the period of September 9, 2009 through August 31, 2010. On February 17, 2011, the Department sent a letter to Dunli granting additional time for it to submit a revised separate rate certification or instead, to submit a no shipments certification if appropriate and withdraw its separate rate application.

On February 25, 2011, Dunli withdrew its separate rate certification and filed a no shipments certification. In order to examine this claim, the Department sent two inquiries, one for each POR, to CBP asking if any CBP office had any information contrary to Dunli's no shipments claim and requesting CBP alert the Department of any such information within ten days of receiving our inquiry. CBP received our inquiry on March 7, 2011. On March 14, 2011 we received notice from CBP that Dunli appeared to have an entry of subject merchandise during the POR. On March 15, 2011, the Department requested the entry documents corresponding to the entry noted by CBP. The Department received the entry documents from CBP and placed them on the record of the review on August 18, 2011, and requested comments from interested parties.

On August 29, 2011, the Department received comments from Dunli stating that it had overlooked a small quantity of shipments and had, as a result, inadvertently withdrawn its separate rate certification and filed a no shipments certification.[28] Additionally, Dunli argued that it was a harmless clerical error that did not affect respondent selection as it would not have been chosen as a mandatory respondent and that it would be adversely affected should the Department not provide Dunli with an opportunity to correct for the error.[29] As an attachment to its comments, Dunli refiled its separate rate certification. Because of the unusual circumstances of the multiple PORs in this review, as well as the fact that doing so will not impede the review, we will, for these preliminary results, accept Dunli's refiled separate rate certification.

Preliminary Partial Rescission

As discussed in the ''Background'' section above, Hengtong Hardware filed a no shipment certification indicating that it did not export subject merchandise to the United States during the POR. In order to examine this claim, we reviewed the CBP data used for respondent selection and found no discrepancies with the statement made by Hengtong Hardware. Additionally, we sent an inquiry to CBP asking if any CBP office had any information contrary to the no shipments claim and requesting CBP alert the Department of any such information within ten days of receiving our inquiry. CBP received our inquiry on January 6, 2011. We have not received a response from CBP with regard to our inquiry which indicates that CBP did not have information that was contrary to the claim of Hengtong Hardware. Therefore, because the record indicates that Hengtong Hardware did not export subject merchandise to the United States during the POR, we are preliminarily rescinding this administrative review with respect to this company in accordance with 19 CFR 351.213(d)(3) and consistent with our practice.[30]

NME Country Status

In every case conducted by the Department involving the PRC, the PRC has been treated as an NME country.[31]

[21] *See* NKS SSDQR at 23.

[22] *See* NKS SSSAQR at Exhibit SSA–10, and NKS SSDQR at 23.

[23] *See Certain Kitchen Appliance Shelving and Racks From the People's Republic of China: Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination,* 74 FR 9591, 9594 (March 5, 2009), unchanged in *LTFV Investigation Final.*

[24] *See* NKS Supplemental Section A questionnaire response, dated March 28, 2011, at 18.

[25] *See* Memorandum to the File from Kabir Archuletta, Case Analyst, Office 9, through Catherine Bertrand, Program Manager, Office 9, regarding ''First Administrative Review of Certain Kitchen Appliance Shelving and Racks from the People's Republic of China: Affiliations of New King Shan (Zhu Hai) Co., Ltd.,'' dated September 30, 2011.

[26] *See id.*

[27] *See* Letter to Hangzhou Dunli from the Department regarding ''Certain Kitchen Appliance Shelving and Racks from the People's Republic of China (''PRC''),'' dated February 10, 2011.

[28] *See* Letter from Dunli regarding ''Separate Rate Certification of Hangzhou Dunli Import & Export Co., Ltd.,'' dated August 30, 2011 (''Dunli's Sep Rate Letter'').

[29] *See id.*

[30] *See, e.g., Certain Frozen Fish Fillets From the Socialist Republic of Vietnam: Notice of Preliminary Results and Partial Rescission of the Third Antidumping Duty Administrative Review,* 72 FR 53527, 53530 (September 19, 2007), unchanged in *Certain Frozen Fish Fillets From the Socialist Republic of Vietnam: Final Results of Antidumping Duty Administrative Review and Partial Rescission,* 73 FR 15479, 15480 (March 24, 2008).

[31] *See Certain Kitchen Appliance Shelving and Racks From the People's Republic of China:*

Continued

In accordance with section 771(18)(C)(i) of the Act, any determination that a foreign country is an NME country shall remain in effect until revoked by the administering authority. None of the parties to this proceeding have contested such treatment. Accordingly, we calculated NV in accordance with section 773(c) of the Act, which applies to NME countries.

Separate Rates

Purusant to section 771(18)(C) of the Act, a designation of a country as an NME remains in effect until it is revoked by the Department. Accordingly, there is a rebuttable presumption that all companies within the PRC are subject to government control and, thus, should be assessed a single antidumping duty rate.[32] In the *First Initiation,* the Department notified parties of the application process by which exporters and producers may obtain separate rate status in NME proceedings.[33] It is the Department's policy to assign all exporters of the merchandise subject to review in NME countries a single rate unless an exporter can affirmatively demonstrate an absence of government control, both in law (*de jure)* and in fact (*de facto*), with respect to exports. To establish whether a company is sufficiently independent to be entitled to a separate, company-specific rate, the Department analyzes each exporting entity in an NME country under the test established in *Sparklers,*[34] as amplified by *Silicon Carbide.*[35] However, if the Department determines that a company is wholly foreign-owned or located in a market economy (''ME''), then a separate rate analysis is not necessary to determine whether it is independent from government control.[36] In this review, Dunli is the only company, other than the companies under mandatory individual review, that submitted a separate rate certification.[37] Additionally, the Department received separate rate certifications and completed responses to the Section A portion of the NME antidumping questionnaire from Wireking and NKS, which contained information pertaining to each company's eligibility for a separate rate.[38]

We have considered whether each PRC company that submitted a complete application, certification or complete Section A Response as a mandatory respondent is eligible for a separate rate. The Department's separate rate test is not concerned, in general, with macroeconomic/border-type controls, *e.g.,* export licenses, quotas, and minimum export prices, particularly if these controls are imposed to prevent dumping.[39] The test focuses, rather, on controls over the investment, pricing, and output decision-making process at the individual firm level.[40]

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 merchandise under investigation under a test arising from *Sparklers,* as further developed in *Silicon Carbide.* In accordance with the separate rate criteria, the Department assigns separate rates in NME cases only if respondents can demonstrate the absence of both *de jure* and *de facto* governmental control over export activities.

1. Wholly Foreign-Owned

In its Section A response, NKS reported that it is wholly-owned by individuals or companies located in a ME country.[41] Therefore, because it is wholly foreign-owned, and we have no evidence indicating that it is under the control of the PRC, a separate rate analysis is not necessary to determine whether this company is independent from government control.[42] Accordingly, we have preliminarily granted a separate rate to this company.

2. Absence of De Jure Control

The Department considers the following *de jure* criteria in determining whether an individual company may be granted a separate rate: (1) An absence of restrictive stipulations associated with an individual exporter's business and export licenses; (2) any legislative enactments decentralizing control of companies; and (3) other formal measures by the government decentralizing control of companies.[43] The evidence provided by Dunli and Wireking supports a preliminary finding of *de jure* absence of governmental control based on the following: (1) An absence of restrictive stipulations associated with the individual exporter's business and export licenses; (2) the applicable legislative enactments decentralizing control of the companies; and (3) any other formal measures by the government decentralizing control of companies.[44]

3. Absence of De Facto Control

Typically the Department considers four factors in evaluating whether each respondent is subject to *de facto* governmental control of its export functions: (1) Whether the export prices are set by or are subject to the approval of a governmental agency; (2) whether the respondent has authority to negotiate and sign contracts and other agreements; (3) whether the respondent has autonomy from the government in making decisions regarding the selection of management; and (4) whether the respondent retains the proceeds of its export sales and makes independent decisions regarding disposition of profits or financing of losses.[45] The Department has determined that an analysis of *de facto* control is critical in determining whether respondents are, in fact, subject to a degree of governmental control

Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination, 74 FR 9591, 9593 (March 5, 2009) (''*LTFV Investigation Prelim*'', unchanged in *LTFV Investigation Final).*

[32] *See Notice of Final Determination of Sales at Less Than Fair Value, and Affirmative Critical Circumstances, In Part: Certain Lined Paper Products From the People's Republic of China,* 71 FR 53079, 53082 (September 8, 2006); *Final Determination of Sales at Less Than Fair Value and Final Partial Affirmative Determination of Critical Circumstances: Diamond Sawblades and Parts Thereof From the People's Republic of China,* 71 FR 29303, 29307 (May 22, 2006).

[33] *See First Initiation.*

[34] *See Final Determination of Sales at Less Than Fair Value: Sparklers From the People's Republic of China,* 56 FR 20588 (May 6, 1991) (''*Sparklers*'').

[35] *See Notice of Final Determination of Sales at Less Than Fair Value: Silicon Carbide From the People's Republic of China,* 59 FR 22585 (May 2, 1994). (''*Silicon Carbide*'').

[36] *See, e.g., Final Results of Antidumping Duty Administrative Review: Petroleum Wax Candles From the People's Republic of China,* 72 FR 52355, 52356 (September 13, 2007).

[37] *See* Dunli's Sep Rate Letter at Attachment 1.

[38] *See* Separate Rate Certification of Guangdong Wireking Housewares & Hardware Co., Ltd., dated December 29, 2010, and Separate Rate Certification of New King Shan (Zhu Hai) Co., Ltd., dated December 30, 2010 (''NKS Sep Rate Certification'').

[39] *See Notice of Final Determination of Sales at Less Than Fair Value: Certain Preserved Mushrooms From the People's Republic of China,* 63 FR 72255, 72256 (December 31, 1998).

[40] *See Certain Cut-to-Length Carbon Steel Plate from Ukraine: Final Determination of Sales at Less than Fair Value,* 62 FR 61754, 61758 (November 19, 1997), and *Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, from the People's Republic of China: Final Results of Antidumping Duty Administrative Review,* 62 FR 61276, 61279 (November 17, 1997).

[41] *See* NKS Section A questionnaire response dated February 23, 2011, at 2.

[42] *See Notice of Final Determination of Sales at Less Than Fair Value: Creatine Monohydrate From the People's Republic of China,* 64 FR 71104–71105 (December 20, 1999) (where the respondent was wholly foreign-owned, and thus, qualified for a separate rate).

[43] *See Sparklers,* 56 FR at 20589.

[44] *See* Dunli Sep Rate Letter at Attachment 1, pages 5–6; and Wireking's Section A Questionnaire Response, dated February 23, 2011, at 4–5.

[45] *See Silicon Carbide,* 59 FR at 22586–87; *see also Notice of Final Determination of Sales at Less Than Fair Value: Furfuryl Alcohol From the People's Republic of China,* 60 FR 22544, 22545 (May 8, 1995).

which would preclude the Department from assigning separate rates.

We determine that, for Dunli and Wireking the evidence on the record supports a preliminary finding of *de facto* absence of governmental control based on record statements and supporting documentation showing the following: (1) Each exporter sets its own export prices independent of the government and without the approval of a government authority; (2) each exporter retains the proceeds from its sales and makes independent decisions regarding disposition of profits or financing of losses; (3) each exporter has the authority to negotiate and sign contracts and other agreements; and (4) each exporter has autonomy from the government regarding the selection of management.[46]

The evidence placed on the record of this investigation by Dunli and Wireking demonstrates an absence of *de jure* and *de facto* government control with respect to each of the exporter's exports of the merchandise under investigation, in accordance with the criteria identified in *Sparklers* and *Silicon Carbide.* As a result, we have granted Dunli and Wireking separate rate status.

Separate Rate Recipients

As discussed above, the Department initiated this administrative review with respect to seven companies. Additionally, we are preliminarily rescinding this review with respect to Hengtong Hardware because we have preliminarily determined that it had no shipments of subject merchandise during the POR. Thus, including Wireking and NKS, six companies remain subject to this review. While Wireking, NKS and Dunli provided documentation supporting their eligibility for a separate rate, the remaining companies under active review have not demonstrated their eligibility for a separate rate. Furthermore, Weixi, which responded to the Department's Q&V questionnaire and reported shipments during the POR, was chosen by the Department as a mandatory respondent, but did not respond to the Department's full antidumping duty questionnaire. Therefore, the Department preliminarily determines that there were exports of merchandise under review from three PRC exporters that did not demonstrate their eligibility for separate rate status: Weixi, Asia Pacific CIS (Wuxi) Co., Ltd., and Leader Metal Industry Co., Ltd. (aka Marmon Retail Services Asia). As a result, the Department is treating these three PRC exporters as part of the PRC-wide entity, subject to the PRC-wide rate.

Rate for Non-Selected Companies

In accordance with section 777A(c)(2)(B) of the Act, the Department employed a limited examination methodology, as it did not have the resources to examine all companies for which a review request was made. As stated above, the Department selected Wireking and NKS as the mandatory respondents in this review. In addition to the mandatory respondent, only Dunli submitted information as requested by the Department and remains subject to review as a cooperative separate rate respondent.

The statute and the Department's regulations do not address the establishment of a rate to be applied to individual companies not selected for examination where the Department limited its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally we have looked to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance when calculating the rate for respondents we did not examine in an administrative review. Section 735(c)(5)(A) of the Act instructs that we are not to calculate an all-others rate using any zero or *de minimis* margins or any margins based entirely on facts available. Accordingly, the Department's practice in this regard, in reviews involving limited respondent selection based on exporters accounting for the largest volume of trade, has been to average the rates for the selected companies, excluding zero and *de minimis* rates and rates based entirely on facts available.[47] Section 735(c)(5)(B) of the Act also provides that, where all margins are zero, *de minimis,* or based entirely on facts available, we may use ''any reasonable method'' for assigning the rate to non-selected respondents, including ''averaging the estimated weighted average dumping margins determined for the exporters and producers individually investigated.'' In this instance, consistent with our practice, we have preliminarily established a margin for the separate rate respondent, Dunli, based on the rate we calculated for the mandatory respondent whose rate was not *de minimis.*[48]

The PRC-Wide Entity and Use of Adverse Facts Available (''AFA'')

Sections 776(a)(1) and (2) of the Act provide that the Department shall apply ''facts otherwise available'' if, *inter alia,* necessary information is not on the record or an interested party or any other person: (A) Withholds information that has been requested; (B) fails to provide information within the deadlines established, or in the form and manner requested by the Department, subject to subsections (c)(1) and (e) of section 782 of the Act; (C) significantly impedes a proceeding; or (D) provides information that cannot be verified as provided by section 782(i) of the Act.

Where the Department determines that a response to a request for information does not comply with the request, section 782(d) of the Act provides that the Department will so inform the party submitting the response and will, to the extent practicable, provide that party the opportunity to remedy or explain the deficiency. If the party fails to remedy the deficiency within the applicable time limits, subject to section 782(e) of the Act, the Department may disregard all or part of the original and subsequent responses, as appropriate. Section 782(e) of the Act provides that the Department ''shall not decline to consider information that is submitted by an interested party and is necessary to the determination but does not meet all applicable requirements established by the administering authority'' if the information is timely, can be verified, is not so incomplete that it cannot serve as a reliable basis, and if the interested party acted to the best of its ability in providing the information. Where all of these conditions are met, the statute requires the Department to use the information if it can do so without undue difficulties.

Section 776(b) of the Act further provides that the Department may use an adverse inference in applying the facts otherwise available when a party has failed to cooperate by not acting to the best of its ability to comply with a request for information. Section 776(b) of the Act also authorizes the Department to use as adverse facts available (''AFA'') information derived from the petition, the final

[46] *See* Dunli's Sep Rate Letter at Attachment 1, pages 6–7; and Wireking's Section A Questionnaire Response, dated February 23, 2011, at 6–7.

[47] *See Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Final Results and Final Partial Rescission of Antidumping Duty Administrative Review,* 73 FR 52273, 52275 (September 9, 2008) and accompanying Issues and Decision Memorandum at Comment 6.

[48] *See, e.g., Forth Administrative Review of Certain Frozen Warmwater Shrimp From the People's Republic of China: Preliminary Results, Preliminary Partial Rescission of Antidumping Duty Administrative Review and Intent Not To Revoke, In Part,* 75 FR 11855 (March 12, 2010).

determination, a previous administrative review, or other information placed on the record.

Section 776(c) of the Act provides that, when the Department relies on secondary information rather than on information obtained in the course of an investigation or review, it shall, to the extent practicable, corroborate that information from independent sources that are reasonably at its disposal. Secondary information is defined as ''information derived from the petition that gave rise to the investigation or review, the final determination concerning the subject merchandise, or any previous review under section 751 concerning the subject merchandise.'' [49] ''Corroborate'' means that the Department will satisfy itself that the secondary information to be used has probative value.[50] To corroborate secondary information, the Department will, to the extent practicable, examine the reliability and relevance of the information to be used. The SAA explains, however, that the Department need not prove that the selected facts available are the best alternative information.[51]

We have preliminarily determined that three companies did not demonstrate their eligibility for a separate rate and are properly considered part of the PRC-wide entity. As explained above in the ''Separate Rates'' section, all companies within the PRC are considered to be subject to government control unless they are able to demonstrate an absence of government control with respect to their export activities. Such companies are thus assigned a single antidumping duty rate distinct from the separate rate(s) determined for companies that are found to be independent of government control with respect to their export activities. We consider the influence that the government has been found to have over the economy to warrant determining a rate for the entity that is distinct from the rates found for companies that have provided sufficient evidence to establish that they operate freely with respect to their export activities.[52]

Because we have determined that three companies are not entitled to separate rates and are now part of the PRC-wide entity, the PRC-wide entity—which includes Weixi, Asia Pacific CIS (Wuxi) Co., Ltd., and Leader Metal Industry Co., Ltd. (aka Marmon Retail Services Asia)—is now under review. The PRC-wide entity did not respond to our requests for information. Because the PRC-wide entity did not respond to our requests for information, we find it necessary under section 776(a)(2) of the Act to use facts available as the basis for these preliminary results. Because the PRC-wide entity provided no information, we determine that sections 782(d) and (e) of the Act are not relevant to our analysis. We further find that the PRC-wide entity (Weixi, Asia Pacific CIS (Wuxi) Co., Ltd., and Leader Metal Industry Co., Ltd. (aka Marmon Retail Services Asia)) failed to respond to the Department's requests for information and, therefore, did not cooperate to the best of its ability. Therefore, because the PRC-wide entity did not cooperate to the best of its ability in the proceeding, the Department finds it necessary to use an adverse inference in making its determination, pursuant to section 776(b) of the Act.

Selection of the Adverse Facts Available Rate

In deciding which facts to use as AFA, section 776(b) of the Act and 19 CFR 351.308(c)(1) authorize the Department to rely on information derived from (1) The petition, (2) a final determination in the investigation, (3) any previous review or determination, or (4) any other information placed on the record. Because of the PRC-wide entity's failure to cooperate in this administrative review, we have preliminarily assigned the PRC-wide entity an AFA rate of 95.99 percent, which is the PRC-wide rate determined in the *LTFV Investigation* and the only rate ever determined for the PRC-wide entity in this proceeding.[53]

The Department preliminarily determines that this information is the most appropriate from the available sources to effectuate the purposes of AFA, which is to induce respondents to provide the Department with complete and accurate information in a timely manner.[54] The Department's reliance on the PRC-wide rate from the original investigation to determine an AFA rate is subject to the requirement to corroborate secondary information.[55]

Corroboration of Facts Available

Section 776(c) of the Act provides that, when the Department relies on secondary information rather than on information obtained in the course of an investigation or review, it shall to the extent practicable, corroborate that information from independent sources that are reasonably at the Department's disposal. Secondary information is described in the SAA as ''information derived from the petition that gave rise to the investigation or review, the final determination concerning the subject merchandise, or any previous review under section 751 concerning the subject merchandise.'' [56] The SAA explains that ''corroborate'' means to determine that the information used has probative value. The Department has determined that to have probative value, information must be reliable and relevant.[57] The SAA also explains that independent sources used to corroborate such evidence may include, for example, published price lists, official import statistics and customs data, and information obtained from interested parties during the particular investigation.[58]

As stated above, we are applying as AFA the highest and only rate for the PRC-wide entity from any segment of this administrative proceeding, which is 95.99 percent from the *LTFV Investigation Final.* In deriving that rate, the Department relied upon a rate from the Petition.[59] Because only one mandatory respondent, NKS, received an individually calculated weighted-average margin in the *LTFV Investigation Final,* the Department had limited information from which to corroborate the selected AFA rate. To assess the probative value of the total AFA rate selected for the PRC-wide entity in the *LTFV Investigation Final,* the Department compared the transaction-specific rates calculated for NKS to the margins contained in the

[49] *See* SAA at 870.

[50] *See id.*

[51] *See id.* at 869.

[52] *See Notice of Final Determination of Sales at Less Than Fair Value, and Affirmative Critical Circumstances, In Part: Certain Lined Paper Products From the People's Republic of China,* 71 FR 53079, 53080 (September 8, 2006).

[53] *See LTFV Investigation Amended Final,* 74 FR at 46973.

[54] *See Notice of Final Determination of Sales at Less than Fair Value: Static Random Access Memory Semiconductors From Taiwan,* 63 FR 8909, 8932 (February 23, 1998).

[55] *See* Section 776(c) of the Act and the ''Corroboration of Facts Available'' section below.

[56] *See* SAA at 870.

[57] *See Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From Japan, and Tapered Roller Bearings, Four Inches or Less in Outside Diameter, and Components Thereof, From Japan; Preliminary Results of Antidumping Duty Administrative Reviews and Partial Termination of Administrative Reviews,* 61 FR 57391, 57392 (November 6, 1996), unchanged in *Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From Japan, and Tapered Roller Bearings, Four Inches or Less in Outside Diameter, and Components Thereof, From Japan; Final Results of Antidumping Duty Administrative Reviews and Termination in Part,* 62 FR 11825 (March 13, 1997).

[58] *See* SAA at 870; *see also Notice of Final Determination of Sales at Less Than Fair Value: Live Swine From Canada,* 70 FR 12181, 12183 (March 11, 2005).

[59] *See LTFV Investigation Final,* 74 FR at 36660.

petition and found that, by using NKS's highest transaction specific margin in the LTFV Investigation Final as a limited reference point, it could corroborate the 95.99 percent AFA rate.[60] Since the investigation, the Department has found no other corroborating information available in this case, and received no comments from interested parties as to the relevance or reliability of that secondary information. Based upon the above, for these preliminary results, the Department finds that the rate derived from the Petition and assigned to the PRC-wide entity in the *LTFV Investigation Final* is corroborated to the extent practicable for purposes of assigning the PRC-wide entity the same 95.99 percent rate as AFA in this administrative review.

Date of Sale

Section 351.401(i) of the Department's regulations states that, ''in identifying the date of sale of the merchandise under consideration or foreign like product, the Secretary normally will use the date of invoice, as recorded in the exporter or producer's records kept in the normal course of business.'' In *Allied Tube,* the CIT noted that a ''party seeking to establish a date of sale other than invoice date bears the burden of producing sufficient evidence to 'satisfy' the Department that 'a different date better reflects the date on which the exporter or producer establishes the material terms of sale.' ''[61] Additionally, the Secretary may use a date other than the date of invoice if the Secretary is satisfied that a different date better reflects the date on which the exporter or producer establishes the material terms of sale.[62] The date of sale is generally the date on which the parties agree upon all substantive terms of the sale. This normally includes the price, quantity, delivery terms and payment terms.[63]

NKS reported that the date of sale was determined by the invoice issued by the affiliated importer to the unaffiliated United States customer. In this case, as the Department found no evidence contrary to NKS's claims that invoice date was the appropriate date of sale, the Department used invoice date as the date of sale for these preliminary results.

As it did in the *LTFV Investigation,* Wireking reported its U.S. sales for this review as constructed export price (''CEP'') sales because the sales are not made until after importation to the United States. Wireking reported that, while it issues a commercial invoice to the U.S. customer for the quantities of subject merchandise that it shipped, the quantity of each sale is not fixed when it issues the commercial invoice to the U.S. customer.[64] According to Wireking, the U.S. customer does not agree to purchase the final quantity for each of Wireking's reported sales until the U.S. customer issues document X[65] to Wireking, upon which payment and the total value of each sale is based.[66] Additionally, Wireking has reported that it records the date of document X in its accounting records, as well as the payment received pursuant to the sale.[67] Accordingly, based on the record evidence, the Department preliminarily determines that Wireking's date of sale is the date on which document X is issued because all the material terms of sale, *i.e.,* final quantity, value, and payment, are not fixed until the U.S. customer issues document X to Wireking. Therefore, the Department will calculate Wireking's price for its U.S. sales using the date of document X as the date of sale.

Use of Facts Available for Wireking's Unit Weights

Section 776(a)(1) of the Act mandates that the Department use facts available if necessary information is not available on the record of an antidumping proceeding. Section 776(a)(2) of the Act also provides that the Department shall apply ''facts otherwise available'' if, *inter alia,* an interested party or any other person (A) Withholds information that has been requested; (B) fails to provide information within the deadlines established, or in the form and manner requested by the Department, subject to subsections (c)(1) and (e) of section 782 of the Act; (C) significantly impedes a proceeding; or (D) provides information that cannot be verified as provided by section 782(i) of the Act.

In this review, as in the *LTFV Investigation,* Wireking reported that it does not maintain the records to trace the consumption of inputs or materials to the finished products (*i.e.* on a product-specific basis).[68] In the *LTFV Investigation,* the Department applied total AFA to Wireking for the final determination because it found production records at verification that Wireking had failed to submit, in spite of repeated requests from the Department that Wireking provide any documents that could be used to calculated product-specific usage ratios. The Department noted that:

> The Department afforded Wireking numerous opportunities to provide complete and accurate information for the calculation of its antidumping margin. This information is critical because it affects the Department's ability to ascertain whether Wireking has accurately reported its FOPs {factors of production}. Specifically, because Wireking failed to provide the BOMs {bills of materials} and actual production notes in timely manner prior to verification, the Department did not have the opportunity to fully investigate whether Wireking could have reported its FOPs on a more specific basis, nor did the Department have the opportunity to obtain and analyze this data.[69]

In this review, Wireking has used the standard weight of the consumption of steel wire for each finished product from its standard production notes (also referred to as the bill of materials), as the basis for its calculated unit consumption of FOPs for subject merchandise.[70] Specifically, Wireking reported that for this review it reported its factors of production (''FOPs'') by calculating, at each stage of production, the ratio of the finished standard weight of each product code to the finished standard weight of all products, subject and non-subject, generated at that stage. Wireking then applied that ratio to the total actual POR usage of each FOP to obtain a standard consumption of each FOP on a product-specific basis.

In multiple submissions to the Department, Petitioners provided data gathered from Wireking's submitted packing lists and Petitioners' own production experience of certain products that allegedly demonstrated that Wireking's reported unit weights

[60] *See id.*

[61] *See Allied Tube & Conduit Corp.* v. *United States* 132 F. Supp. 2d 1087, 1090 (CIT 2001) (quoting 19 CFR 351.401(i)) (''*Allied Tube*'').

[62] *See* 19 CFR 351.401(i); *see also Allied Tube,* 132 F. Supp. 2d at 1090–1092.

[63] *See Carbon and Alloy Steel Wire Rod from Trinidad and Tobago: Final Results of Antidumping Duty Administrative Review,* 72 FR 62824 (November 7, 2007) and accompanying Issue and Decision Memorandum at Comment 1; *Notice of Final Determination of Sales at Less Than Fair Value; Certain Cold-Rolled Flat-Rolled Carbon Quality Steel Products from Turkey,* 65 FR 15123 (March 21, 2000) and accompanying Issues and Decision Memorandum at Issue 2.

[64] *See* Wireking's Section A Response, dated February 23, 2011, at 13.

[65] The description of this document is business proprietary; for further discussion of this document, *see, e.g.,* Wireking's Supplemental Section A Response, dated February 23, 2011, at 14, and Wireking's Supplemental Section A & C Response, dated April 27, 2011, at 2.

[66] *See* Wireking's Supplemental Questionnaire Response, dated May 26, 2011, at 7.

[67] *See* Wireking's Supplemental Section A Response, dated (March 17, 2011), at 7.

[68] *See* Wireking's Section D Response, dated March 21, 2011, at 5.

[69] *See LTFV Investigation Final* and accompanying Issues and Decision Memorandum at Comment 16.

[70] *See* Wireking's Section D Response, dated March 21, 2011, at 11.

were understated.[71] After comparing the unit weight of products reported in Wireking's packing lists to Wireking's reported unit weights, we preliminarily find that Wireking has understated the unit weights of its finished products.[72] Furthermore, we note that Wireking has stated that the weights on its packing lists are higher than its reported standard weights because it intentionally overstates the weights on the packing list to ensure that the packing list weight will not be lower than the actual weight when the container is checked by CBP. However, we find that overstating the weight on the packing lists to the extent done by Wireking would subject Wireking to unnecessary, additional shipping costs, and does not reflect a reasonable business decision. For a detailed discussion of the specific weight variations between documents, please *see* Wireking's Analysis Memo and Wireking's Supplemental Questionnaire Response, dated July 20, 2011, at Exhibit S4–3. Additionally, the Department notes that Petitioners have argued that weights quoted by Wireking in e-mail correspondence with its U.S. customer would serve as a more appropriate benchmark to determine to what extent Wireking has understated the unit weights of its finished product. However, the Department finds that the packing lists, which are prepared by Wireking for use by an outside third party, are more reliable than the informal and internal business emails between Wireking and its customer.

Because Wireking reported that it multiplied its FOP ratios by the unit weight of the finished product to obtain the per-unit consumption ratio of finished product, we further find that Wireking has understated its FOP ratios. Therefore, pursuant to section 776(a)(2)(B) of the Act, we preliminarily determine that Wireking has not provided accurate information relevant to the Department's analysis. Thus, consistent with sections 776(a)(2)(B) and 782(d) of the Act, and consistent with the Department's determination in the *LTFV Investigation Final,* the Department is disregarding the standard weights reported by Wireking for each finished product and is applying facts otherwise available to Wireking's unit weight of each finished product to calculate Wireking's NV based on its reported FOP data. To account for the correct per-unit consumption ratio of each of Wireking's finished products, the Department has preliminarily determined to increase Wireking's reported FOP data by the difference in Wireking's reported unit weight and the product-specific unit weight reported in Wireking's packing list. Moreover, the Department has made the necessary corresponding changes to the variables reported in the U.S. sales database.[73]

Wireking's Production Records

As explained above in the ''Use of Facts Available for Wireking's Unit Weights'' section, for these preliminary results, the Department is accepting Wireking's reported standard allocation methodology and applying FA to its reported unit weights. However, the Department now advises Wireking that it must, going forward and in all future segements of this proceeding, generate and maintain detailed production records sufficient to allow Wireking to report its FOP usage on an actual, CONNUM-specific basis.

NKS's Reported U.S. Sales Variable [74]

In its U.S. Sales database, NKS has reported a variable that it argues should be accounted for in the Department's margin calculation. However, based on information placed on the record by NKS and its U.S. customer, the Department has determined not to include this variable in the margin calculation for these preliminary results. Due to the proprietary nature of the factual information concerning this discussion, a detailed explanation of this issue is provided in a separate business proprietary memorandum.[75]

NKS's Reported Indirect Selling Expenses

In the *LTFV Investigation* the Department determined that, in accordance with section 776(a)(1) of the Act, the use of facts available was warranted for the calculation of indirect selling expenses (''ISEs'') for the affiliates of NKS.[76] The Department further stated that it would deduct ISEs for NKS's U.S. affiliate and other affiliated companies from NKS's CEP in accordance with 19 CFR 351.402(b), which states that ''the Secretary will make adjustments for expenses associated with commercial activities in the United States that relate to the sale to the unaffiliated purchaser, no matter where or when paid.'' [77]

In this review, NKS initially submitted an ISE calculation that only included certain expenses for one of its affiliates. The Department requested that NKS revise its reported ISEs to include additional line item expenses and to include expenses for its other affiliates. Subsequently, NKS submitted a revised calculation which included additional expenses as well as certain expenses related to a second affiliate. However, NKS argued that the Department should not include all reported expenses and should instead accept NKS's suggested calculation. We have determined, based on the information on the record of this review, to apply the second, more complete ISE calculation submitted by NKS which includes all additional requested expenses, because there is not sufficient information currently on the record of this review to determine whether NKS's requested line item exclusions are appropriate. Therefore, the Department has requested additional information from NKS regarding each line item expense included in its submitted ISE calculations.[78]

Additionally, NKS declined to submit calculated ISEs for a third affiliate that it claims did not take title to the goods, did not arrange for shipping details, did not warehouse the goods, and did not sell the goods.[79] Although NKS claims that this affiliate is in no way involved in the sale of subject merchandise, the Department finds that the record of this review does not provide sufficient information to definitively determine that this is the case. The Department notes that, while we deducted ISEs for this affiliate in the *LTFV Investigation,* certain circumstances have since changed and the extent of the involvement of this affiliate in the sale of subject merchandise has yet to be

[71] *See* Petitioners' Letter regarding ''Deficiencies in Sections C and D of Wireking's Response,'' dated March 28, 2011; Petitioners' letter regarding ''The True Weight of Finished Products and The Relationship to the True Weight of Direct Material Inputs,'' dated May 9, 2011; Petitioners' Letter regarding ''Petitioners' Commercial Experience For Benchmarking Wireking's Factors of Production,'' dated May 31, 2011; and Petitioners' Letter regarding ''Factual Information Regarding Production Requirements (U.S. Petitioner's Business Proprietary Information),'' dated May 26, 2011.

[72] *See* Memorandum to The File, through Catherine Bertrand, Program Manager, Office 9, from Katie Marksberry, International Trade Specialist, Office 9, regarding ''Analysis Memorandum for the Preliminary Results of the First Antidumping Duty Review of Certain Kitchen Appliance Shelving and Racks from the People's Republic of China: Guandong Wireking Housewares and Hardware Co., Ltd. (''Wireking''),'' dated September 30, 2011 (''Wireking Analysis Memo'').

[73] *See* Wireking's Analysis Memo.

[74] *See* Memorandum to the File from Kabir Archuletta, Analyst, Office 9, regarding ''Information Related to New King Shan's Reported Gross Unit Price and Billing Adjustments,'' dated September 30, 2011 (''NKS BPI Memo'').

[75] *See id.*

[76] *See LTFV Investigation Final,* 74 FR at 36659.

[77] *See* 19 CFR 351.402(b).

[78] *See* Letter from Catherine Bertrand, Program Manager, Office 9, to NKS regarding ''Sixth Supplemental Questionnaire.'' dated September 13, 2011 (''Sixth Supplemental Questionnaire'').

[79] *See* NKS August 1 Response at Exhibit SSSC–4.

fully explained on the record of this review.[80]

Therefore, the Department has requested additional information from NKS that specifically addresses the involvement of this affiliate in the sale of subject merchandise and the propriety of excluding certain expenses from the ISE calculations of its other affiliates.[81] Although the late timing of this questionnaire will not allow us to consider the response of NKS in these preliminary results, the information will be reviewed and incorporated into the final results. Therefore, for the preliminary results, we will use the INDIRSU1 ISE calculation provided by NKS pending NKS's response to its outstanding supplemental questionnaire.[82]

Allegations of NKS's Failure To Disclose Third Country Transshipments

On June 16, 2011, Petitioners submitted comments requesting that the Department resort to total AFA for NKS based on allegations that it concealed U.S. sales shipped through third countries.[83] These claims were based on price quotes submitted by NKS, a comparison of sales in the *LTFV Investigation* and those reported in this review, and email correspondence between NKS and its U.S. customer.[84] Alternatively, Petitioners requested that the Department solicit further information and pointed to a number of specific issues for further clarification.[85] Between May 2, 2011, and August 1, 2011, the Department requested clarification and received responses from NKS related to the allegations made by Petitioners.[86] However, based on the information reported in these responses, the Department has determined, for these preliminary results, that there is not adequate information on the record of this review to determine that NKS has failed to report U.S. sales to the Department. Therefore, we are not requiring NKS to revise its Section C questionnaire responses or databases to include sales of merchandise from third countries for these preliminary results. Additionally, the Department has obtained CBP data related to Petitioners' allegations and is placing the data on the record of this review and requesting comments from interested parties related to this issue within ten days of publication of this notice, rebuttal comments pertaining to the CBP data will be due five days after affirmative comments.[87]

Surrogate Country and Surrogate Values

When the Department investigates imports from an NME country, section 773(c)(1) of the Act directs it to base NV, in most circumstances, on the NME producer's FOPs, valued in a surrogate market economy country or countries considered to be appropriate by the Department. In accordance with section 773(c)(4) of the Act, in valuing the FOPs, the Department shall utilize, to the extent possible, the prices or costs of FOPs in one or more market economy countries that are at a level of economic development comparable to that of the NME country and significant producers of comparable merchandise.

On January 3, 2011, the Department sent interested parties a letter requesting comments on the surrogate country and information pertaining to the valuation of FOPs.[88] On April 18, 2011, the Department received comments from Wireking regarding the valuation of FOPs. On August 1, 2011, the Department received comments from Petitioners regarding the valuation of FOPs. Wireking submitted rebuttal surrogate value comments on August 11, 2011. We did not receive surrogate value comments from any other interested parties.

As discussed in the *NME Country Status* section, above, the Department considers the PRC to be an NME country. The Department determined that India, Indonesia, the Philippines, Thailand, Ukraine and Peru are countries comparable to the PRC in terms of economic development.[89] Moreover, it is the Department's practice to select an appropriate surrogate country based on the availability and reliability of data from these countries.[90] The Department finds India to be a reliable source for surrogate values because India is at a comparable level of economic development pursuant to 773(c)(4) of the Act, is a significant producer of comparable merchandise, and has publicly available and reliable data.[91] Furthermore, the Department notes that India has been the primary surrogate country in the past segment.[92] As noted above, Wireking and Petitioners submitted surrogate value data for FOPs, including that from India. Given the above facts, the Department has selected India as the primary surrogate country for this review.[93] The sources of the surrogate factor values are discussed under the *Normal Value* section below and in the Surrogate Value Memo.

U.S. Price

Constructed Export Price

Both Wireking and NKS reported that all of their POR sales were constructed export price (''CEP'') in accordance with section 772(b) of the Act. For these sales, we based CEP on prices to the first unaffiliated purchaser in the United States. Where appropriate, we made deductions from the starting price (gross unit price) for foreign movement expenses, international movement expenses, U.S. movement expenses, and appropriate selling expenses, in accordance with section 772(c)(2)(A) of the Act. Additionally, in accordance with section 772(c)(1)(C) of the Act, we adjusted CEP where appropriate to account for countervailing duties attributable to subject merchandise in order to offset export subsidies preliminarily found in the concurrent administrative review of the countervailing duty order on certain kitchen appliance shelving and racks from the PRC.

[80] *See* NKS August 1 Response at 18; NKS Supplemental Section C Questionnaire Response, dated May 27, 2011 (''NKS SSCQR''), at 25; and NKS Fourth Supplemental Questionnaire and First Addendum Response, dated August 30, 2011 (''NKS August 30 Response''), at 1–4.

[81] *See* Letter from Catherine Bertrand, Program Manager, Office 9, to NKS regarding ''Sixth Supplemental Questionnaire.'' dated September 13, 2011.

[82] *See* Memorandum to the File from Kabir Archuletta, Case Analyst, Office 9, through Catherine Bertrand, Program Manager, Office 9, regarding ''Analysis Memorandum for the Preliminary Results of the First Antidumping Duty Administrative Review of Certain Kitchen Appliance Shelving and Racks from the People's Republic of China: New King Shan (Zhu Hai) Co., Ltd.'', dated September 30, 2011 (''NKS Analysis Memo'').

[83] *See* Petitioners' June 16 Comments at 2–5; *see also* Petitioners' April 15 Comments at 2–5.

[84] *See id.*

[85] *See id.*

[86] *See* NKS SSCQR, NKS SSDQR, and NKS August 1 Response.

[87] *See* Memorandum to The File, from Katie Marksberry, International Trade Specialist, Office 9; regarding ''Release of CBP Data for Comment,'' dated September 30, 2011.

[88] *See* Letter to Interested Parties from Catherine Bertrand, Program Manager, Office 9, regarding ''First Administrative Review of Certain Kitchen Appliance Shelving and Racks from the People's Republic of China: Deadlines for Surrogate Country and Surrogate Value Comments,'' dated January 3, 2011.

[89] *See* Letter from the Department to Interested Parties, regarding ''First Administrative Review of Certain Kitchen Appliance Shelving and Racks from the People's Republic of China: Deadlines for Surrogate Country and Surrogate Value Comments,'' dated January 3, 2011.

[90] *See* Department Policy Bulletin No. 04.1: Non-Market Economy Surrogate Country Selection Process, dated March 1, 2004.

[91] *See* Memorandum to the File through Catherine Bertrand, Program Manager, Office 9, from Katie Marksberry, Case Analyst, Office 9, regarding ''First Administrative Review of Certain Kitchen Appliance Shelving and Racks From the People's Republic of China: Surrogate Factor Valuations for the Preliminary Results,'' dated concurrently with this notice (''Surrogate Value Memo'').

[92] *See LTFV Investigation Final,* 74 FR at 36659.

[93] *See* Surrogate Value Memo.

In accordance with section 772(d)(1) of the Act, we also deducted those selling expenses associated with economic activities occurring in the United States where appropriate. We deducted, where appropriate, commissions, inventory carrying costs, credit expenses, and indirect selling expenses. Where foreign movement expenses, international movement expenses, or U.S. movement expenses were provided by Chinese service providers or paid for in Chinese renminbi, we valued these services using surrogate values.[94] For those expenses that were provided by a market-economy provider and paid for in market-economy currency, we used the reported expense.[95] Due to the proprietary nature of certain adjustments to U.S. price, for a detailed description of all adjustments made to U.S. price for Wireking and NKS, *see* company specific analysis memos.

Normal Value

Methodology

Section 773(c)(1)(B) of the Act provides that the Department shall determine the NV using an FOP methodology if the merchandise is exported from an NME and the information does not permit the calculation of NV using home-market prices, third-country prices, or constructed value under section 773(a) of the Act. The Department bases NV on the FOPs because the presence of government controls on various aspects of NMEs renders price comparisons and the calculation of production costs invalid under the Department's normal methodologies.[96]

Factor Valuations

In accordance with section 773(c) of the Act, we calculated NV based on FOP data reported by the respondents for the POR. Because we had two effective PORs for this review, we used FOP data specific to the separate PORs, where possible. For more details, *see* Surrogate Value Memo. To calculate NV, we multiplied the reported per-unit factor-consumption rates by publicly available surrogate values (except as discussed below).

In selecting the surrogate values, we considered the quality, specificity, and contemporaneity of the data. As appropriate, we adjusted input prices by including freight costs to make them delivered prices. We added to each Indian import surrogate value a surrogate freight cost calculated from the shorter of the reported distance from the domestic supplier to the factory or the distance from the nearest seaport to the factory, where appropriate. *See Sigma Corp.* v. *United States,* 117 F.3d 1401, 1407–1408 (Fed. Cir. 1997). Where we could not obtain publicly available information contemporaneous to the POR with which to value FOPs, we adjusted the surrogate values, where appropriate, using the Indian Wholesale Price Index (''WPI'') as published in the International Monetary Fund's *International Financial Statistics. See* Surrogate Value Memo.

The Department used Indian import statistics from Global Trade Atlas to value the raw material and packing material inputs that Wireking and NKS used to produce subject merchandise during the POR, except where listed below.

To value low carbon steel wire rod, we used price data from the Indian Join Plant Committee (''JPC''), which is a joint industry/government board that monitors Indian steel prices. These data are fully contemporaneous with the POR, and are specific to the reported inputs of the respondents. Further, in accordance with 19 CFR 351.408(c)(1), these data are publicly available, represent a broad market average, and we are able to calculate them on a tax-exclusive basis. For a detailed discussion of all surrogate values used for these preliminary results, *see* Surrogate Value Memo.

The Department valued electricity using the updated electricity price data for small, medium, and large industries, as published by the Central Electricity Authority, an administrative body of the Government of India, in its publication titled *Electricity Tariff & Duty and Average Rates of Electricity Supply in India,* dated March 2008. These electricity rates represent actual country-wide, publicly-available information on tax-exclusive electricity rates charged to small, medium, and large industries in India. We did not inflate this value because utility rates represent current rates, as indicated by the effective dates listed for each of the rates provided.

The Department valued water using data from the Maharashtra Industrial Development Corporation (''MIDC'') as it includes a wide range of industrial water tariffs. To value water, we used the average rate for industrial use from MIDC water rates at *http://www.midcindia.org.*

The Department valued truck freight expenses using a per-unit average rate calculated from data on the Infobanc *Web site: http://www.infobanc.com/logistics/logtruck.htm.* The logistics section of this Web site contains inland freight truck rates between many large Indian cities. Since this value is not contemporaneous with the POR, the Department deflated the rate using WPI.

To value factory overhead, selling, general, and administrative (''SG&A'') expenses, and profit, the Department used the audited financial statements of Bansidhar Granites and Mekins Agro Products (''Mekins''). Although the Department notes that Wireking has argued that Mekins financial statement includes a packing credit which indicates that it receives countervailable subsidies, there is not enough information on the record to determine whether the packing credit has been found to be a countervailable subsidy by the Department.[97] Therefore, for these preliminary results, we are using both the financial statement of Mekins and Bansidhar Granites to value overhead, SG&A, and profit.

Previously, the Department used regression-based wages that captured the worldwide relationship between per capita Gross National Income (''GNI'') and hourly manufacturing wages, pursuant to 19 CFR 351.408(c)(3), to value the respondent's cost of labor. However, on May 14, 2010, the Court of Appeals for the Federal Circuit (''CAFC''), in *Dorbest Ltd.* v. *United States,* 604 F.3d 1363, 1372 (Fed. Cir. 2010) (''*Dorbest*''), invalidated 19 CFR 351.408(c)(3). As a consequence of the CAFC's ruling in *Dorbest,* the Department no longer relies on the regression-based wage rate methodology described in its regulations.

On June 21, 2011, the Department revised its methodology for valuing the labor input in NME antidumping proceedings.[98] In *Labor Methodologies,* the Department determined that the best methodology to value the labor input is to use industry-specific labor rates from the primary surrogate country. Additionally, the Department determined that the best data source for industry-specific labor rates is Chapter 6A: Labor Cost in Manufacturing, from

[94] *See* Surrogate Value Memo for details regarding the surrogate values for movement expenses.

[95] *See* NKS Analysis Memo.

[96] *See, e.g., Preliminary Determination of Sales at Less Than Fair Value, Affirmative Critical Circumstances, In Part, and Postponement of Final Determination: Certain Lined Paper Products From the People's Republic of China,* 71 FR 19695, 19703 (April 17, 2006), unchanged in *Notice of Final Determination of Sales at Less Than Fair Value, and Affirmative Critical Circumstances, In Part: Certain Lined Paper Products From the People's Republic of China,* 71 FR 53079 (September 8, 2006).

[97] *See* Surrogate Value Memo.

[98] *See Antidumping Methodologies in Proceedings Involving Non-Market Economies: Valuing the Factor of Production: Labor,* 76 FR 36092 (June 21, 2011) (''*Labor Methodologies*'').

the International Labor Organization (ILO) Yearbook of Labor Statistics (''Yearbook'').

In these preliminary results, the Department calculated the labor input using the wage method described in *Labor Methodologies.* To value the respondent's labor input, the Department relied on data reported by India to the ILO in Chapter 6A of the Yearbook. The Department further finds the two-digit description under ISIC–Revision 3 (''Manufacture of Fabricated Metal Products, Except Machinery and Equipment'') to be the best available information on the record because it is specific to the industry being examined, and is therefore derived from industries that produce comparable merchandise. Accordingly, relying on Chapter 6A of the Yearbook, the Department calculated the labor input using labor data reported by India to the ILO under Sub-Classification 28 of the ISIC-Revision 3 standard, in accordance with section 773(c)(4) of the Act. For these preliminary results, the calculated industry-specific wage rate is $1.22. A more detailed description of the wage rate calculation methodology is provided in the Surrogate Value Memo.

As stated above, the Department used India ILO data reported under Chapter 6A of Yearbook, which reflects all costs related to labor, including wages, benefits, housing, training, *etc.* Because the financial statements used to calculate the surrogate financial ratios include itemized detail of labor costs, the Department made adjustments to certain labor costs in the surrogate financial ratios. *See Labor Methodologies,* 76 FR at 36093.

We valued brokerage and handling using a price list of export procedures necessary to export a standardized cargo of goods in India. The price list is compiled based on a survey case study of the procedural requirements for trading a standard shipment of goods by ocean transport in India that is published in *Doing Business 2010: India,* published by the World Bank.

Where appropriate, we made currency conversions into U.S. dollars, in accordance with section 773A(a) of the Act, based on the exchange rates in effect on the dates of the U.S. sales as certified by the Federal Reserve Bank.

Export Subsidy Adjustment

Section 772(c)(1)(C) of the Act unconditionally states that U.S. price ''shall be increased by the amount of any countervailing duty imposed on the subject merchandise * * * to offset an export subsidy.'' [99] The Department determined in its preliminary results of the companion countervailing duty administrative review that NKS and Wireking's merchandise benefited from export subsidies.[100] Therefore, we have increased each company's U.S. price for countervailing duties imposed attributable to export subsidies, where appropriate.[101]

Verification

As provided in section 782(i)(1) of the Act, we intend to verify the information upon which we will rely in making our final determination.

Preliminary Results of the Review

The Department has determined that the following preliminary dumping margins exist for the period March 5, 2009 through August 31, 2010:

Exporter	Margin (percent)
Guangdong Wireking Housewares & Hardware Co., Ltd. (a/k/a Foshan Shunde Wireking Housewares & Hardware Co., Ltd.) [102]	5.18.
New King Shan (Zhu Hai) Co., Ltd.[103]	0.00 (zero).
Hangzhou Dunli Import & Export Co., Ltd.	5.18.
PRC-Wide Entity [104]	95.99.

As stated above in the *Rate for Non-Selected Companies* section of this notice, Dunli qualified for a separate rate in this review. Moreover, as stated above in the *Respondent Selection* section of this notice, we limited this review by selecting the largest exporter and did not select Dunli as a mandatory respondent. Therefore, we have preliminarily assigned to Dunli a dumping margin based on its most recently assigned rate in the *LTFV Investigation* because the mandatory respondents in this review received *de minimis* rates and it is not the Department's practice to assign separate rates based on rates that are *de minimis* or zero, or based entirely on facts available.

The Department will disclose calculations performed for these preliminary results to the parties within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

In accordance with 19 CFR 351.301(c)(3)(ii), for the final results of this administrative review, interested parties may submit publicly available information to value FOPs within 20 days after the date of publication of these preliminary results. Interested parties must provide the Department with supporting documentation for the publicly available information to value each FOP. Additionally, in accordance with 19 CFR 351.301(c)(1), for the final results of this administrative review, interested parties may submit factual information to rebut, clarify, or correct factual information submitted by an interested party less than ten days before, on, or after, the applicable deadline for submission of such factual information. However, the Department notes that 19 CFR 351.301(c)(1) permits new information only insofar as it rebuts, clarifies, or corrects information recently placed on the record. The Department generally cannot accept the submission of additional, previously absent-from-the-record alternative surrogate value information pursuant to 19 CFR 351.301(c)(1).[105]

Because, as discussed above, the Department intends to verify the information upon which we will rely in making our final determination, the Department will establish the briefing schedule at a later time, and will notify parties of the schedule in accordance with 19 CFR 351.309. Parties who submit case briefs or rebuttal briefs in this proceeding are requested to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities. *See* 19 CFR 351.309(c) and (d).

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, or to participate if one is

[99] *See, e.g., Carbazole Violet Pigment 23 from India: Final Results of Antidumping Duty Administrative Review,* 75 FR 38076, 38077 (July 1, 2010), and accompanying Issues and Decision Memorandum at Comment 1.

[100] *See Certain Kitchen Appliance Shelving and Racks from the People's Republic of China: Preliminary Results of the Countervailing Duty Administrative Review,* dated concurrently with this notice.

[101] *See* NKS Analysis Memo; *see also* Wireking Analysis Memo.

[102] In the *LTFV Investigation* the Department found that Wireking was a single entity with Company G (the name of this company is business proprietary; *see* Wireking Analysis Memo). The information placed on the record of this review demonstrates that there have not been changes to the ownership structure. Therefore, we continue to find Wireking and Company G to constitute a single entity.

[103] New King Shan (Zhu Hai) Co., Ltd., is the only entity receiving this rate calculated in this administrative review.

[104] The PRC-wide entity includes Jiangsu Weixi Group Co., Asia Pacific CIS (Wuxi) Co., Ltd., and Leader Metal Industry Co., Ltd. (aka Marmon Retail Services Asia), as well as any company that does not have a separate rate.

[105] *See Glycine From the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Rescission, in Part,* 72 FR 58809 (October 17, 2007) and accompanying Issues and Decision Memorandum at Comment 2.

requested, must submit a written request to the Assistant Secretary for Import Administration, Room 1117, within 30 days of the date of publication of this notice. Requests should contain: (1) The party's name, address and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs.

Extension of the Time Limits for the Final Results

Section 751(a)(3)(A) of the Act requires that the Department issue the final results of an administrative review within 120 days after the date on which the preliminary results are published. If it is not practicable to complete the review within that time period, section 751(a)(3)(A) of the Act allows the Department to extend the deadline for the final results to a maximum of 180 days after the date on which the preliminary results are published.

In this proceeding, the Department requires additional time to complete the final results of this administrative review to issue additional supplemental questionnaires, conduct verifications, generate the reports of the verification findings, and properly consider the issues raised in case briefs from interested parties. Thus, it is not practicable to complete this administrative review within the original time limit. Consequently, the Department is extending the time limit for completion of the final results of this review by 60 days, in accordance with section 751(a)(3)(A) of the Act. The final results are now due no later 180 days after the publication date of these preliminary results.

Assessment Rates

Upon issuance of the final results, the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review. The Department intends to issue assessment instructions to CBP 15 days after the publication date of the final results of this review excluding any reported sales that entered during the gap period. In accordance with 19 CFR 351.212(b)(1), we are calculating importer- (or customer-) specific assessment rates for the merchandise subject to this review. Where the respondent has reported reliable entered values, we calculate importer- (or customer-) specific *ad valorem* rates by aggregating the dumping margins calculated for all U.S. sales to each importer (or customer) and dividing this amount by the total entered value of the sales to each importer (or customer). Where an importer- (or customer-) specific *ad valorem* rate is greater than *de minimis,* we will apply the assessment rate to the entered value of the importers'/customers' entries during the POR, pursuant to 19 CFR 351.212(b)(1).

Where we do not have entered values for all U.S. sales to a particular importer/customer, we calculate a per-unit assessment rate by aggregating the antidumping duties due for all U.S. sales to that importer (or customer) and dividing this amount by the total quantity sold to that importer (or customer).[106] To determine whether the duty assessment rates are *de minimis,* in accordance with the requirement set forth in 19 CFR 351.106(c)(2), we calculated importer- (or customer-) specific *ad valorem* ratios based on the estimated entered value. Where an importer- (or customer-) specific *ad valorem* rate is zero or *de minimis,* we will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[107] For the company receiving a separate rate that were not selected for individual review, we will assign an assessment rate based on rates calculated in previous segment as discussed above.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For the exporters listed above, the cash deposit rate will be the rate established in the final results of this review (except, if the rate is zero or *de minimis, i.e.,* less than 0.5 percent, a zero cash deposit rate will be required for that company); (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (3) for all PRC exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the PRC-wide rate of 95.99 percent;[108] and (4) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporter(s) that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

These preliminary results are issued and published in accordance with sections 751(a)(1), 751(a)(2)(B) and 777(i)(1) of the Act, 19 CFR 351.221(b)(4), and 19 CFR 351.214.

Dated: September 30, 2011.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 2011–26205 Filed 10–7–11; 8:45 am]

BILLING CODE 3510–DS–P

[106] *See* 19 CFR 351.212(b)(1).

[107] *See* 19 CFR 351.106(c)(2).

[108] *See Notice of Final Determination of Sales at Less Than Fair Value: Chlorinated Isocyanurates From the People's Republic of China,* 70 FR 24502, 24505 (May 10, 2005) (explaining the derivation of the PRC-wide rate.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–898]

Chlorinated Isocyanurates From the People's Republic of China: Notice of Court Decision Not in Harmony With the Final Results of Administrative Review and Notice of Amended Final Results of Administrative Review Pursuant to Court Decision

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

DATES: *Effective Date:* September 23, 2011.

SUMMARY: On September 13, 2011, the United States Court of International Trade (''Court'' or ''CIT'') sustained the Department of Commerce's (''Department'') final results of redetermination pursuant to the Court's remand.[1] Consistent with the decision of the United States Court of Appeals for the Federal Circuit (''CAFC'') in *Timken Co. v. United States,* 893 F.2d 337 (Fed.

[1] *See Arch Chemicals, Inc. and Hebei Jiheng Chemicals, Co., Ltd. v. United States and Clearon Corporation and Occidental Chemical Corporation,* Court No. 08–00040: *Final Results of Redetermination Pursuant To Remand,* dated July 15, 2011 (''*Arch Chemicals III*'').

Cir. 1990) (''*Timken*''), as clarified by *Diamond Sawblades Mfrs. Coalition v. United States,* 626 F.3d 1374 (Fed. Cir. 2010) (''*Diamond Sawblades*''), the Department is notifying the public that the final judgment in this case is not in harmony and is amending the final results of the administrative review (''AR'') of the antidumping duty order on chlorinated isocyanurates from the People's Republic of China (''PRC'') covering the period of review (''POR'') of December 16, 2004, through May 31, 2006.[2]

FOR FURTHER INFORMATION CONTACT: Bobby Wong, AD/CVD Operations, Office 8, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–0409.

SUPPLEMENTARY INFORMATION:

Background

In *Chlorinated Isocyanurates from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review,* 72 FR 39053 (July 17, 2007) (''*Preliminary Results*''), the Department granted Hebei Jiheng Chemicals, Co., Ltd. (''Jiheng'') by-product offsets for chlorine, ammonia gas, hydrogen, and recovered sulfuric acid. However, in the *Final Results,* the Department denied Jiheng these by-product offsets, stating that Jiheng had not provided the Department with the information necessary to grant the by-product offsets. *See Final Results,* 73 FR at 160; *see* also Issues and Decision Memo at Comment 15. Specifically, the Department found that Jiheng had failed to provide documentation supporting the claimed production quantities of by-products. *Id.*

On July 13, 2009, pursuant to *Arch Chemicals, Inc.* v. *United States,* Consol. Court No. 08–00040, Slip. Op. 09–71 (''*Arch Chemicals I*''), the Court instructed the Department to reopen the record of the underlying review and provide Jiheng with sufficient opportunity to submit documentation relevant to the methodology the Department employs in its by-product analysis. On December 22, 2009, in its final remand redetermination, the Department granted Jiheng a by-product offset for its production of chlorine, ammonia gas, hydrogen, and sulfuric acid recovered during the POR.

However, after reviewing interested parties' comments with respect to the *Arch Chemicals I* final remand redetermination, the Department requested a voluntary remand to reconsider our results with regard to Jiheng's hydrogen gas, sulfuric acid, and chlorine gas by-products. The Court issued an order granting the Department's request to reconsider and fully explain Jiheng's hydrogen gas, sulfuric acid, and chlorine gas by-products offsets. *See Arch Chemicals, Inc. and Hebei Jiheng Chemicals, Co., Ltd.* v. *United States,* Consol. Court No. 08–00040 (April 22, 2010) (''*Arch Chemicals II*''). On June 21, 2010, the Department filed the results of its voluntary remand redetermination.

On April 15, 2011, while affirming other aspects of the Department's remand redetermination in *Arch Chemicals II,* the Court found that Jiheng was not entitled to an offset for chlorine gas discharged during liquefaction because this portion of chlorine gas was not attributable to subject merchandise production. In *Arch Chemicals III,* the Court remanded the proceeding to the Department to eliminate the by-product offset for this portion of chlorine gas and to recalculate the antidumping margin for Jiheng accordingly.

On July 15, 2011, in the Department's final remand redetermination pursuant to *Arch Chemicals III,* and in response to the Court's ruling, the Department removed the quantity of chlorine gas discharged as a result of the liquefaction process of purified chlorine during the chlor-alkali stage of production from Jiheng's by-product offset.

Timken Notice

In its decision in *Timken,* 893 F.2d at 341, as clarified by *Diamond Sawblades,* the CAFC has held that, pursuant to section 516A(e) of the Tariff Act of 1930, as amended (the ''Act''), the Department must publish a notice of a court decision that is not ''in harmony'' with a Department determination and must suspend liquidation of entries pending a ''conclusive'' court decision. The CIT's decision in *Arch Chemicals III,* issued on September 13, 2011, constitutes a final decision of that Court that is not in harmony with the Department's *Final Results* and *Amended Final Results.* This notice is published in fulfillment of the publication requirements of *Timken.* Accordingly, the Department will continue the suspension of liquidation of all enjoined entries, pending the expiration of the period of appeal or, if appealed, pending a final and conclusive court decision. The cash deposit rate will remain the company-specific rate established for the subsequent and most recent period during which the respondent was reviewed. *See Chlorinated Isocyanurates from the People's Republic of China: Final Results of 2008–2009 Antidumping Duty Administrative Review,* 75 FR 70212 (November 17, 2010), as amended, 75 FR 76699 (December 9, 2010).

Amended Final Results

Because there is now a final court decision, we are amending the *Final Results* to reflect the results of the *Arch Chemicals III* litigation. The revised dumping margin is:

Exporter	Percent margin
Hebei Jiheng Chemicals, Co., Ltd.	9.19

In the event the CIT's ruling is not appealed or, if appealed, upheld by the CAFC, the Department will instruct U.S. Customs and Border Protection to assess antidumping duties on entries of the subject merchandise during the POR from Jiheng on the revised assessment rate calculated by the Department.

This notice is issued and published in accordance with sections 516A(c)(1), 516A(e), and 777(i)(1) of the Act.

Dated: September 30, 2011.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 2011–26213 Filed 10–7–11; 8:45 am]

BILLING CODE 3510–DS–P

[2] *See Chlorinated Isocyanurates from the People's Republic of China: Final Results of Antidumping Duty Administrative Review,* 73 FR 153 (January 8, 2008). (''*Final Results*''), and accompanying Issues and Decision Memorandum, and as amended by *Chlorinated Isocyanurates From the People's Republic of China: Amended Final Results of Antidumping Duty Administrative Review,* 73 FR 9091 (February 19, 2008) (''*Amended Final Results*'').

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Forum—Trends and Causes of Observed Changes in Heat Waves, Cold Waves, Floods and Drought

AGENCY: National Environmental Satellite, Data, and Information Service (NESDIS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of open public forum.

SUMMARY: This notice sets forth the schedule and topics of an upcoming forum hosted by the NOAA National Climatic Data Center in Asheville, North Carolina on November 8–10, 2011. Invited participants will discuss topics as outlined below.

Members of the public are invited to attend the forum, and are required to RSVP to *Brooke.Stewart@noaa.gov* by 5 p.m. EDT, Tuesday, October 25, 2011 if they wish to attend. The forum is to be held in a Federal facility; building security restrictions preclude attendance by members of the public who do not RSVP by the deadline. Space is also limited and public attendees will be admitted based on the order in which RSVPs are received.

Members of the public will be invited to offer their comments during a 30-minute period to be held from 9:30 to 10 a.m. on Tuesday, November 8, 2011. Each individual or group making a verbal presentation will be limited to a total time of five minutes. Please indicate your intention to participate in the public comment period when submitting the RSVP. Time for public comments will be allotted based on the order in which RSVPs are received. Written comments may be submitted via email or in hardcopy and must be received by October 25, 2011. Please see addresses below.

DATES: *Forum Date and Time:* The forum will be held on November 8–10, 2011 at the following times: November 8, 2011 from 8:15 a.m. to 5 p.m. EST; November 9, 2011 from 8:15 a.m. to 5:45 p.m. EST; and November 10, 2011 from 8:15 a.m. to 2 p.m. EST.

RSVP Deadline: Any member of the public wishing to attend the forum must RSVP no later than 5 p.m. EDT, Tuesday, October 25, 2011.

Deadline for Written Comments: Written comments must be received by October 25, 2011.

ADDRESSES: The forum will be held at the Veach-Baley Federal Complex, located at 151 Patton Avenue, Asheville, North Carolina 28801.

Written comments may be submitted to *Brooke.Stewart@noaa.gov* or in hard copy to Brooke Stewart, 151 Patton Avenue, Room 563, Asheville, North Carolina 28801.

For changes in the schedule, agenda, and updated information, please check the forum website at *https://sites.google.com/a/noaa.gov/heatwaves-coldwaves-floods-drought/.*

FOR FURTHER INFORMATION CONTACT: Brooke Stewart, National Climatic Data Center, 151 Patton Avenue, Room 563, Asheville, North Carolina 28801. (Phone: 828–257–3020, E-mail: *brooke.stewart@noaa.gov*).

SUPPLEMENTARY INFORMATION: This forum will provide an update to the climate science surrounding extreme events. The intent is to make key input available to the National Climate Assessment (NCA) for consideration. Further information regarding the NCA is available at *http://www.globalchange.gov/what-we-do/assessment.* NOAA is sponsoring this forum in support of the National Climate Assessment process.

As materials for this forum become available, they may be found at *https://sites.google.com/a/noaa.gov/heatwaves-coldwaves-floods-drought/.*

Topics To Be Addressed

This forum will address observed changes and their causes with regard to specific types of extreme weather and climate events, including heat waves, cold waves, floods, and drought.

Participants Will Consider

- Observed changes and degree of confidence in those changes for heat waves, cold waves, floods, and drought
- Current state of mechanistic understanding of the above-mentioned extreme events
- Potential causes of observed changes in extreme events

The forum will feature invited speakers and discussions. The forum is designed to produce a detailed draft outline of an article for submission to a peer-reviewed scientific journal.

Mary E. Kicza.

Assistant Administrator for Satellite and Information Services.

[FR Doc. 2011–26230 Filed 10–7–11; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XA480

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Operation of the Northeast Gateway Liquefied Natural Gas Port Facility in Massachusetts Bay

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

ACTION: Notice of issuance of an incidental harassment authorization.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that NMFS has issued an Incidental Harassment Authorization (IHA) to the Northeast Gateway® Energy Bridge™ L.P. (Northeast Gateway or NEG) to incidentally harass, by Level B harassment only, small numbers of marine mammals during operation of an offshore liquefied natural gas (LNG) facility in the Massachusetts Bay for a period of 1 year.

DATES: This authorization is effective from October 6, 2011, until October 5, 2012.

ADDRESSES: A copy of the application, IHA, and a list of references used in this document may be obtained by writing to P. Michael Payne, Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910. A copy of the application may be obtained by writing to this address or by telephoning the contact listed here and is also available at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm#applications.*

FOR FURTHER INFORMATION CONTACT: Shane Guan, Office of Protected Resources, NMFS, (301) 247–8401.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (Secretary) to allow, upon request, the incidental, but not intentional taking of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

Authorization shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such taking are set forth.

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as:

> an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

Section 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the U.S. can apply for an authorization to incidentally take small numbers of marine mammals by harassment. Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as:

> any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine

mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].

Section 101(a)(5)(D) establishes a 45-day time limit for NMFS review of an application followed by a 30-day public notice and comment period on any proposed authorizations for the incidental harassment of marine mammals. Within 45 days of the close of the comment period, NMFS must either issue or deny issuance of the authorization.

Summary of Request

On April 8, 2011, NMFS received an application from Excelerate Energy, L.P. (Excelerate) and Tetra Tech EC, Inc., on behalf of Northeast Gateway for an authorization to take 13 species of marine mammals by Level B harassment incidental to operations of an LNG port facility in Massachusetts Bay. They are: North Atlantic right whale, humpback whale, fin whale, minke whale, long-finned pilot whale, Atlantic white-sided dolphin, bottlenose dolphin, common dolphin, killer whale, Risso's dolphin, harbor porpoise, harbor seal, and gray seal. Since LNG Port operation activities have the potential to take marine mammals, a marine mammal take authorization under the MMPA is warranted. On May 7, 2007, NMFS issued an IHA to Northeast Gateway and Algonquin Gas Transmission, L.L.C. (Algonquin) to allow for the incidental harassment of small numbers of marine mammals resulting from the construction and operation of the NEG Port and the Algonquin Pipeline Lateral (72 FR 27077; May 14, 2007). Subsequently, NMFS issued three one-year IHAs for the take of marine mammals incidental to the operation of the NEG Port activity pursuant to section 101(a)(5)(D) of the MMPA (73 FR 29485; May 21, 2008; 74 FR 45613; September 3, 2009, and 75 FR 53672; September 1, 2010). The company is seeking new IHA for the upcoming year, because it is believed that marine mammals could be affected by noise generated by operating the dynamic positioning system during the docking of LNG vessels at the NEG Port.

Description of the Activity

The Northeast Gateway Port is located in Massachusetts Bay and consists of a submerged buoy system to dock specially designed LNG carriers approximately 13 mi (21 km) offshore of Massachusetts in federal waters approximately 270 to 290 ft (82 to 88 m) in depth. This facility delivers regasified LNG to onshore markets via the Algonquin Pipeline Lateral (Pipeline Lateral). The Pipeline Lateral consists of a 16.1-mile (25.8-kilometer) long, 24-inch (61-centimeter) outside diameter natural gas pipeline which interconnects the Port to an offshore natural gas pipeline known as the HubLine.

The Northeast Gateway Port consists of two subsea Submerged Turret Loading™ (STL) buoys, each with a flexible riser assembly and a manifold connecting the riser assembly, via a steel Flowline, to the subsea Pipeline Lateral. Northeast Gateway utilizes vessels from its current fleet of specially designed Energy Bridge™ Regasification Vessels (EBRVs), each capable of transporting approximately 2.9 billion ft^3 (82 million m^3) of natural gas condensed to 4.9 million ft^3 (138,000 m^3) of LNG. Northeast Gateway has recently added two vessels to its fleet that have a cargo capacity of approximately 151,000 m^3 (5.3 million ft^3). The mooring system installed at the Northeast Gateway Port is designed to handle each class of vessel. The EBRVs would dock to the STL buoys, which would serve as both the single-point mooring system for the vessels and the delivery conduit for natural gas. Each of the STL buoys is secured to the seafloor using a series of suction anchors and a combination of chain/cable anchor lines.

The proposed activity includes Northeast Gateway LNG Port operations. A detailed description of these activities is provided in the **Federal Register** notice for the proposed IHA (76 FR 43639; July 21, 2011), and is not repeated here.

Comments and Responses

A notice of receipt and request for public comment on the application and proposed authorization was published on July 21, 2011 (76 FR 43639). During the 30-day public comment period, NMFS received comments from the Marine Mammal Commission (Commission).

Comment 1: The Commission recommends that NMFS issue the requested authorization, subject to inclusion of the proposed mitigation and monitoring measures, including a condition that requires suspension of the proposed activities if an injury or death of a marine mammal occurs that may have resulted from those activities, pending authorization from NMFS to proceed.

Response: NMFS concurs with the Commission's recommendation. A condition that requires suspension of the proposed activities if an injury or death of a marine mammal occurs that may have resulted from the LNG Port operations, pending authorization from NMFS to proceed, is included in the mitigation and monitoring measures in the IHA issued to Northeast Gateway.

Description of Marine Mammals in the Area of the Specified Activities

Marine mammal species that potentially occur in the vicinity of the Northeast Gateway facility include several species of cetaceans and pinnipeds:

North Atlantic right whale (*Eubalaena glacialis*),
humpback whale (*Megaptera novaeangliae*),
fin whale (*Balaenoptera physalus*),
minke whale (*B. acutorostrata*),
long-finned pilot whale (*Globicephala melas*),
Atlantic white-sided dolphin (*Lagenorhynchus acutus*),
bottlenose dolphin (*Tursiops truncatus*),
common dolphin (*Delphinus delphis*),
killer whale (*Orcinus orca*),
Risso's dolphin (*Grampus griseus*),
harbor porpoise (*Phocoena phocoena*),
harbor seal (*Phoca vitulina*), and
gray seal (*Halichoerus grypus*).

Information on those species that may be affected by this activity is discussed in detail in the USCG Final EIS on the Northeast Gateway LNG proposal. Please refer to that document for more information on these species and potential impacts from operation of this LNG facility. In addition, general information on these marine mammal species can also be found in Würsig *et al.* (2000) and in the NMFS Stock Assessment Reports (Waring *et al.,* 2011). This latter document is available at: *http://www.nefsc.noaa.gov/publications/tm/tm219/.* Additional information on those species that may be affected by this activity is provided in detail in the **Federal Register** published on July 21, 2011 (76 FR 43639).

Brief Background on Marine Mammal Hearing

When considering the influence of various kinds of sound on the marine environment, it is necessary to understand that different kinds of marine life are sensitive to different frequencies of sound. Based on available behavioral data, audiograms derived using auditory evoked potential techniques, anatomical modeling, and other data, Southall *et al.* (2007) designate ''functional hearing groups'' for marine mammals and estimate the

lower and upper frequencies of functional hearing of the groups. The functional groups and the associated frequencies are indicated below (though animals are less sensitive to sounds at the outer edge of their functional range and most sensitive to sounds of frequencies within a smaller range somewhere in the middle of their functional hearing range):

- Low frequency cetaceans (13 species of mysticetes): functional hearing is estimated to occur between approximately 7 Hz and 22 kHz;
- Mid-frequency cetaceans (32 species of dolphins, six species of larger toothed whales, and 19 species of beaked and bottlenose whales): functional hearing is estimated to occur between approximately 150 Hz and 160 kHz;
- High frequency cetaceans (eight species of true porpoises, six species of river dolphins, Kogia, the franciscana, and four species of cephalorhynchids): functional hearing is estimated to occur between approximately 200 Hz and 180 kHz; and
- Pinnipeds in Water: functional hearing is estimated to occur between approximately 75 Hz and 75 kHz, with the greatest sensitivity between approximately 700 Hz and 20 kHz.

As mentioned previously in this document, 13 marine mammal species (11 cetacean and two pinniped species) are likely to occur in the NEG Port area. Of the 11 cetacean species likely to occur in NEG's project area, four are classified as low frequency cetaceans (*i.e.,* North Atlantic right, humpback, fin, and minke whales), six are classified as mid-frequency cetaceans (*i.e.,* killer and pilot whales and bottlenose, common, Risso's, and Atlantic white-sided dolphins), and one is classified as a high-frequency cetacean (*i.e.,* harbor porpoise) (Southall *et al.,* 2007).

Potential Effects of the Specified Activity on Marine Mammals

Potential effects of NEG's port operations would most likely be acoustic in nature. LNG port operations introduce sound into the marine environment. The effects of noise on marine mammals are highly variable, and can be categorized as follows (based on Richardson *et al.,* 1995): (1) The noise may be too weak to be heard at the location of the animal (*i.e.,* lower than the prevailing ambient noise level, the hearing threshold of the animal at relevant frequencies, or both); (2) The noise may be audible but not strong enough to elicit any overt behavioral response; (3) The noise may elicit reactions of variable conspicuousness and variable relevance to the well being of the marine mammal; these can range from temporary alert responses to active avoidance reactions such as vacating an area at least until the noise event ceases; (4) Upon repeated exposure, a marine mammal may exhibit diminishing responsiveness (habituation), or disturbance effects may persist; the latter is most likely with sounds that are highly variable in characteristics, infrequent and unpredictable in occurrence, and associated with situations that a marine mammal perceives as a threat; (5) Any anthropogenic noise that is strong enough to be heard has the potential to reduce (mask) the ability of a marine mammal to hear natural sounds at similar frequencies, including calls from conspecifics, and underwater environmental sounds such as surf noise; (6) If mammals remain in an area because it is important for feeding, breeding or some other biologically important purpose even though there is chronic exposure to noise, it is possible that there could be noise-induced physiological stress; this might in turn have negative effects on the well-being or reproduction of the animals involved; and (7) Very strong sounds have the potential to cause temporary or permanent reduction in hearing sensitivity. In terrestrial mammals, and presumably marine mammals, received sound levels must far exceed the animal's hearing threshold for there to be any temporary threshold shift (TTS) in its hearing ability. For transient sounds, the sound level necessary to cause TTS is inversely related to the duration of the sound. Received sound levels must be even higher for there to be risk of permanent hearing impairment. In addition, intense acoustic (or explosive events) may cause trauma to tissues associated with organs vital for hearing, sound production, respiration and other functions. This trauma may include minor to severe hemorrhage.

There are three general categories of sounds recognized by NMFS: continuous (such as shipping sounds), intermittent (such as vibratory pile driving sounds), and impulse. No impulse noise activities, such as blasting or standard pile driving, are associated with this project. The noise sources of potential concern are regasification/offloading (which is a continuous sound) and dynamic positioning of vessels using thrusters (an intermittent sound) from EBRVs during docking at the NEG port facility. Noise generated from regasification/offloading is modeled to be under 120 dB, therefore, no take is expected from this activity. Based on research by Malme *et al.* (1983; 1984), for both continuous and intermittent sound sources, Level B harassment is presumed to begin at received levels of 120-dB. The detailed description of the noise that would result from the LNG Port operations is provided in the **Federal Register** notice for the initial construction and operations of the NEG LNG Port facility and Pipeline Lateral in 2007 (72 FR 27077; May 14, 2007).

NEG Port Activities

Underwater noise generated at the NEG Port has the potential to result from two distinct actions, including closed-loop regasification of LNG and/or EBRV maneuvering during coupling and decoupling with STL buoys. To evaluate the potential for these activities to result in underwater noise that could harass marine mammals, Excelerate conducted field sound survey studies during periods of March 21 to 25, 2005, and August 6 to 9, 2006, while the EBRV *Excelsior* was both maneuvering and moored at the operational Gulf Gateway Port located 116 mi (187 km) offshore in the Gulf of Mexico (the Gulf) (see Appendices B and C of the NEG application). EBRV maneuvering conditions included the use of both stern and bow thrusters required for dynamic positioning during coupling. These data were used to model underwater sound propagation at the NEG Port. The pertinent results of the field survey are provided as underwater sound source pressure levels as follows:

- Sound levels during closed-loop regasification ranged from 104 to 110 dB. Maximum levels during steady state operations were 108 dB.
- Sound levels during coupling operations were dominated by the periodic use of the bow and stern thrusters and ranged from 160 to 170 dBL.

Figures 1–1 and 1–2 of NEG's IHA application present the net acoustic impact of one EBRV operating at the NEG Port. Thrusters are operated intermittently and only for relatively short durations of time. The resulting area within the 120 dB isopleth is less than 1 km^2 with the linear distance to the isopleths extending 430 m (1,411 ft). The area within the 180 dB isopleth is very localized and will not extend beyond the immediate area where EBRV coupling operations are occurring.

The potential impacts to marine mammals associated with sound propagation from vessel movements, anchors, chains and LNG regasification/offloading could be the temporary and short-term displacement of seals and

whales from within the 120-dB zones ensonified by these noise sources. Animals would be expected to re-occupy the area once the noise ceases.

Anticipated Effects on Habitat

Approximately 4.8 acres of seafloor has been converted from soft substrate to artificial hard substrate. The soft-bottom benthic community may be replaced with organisms associated with naturally occurring hard substrate, such as sponges, hydroids, bryozoans, and associated species. The benthic community in the up to 43 acres (worst case scenario based on severe 100-year storm with EBRVs occupying both STL buoys) of soft bottom that may be swept by the anchor chains while EBRVs are docked will have limited opportunity to recover, so this area will experience a long-term reduction in benthic productivity. In addition, disturbance from anchor chain movement would result in increased turbidity levels in the vicinity of the buoys that could affect prey species for marine mammals; however, as indicated in the final EIS/EIR, these impacts are expected to be short-term, indirect, and minor.

Daily removal of sea water from EBRV intakes will reduce the food resources available for planktivorous organisms. Water usage would be limited to the standard requirements of NEG's normal support vessel. As with all vessels operating in Massachusetts Bay, sea water uptake and discharge is required to support engine cooling, typically using a once-through system. The rate of seawater uptake varies with the ship's horsepower and activity and therefore will differ between vessels and activity type. For example, the GATEWAY ENDEAVOR is a 90-ft (27 m) vessel powered with a 1,200 horsepower diesel engine with a four-pump seawater cooling system. This system requires seawater intake of about 68 gallons per minute (gpm) while idling and up to about 150 gpm at full power. Use of full power is required generally for transit. A conservatively high estimate of vessel activity for the GATEWAY ENDEAVOR would be operation at idle for 75% of the time and full power for 25% of the time. During routine activities, this would equate to approximately 42,480 gallons of seawater per 8-hour work day. When compared to the engine cooling requirements of an EBRV over an 8-hour period (approximately 17.62 million gallons), the GATEWAY ENDEAVOUR uses about 0.2% of the EBRV requirement. To put this water use into context, the final EIS/EIR for the NEG Port concluded that the impacts to fish populations and to marine mammals that feed on fish or plankton resulting from water use by an EBRV during port operations (approximately 39,780,000 gallons over each 8-day regasification period) would be minor. Water use by support vessels during routine port activities would not materially add to the overall impacts evaluated in the final EIS/EIR. Additionally, discharges associated with the GATEWAY ENDEAVOR and/or other support/maintenance vessels that are 79 feet or greater in length, are now regulated under the Clean Water Act (CWA) and must receive and comply with the United States Environmental Protection Agency (EPA) Vessel General Permit (VGP). The permit incorporates the USCG mandatory ballast water management and exchange standards, and provides technology- and water quality-based effluent limits for other types of discharges, including deck runoff, bilge water, graywater, and other pollutants. It also establishes specific corrective actions, inspection, and monitoring requirements and recordkeeping and reporting requirements for each vessel. Massachusetts Bay circulation will not be altered, so plankton will be continuously transported into the NEG Port area. The removal of these species is minor and unlikely to affect in a measurable way the food sources available to marine mammals.

In conclusion, NMFS has determined that NEG's port operations are not expected to have any habitat-related effects that could cause significant or long-term consequences for individual marine mammals or on the food sources that they utilize.

Monitoring and Mitigation Measures

In order to issue an incidental take authorization (ITA) under the MMPA, NMFS must, where applicable, set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable adverse impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses (where relevant). In addition, NMFS must, where applicable, set forth ''requirements pertaining to the monitoring and reporting of such taking''. The MMPA implementing regulations at 50 CFR 216.104 (a)(13) indicate that requests for ITAs must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the action area.

During the construction and operations of the NEG LNG Port facility in prior years, Northeast Gateway submitted reports on marine mammal sightings in the area. While it is difficult to draw biological conclusions from these reports, NMFS can make some general conclusions. Data gathered by protected species observers (PSOs) are generally useful to indicate the presence or absence of marine mammals (often to a species level) within the exclusion zones (and sometimes without) and to document the implementation of mitigation measures. Though it is by no means conclusive, it is worth noting that no instances of obvious behavioral disturbance as a result of Northeast Gateway's activities were observed by the PSOs.

In addition, Northeast Gateway was required to maintain an array of Marine Autonomous Recording Units (MARUs) to monitor calling North Atlantic right whales (humpback, fin, and minke whale calls were also able to be detected).

For the issuance of the IHA to NEG for LNG port operations, NMFS requires the following monitoring and mitigation measures.

Protected Species Observers

For activities related to the NEG LNG port operations, all individuals onboard the EBRVs responsible for the navigation and lookout duties on the vessel must receive training prior to assuming navigation and lookout duties, a component of which will be training on marine mammal sighting/reporting and vessel strike avoidance measures. Crew training of EBRV personnel will stress individual responsibility for marine mammal awareness and reporting.

If a marine mammal is sighted by a crew member, an immediate notification will be made to the Person-in-Charge on board the vessel and the Northeast Port Manager, who will ensure that the required vessel strike avoidance measures and reporting procedures are followed.

Vessel Strike Avoidance

(1) All EBRVs approaching or departing the port will comply with the Mandatory Ship Reporting (MSR) system to keep apprised of right whale sightings in the vicinity. Vessel operators will also receive active detections from an existing passive acoustic array prior to and during transit through the northern leg of the Boston TSS where the buoys are installed.

(2) In response to active right whale sightings (detected acoustically or reported through other means such as the MSR or Sighting Advisory System (SAS)), and taking into account safety and weather conditions, EBRVs will take appropriate actions to minimize the risk of striking whales, including reducing speed to 10 knots or less and alerting personnel responsible for navigation and lookout duties to concentrate their efforts.

(3) EBRVs will maintain speeds of 12 knots or less while in the TSS until reaching the vicinity of the buoys (except during the seasons and areas defined below, when speed will be limited to 10 knots or less). At 1.86 mi (3 km) from the NEG port, speed will be reduced to 3 knots, and to less than 1 knot at 1,640 ft (500 m) from the buoy.

(4) EBRVs will reduce transit speed to 10 knots or less over ground from March 1–April 30 in all waters bounded by straight lines connecting the following points in the order stated below. This area is known as the Off Race Point SMA and tracks NMFS regulations at 50 CFR 224.105: 42°30′00.0″ N–069°45′00.0″ W; thence to 42°30′00.0″ N–070°30′00.0″ W; thence to 42°12′00.0″ N–070°30′00.0″ W; thence to 42°12′00.0″ N–070°12′00.0″ W; thence to 42°04′56.5″ N–070°12′00.0″ W; thence along charted mean high water line and inshore limits of COLREGS limit to a latitude of 41°40′00.0″ N; thence due east to 41°41′00.0″ N–069°45′00.0″ W; thence back to starting point.

(5) EBRVs will reduce transit speed to 10 knots or less over ground from April 1–July 31 in all waters bounded by straight lines connecting the following points in the order stated below. This area is also known as the Great South Channel SMA and tracks NMFS regulations at 50 CFR 224.105:
42°30′00.0″ N–69°45′00.0″ W,
41°40′00.0″ N– 69°45′00.0″ W,
41°00′00.0″ N– 69°05′00.0″ W,
42°09′00.0″ N– 67°08′24.0″ W,
42°30′00.0″ N– 67°27′00.0″ W,
42°30′00.0″ N– 69°45′00.0″ W.

(6) LNGRVs are not expected to transit Cape Cod Bay. However, in the event transit through Cape Cod Bay is required, LNGRVs will reduce transit speed to 10 knots or less over ground from January 1–May 15 in all waters in Cape Cod Bay, extending to all shorelines of Cape Cod Bay, with a northern boundary of 42°12′00.0″ N latitude.

(7) A vessel may operate at a speed necessary to maintain safe maneuvering speed instead of the required 10 knots only if justified because the vessel is in an area where oceanographic, hydrographic, and/or meteorological conditions severely restrict the maneuverability of the vessel and the need to operate at such speed is confirmed by the pilot on board or, when a vessel is not carrying a pilot, the master of the vessel. If a deviation from the 10-knot speed limit is necessary, the reasons for the deviation, the speed at which the vessel is operated, the latitude and longitude of the area, and the time and duration of such deviation shall be entered into the logbook of the vessel. The master of the vessel shall attest to the accuracy of the logbook entry by signing and dating it.

Research Passive Acoustic Monitoring (PAM) Program

Northeast Gateway shall monitor the noise environment in Massachusetts Bay in the vicinity of the NEG Port using an array of 19 MARUs that were deployed initially in April 2007 to collect data during the preconstruction and active construction phases of the NEG Port and Algonquin Pipeline Lateral. A description of the MARUs can be found in Appendix A of the NEG and Algonquin application. These 19 MARUs will remain in the same configuration during full operation of the NEG Port. The MARUs collect archival noise data and are not designed to provide real-time or near-real-time information about vocalizing whales. Rather, the acoustic data collected by the MARUs shall be analyzed to document the seasonal occurrences and overall distributions of whales (primarily fin, humpback, and right whales) within approximately 10 nautical miles (18 km) of the NEG Port and shall measure and document the noise ''footprint'' of Massachusetts Bay so as to eventually assist in determining whether an overall increase in noise in the Bay associated with the NEG Port might be having a potentially negative impact on marine mammals. The overall intent of this system is to provide better information for both regulators and the general public regarding the acoustic footprint associated with long-term operation of the NEG Port in Massachusetts Bay and the distribution of vocalizing marine mammals during NEG Port activities.

In addition to the 19 MARUs, Northeast Gateway will deploy 10 auto-detection buoys (ABs) within the TSS for the operational life of the NEG Port. A description of the ABs is provided in Appendix A of NEG and Algonquin's application. The purpose of the ABs shall be to detect a calling North Atlantic right whale an average of 5 nm (9.26 km) from each AB (detection ranges will vary based on ambient underwater conditions). The AB system shall be the primary detection mechanism that alerts the EBRV captains to the occurrence of right whales, heightens EBRV awareness, and triggers necessary mitigation actions as described in the Marine Mammal Detection, Monitoring, and Response Plan included as Appendix A of the NEG application.

Northeast Gateway has engaged representatives from Cornell University's Bioacoustics Research Program and the Woods Hole Oceanographic Institution as the consultants for developing, implementing, collecting, and analyzing the acoustic data; reporting; and maintaining the acoustic monitoring system.

Further information detailing the deployment and operation of arrays of 19 passive seafloor acoustic recording units (MARUs) centered on the terminal site and the 10 ABs that are to be placed at approximately 5-m (8.0-km) intervals within the recently modified TSS can be found in the Marine Mammal Detection, Monitoring, and Response Plan included as Appendix A of the NEG and Algonquin application.

Mitigation Conclusions

NMFS has carefully evaluated the mitigation measures in the context of ensuring that NMFS prescribes the means of effecting the least practicable impact on the affected marine mammal species and stocks and their habitat. Our evaluation of potential measures included consideration of the following factors in relation to one another:

- The manner in which, and the degree to which, the successful implementation of the measure is expected to minimize adverse impacts to marine mammals;
- The proven or likely efficacy of the specific measure to minimize adverse impacts as planned; and
- The practicability of the measure for applicant implementation.

Based on our evaluation, NMFS has determined that the monitoring and mitigation measures provide the means of effecting the least practicable impact on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Reporting

The Project area is within the Mandatory Ship Reporting Area (MSRA), so all vessels entering and exiting the MSRA will report their activities to WHALESNORTH. During all phases of the Northeast Gateway LNG Port operations, sightings of any injured or dead marine mammals will

be reported immediately to the USCG and NMFS, regardless of whether the injury or death is caused by project activities.

An annual report on marine mammal monitoring and mitigation shall be submitted to NMFS Office of Protected Resources and NMFS Northeast Regional Office within 90 days after the expiration of the IHA. The annual report shall include data collected for each distinct marine mammal species observed in the project area in Massachusetts Bay during the period of LNG facility operation. Description of marine mammal behavior, overall numbers of individuals observed, frequency of observation, and any behavioral changes and the context of the changes relative to operation activities shall also be included in the annual report.

General Conclusions Drawn From Previous Monitoring Reports

Based on monthly activity reports submitted to NMFS for the period between August 2010 and May 2011, there were no activities at the NEG Port during the period. Therefore, no take of marine mammals occurred or were reported during this period.

Estimated Take by Incidental Harassment

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: any act of pursuit, torment, or annoyance which (i) Has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment]. Only take by Level B harassment is anticipated as a result of NEG's operational activities. Anticipated take of marine mammals is associated with operation of dynamic positioning during the docking of the LNG vessels. The regasification process itself is an activity that does not rise to the level of taking, as the modeled source level for this activity is 108 dB. Certain species may have a behavioral reaction to the sound emitted during the activities. Hearing impairment is not anticipated. Additionally, vessel strikes are not anticipated, especially because of the speed restriction measures that were described earlier in this document.

Although Northeast Gateway stated that the ensonified area of 120-dB isopleths by EBRV's decoupling would be less than 1 km^2 as measured in the Gulf of Mexico in 2005, due to the lack of more recent sound source verification and the lack of source measurement in Massachusetts Bay, NMFS uses a more conservative spreading model to calculate the 120 dB isopleth received sound level. This model was also used to establish the 120-dB zone of influence (ZOI) for the previous IHAs issued to Northeast Gateway. In the vicinity of the LNG Port, where the water depth is about 80 m (262 ft), the 120-dB radius is estimated to be 2.56 km (1.6 mi) maximum from the sound source during dynamic positioning for the container ship, making a maximum ZOI of 21 km^2 (8.1 mi^2). For shallow water depth (40 m or 131 ft) representative of the northern segment of the Algonquin Pipeline Lateral, the 120-dB radius is estimated to be 3.31 km (2.06 mi), the associated ZOI is 34 km^2 (13.1 mi^2).

The basis for Northeast Gateway and Algonquin's ''take'' estimate is the number of marine mammals that would be exposed to sound levels in excess of 120 dB, which is the threshold used by NMFS for continuous sounds. For the NEG port facility operations, the take estimates are determined by multiplying the area of the EBRV's ZOI (34 km^2) by local marine mammal density estimates, corrected to account for 50 percent more marine mammals that may be underwater, and then multiplying by the estimated LNG container ship visits per year. In the case of data gaps, a conservative approach was used to ensure the potential number of takes is not underestimated, as described next.

NMFS recognizes that baleen whale species other than North Atlantic right whales have been sighted in the project area from May to November. However, the occurrence and abundance of fin, humpback, and minke whales is not well documented within the project area. Nonetheless, NMFS uses the data on cetacean distribution within Massachusetts Bay, such as those published by the National Centers for Coastal Ocean Science (NCCOS, 2006), to estimate potential takes of marine mammals species in the vicinity of project area.

The NCCOS study used cetacean sightings from two sources: (1) The North Atlantic Right Whale Consortium (NARWC) sightings database held at the University of Rhode Island (Kenney, 2001); and (2) the Manomet Bird Observatory (MBO) database, held at NMFS Northeast Fisheries Science Center (NEFSC). The NARWC data contained survey efforts and sightings data from ship and aerial surveys and opportunistic sources between 1970 and 2005. The main data contributors included: Cetacean and Turtles Assessment Program (CETAP), Canadian Department of Fisheries and Oceans, PCCS, International Fund for Animal Welfare, NOAA's NEFSC, New England Aquarium, Woods Hole Oceanographic Institution, and the University of Rhode Island. A total of 653,725 km (406,293 mi) of survey track and 34,589 cetacean observations were provisionally selected for the NCCOS study in order to minimize bias from uneven allocation of survey effort in both time and space. The sightings-per-unit-effort (SPUE) was calculated for all cetacean species by month covering the southern Gulf of Maine study area, which also includes the project area (NCCOS, 2006).

The MBO's Cetacean and Seabird Assessment Program (CSAP) was contracted from 1980 to 1988 by NMFS NEFSC to provide an assessment of the relative abundance and distribution of cetaceans, seabirds, and marine turtles in the shelf waters of the northeastern United States (MBO, 1987). The CSAP program was designed to be completely compatible with NMFS NEFSC databases so that marine mammal data could be compared directly with fisheries data throughout the time series during which both types of information were gathered. A total of 5,210 km (8,383 mi) of survey distance and 636 cetacean observations from the MBO data were included in the NCCOS analysis. Combined valid survey effort for the NCCOS studies included 567,955 km (913,840 mi) of survey track for small cetaceans (dolphins and porpoises) and 658,935 km (1,060,226 mi) for large cetaceans (whales) in the southern Gulf of Maine. The NCCOS study then combined these two data sets by extracting cetacean sighting records, updating database field names to match the NARWC database, creating geometry to represent survey tracklines and applying a set of data selection criteria designed to minimize uncertainty and bias in the data used.

Owing to the comprehensiveness and total coverage of the NCCOS cetacean distribution and abundance study, NMFS calculated the estimated take number of marine mammals based on the most recent NCCOS report published in December 2006. For a detailed description and calculation of the cetacean abundance data and SPUE, please refer to the NCCOS study (NCCOS, 2006). These data show that the relative abundance of North Atlantic right, fin, humpback, minke, and pilot whales, and Atlantic white-sided dolphins for all seasons, as calculated by SPUE in number of animals per square kilometer, is 0.0082, 0.0097,

0.0265, 0.0059, 0.0407, and 0.1314 n/km, respectively.

In calculating the area density of these species from these linear density data, NMFS used 1.15 mi (1.85 km) as the strip width (W). This strip width is based on the distance of visibility used in the NARWC data that was part of the NCCOS (2006) study. However, those surveys used a strip transect instead of a line transect methodology. Therefore, in order to obtain a strip width, one must divide the visibility or transect value in half. Since the visibility value used in the NARWC data was 2.3 mi (3.7 km), it thus gives a strip width of 1.15 mi (1.85 km). Based on this information, the area density (D) of these species in the project area can be obtained by the following formula:

D = SPUE/2W.

Based on this calculation method, the estimated take numbers per year for North Atlantic right, fin, humpback, minke, and pilot whales, and Atlantic white-sided dolphins by the NEG Port facility operations, based on an average of 65 visits by LNG container ships to the project area per year (or approximately 1.25 visits per week), operating the vessels' thrusters for dynamic positioning before offloading natural gas, corrected for 50 percent underwater, are 5, 5, 15, 3, 23, and 73, respectively. These numbers represent maximum of 1.32, 0.24, 1.73, 0.10, 0.08, and 0.11 percent of the populations for these species, respectively. Since it is very likely that individual animals could be ''taken'' by harassment multiple times, these percentages are the upper boundary of the animal population that could be affected. Therefore, the actual number of individual animals being exposed or taken would be far less. There is no danger of injury, death, or hearing impairment from the exposure to these noise levels.

In addition, bottlenose dolphins, common dolphins, killer whales, Risso's dolphins, harbor porpoises, harbor seals, and gray seals could also be taken by Level B harassment as a result of deepwater LNG port operations. Since these species are less likely to occur in the area, and there are no density estimates specific to this particular area, NMFS based the take estimates on typical group size. Therefore, NMFS estimates that up to approximately 10 bottlenose dolphins, 20 common dolphins, 20 Risso's dolphins, 20 killer whales, 5 harbor porpoises, 15 harbor seals, and 15 gray seals could be exposed to continuous noise at or above 120 dB re 1 μPa rms incidental to operations during the one year period of the IHA, respectively.

Since Massachusetts Bay represents only a small fraction of the western North Atlantic basin where these animals occur NMFS has determined that only small numbers of the affected marine mammal species or stocks would be potentially affected by the Northeast Gateway LNG deepwater project. The take estimates presented in this section of the document do not take into consideration the mitigation and monitoring measures that are included in the IHA.

Negligible Impact and Small Numbers Analysis and Determination

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''* * * an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.'' In making a negligible impact determination, NMFS considers a variety of factors, including but not limited to: (1) The number of anticipated mortalities; (2) the number and nature of anticipated injuries; (3) the number, nature, intensity, and duration of Level B harassment; and (4) the context in which the takes occur.

No injuries or mortalities are anticipated to occur as a result of Northeast Gateway's proposed port operation activities, and none are authorized by NMFS. Additionally, animals in the area are not anticipated to incur any hearing impairment (*i.e.,* TTS or PTS), as the modeling of source levels indicates that none of the source received levels exceed 180 dB (rms).

While some of the species occur in the proposed project area year-round, some species only occur in the area during certain seasons. Humpback and minke whales are not expected in the project area in the winter. During the winter, a large portion of the North Atlantic right whale population occurs in the southeastern U.S. calving grounds (*i.e.,* South Carolina, Georgia, and northern Florida). The fact that certain activities will occur during times when certain species are not commonly found in the area will help reduce the amount of Level B harassment for these species.

Many animals perform vital functions, such as feeding, resting, traveling, and socializing, on a diel cycle (24-hr cycle). Behavioral reactions to noise exposure (such as disruption of critical life functions, displacement, or avoidance of important habitat) are more likely to be significant if they last more than one diel cycle or recur on subsequent days (Southall *et al.,* 2007). Consequently, a behavioral response lasting less than one day and not recurring on subsequent days is not considered particularly severe unless it could directly affect reproduction or survival (Southall *et al.,* 2007). Operational activities are not anticipated to occur at the Port on consecutive days. In addition, Northeast Gateway EBRVs are expected to make 65 port calls throughout the year, with thruster use needed for a couple of hours. Therefore, Northeast Gateway will not be creating increased sound levels in the marine environment for prolonged periods of time.

Of the 13 marine mammal species likely to occur in the area, four are listed as endangered under the ESA: North Atlantic right, humpback, and fin whales. All of these species, as well as the northern coastal stock of bottlenose dolphin, are also considered depleted under the MMPA. There is currently no designated critical habitat or known reproductive areas for any of these species in or near the proposed project area. However, there are several well known North Atlantic right whale feeding grounds in the Cape Cod Bay and Great South Channel. No mortality or injury is expected to occur, and due to the nature, degree, and context of the Level B harassment anticipated, the activity is not expected to impact rates of recruitment or survival.

From the most conservative estimates of both marine mammal densities in the project area and the size of the 120-dB ZOI, the maximum calculated number of individual marine mammals for each species that could potentially be harassed annually is small relative to the overall population sizes (1.73 percent for humpback whales and 1.32 percent for North Atlantic right whales and no more than 1 percent of any other species).

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the mitigation and monitoring measures, NMFS finds that the operation activities of the Northeast Gateway LNG Port will result in the incidental take of small numbers of marine mammals, by Level B harassment only, and that the total taking from Northeast Gateway's proposed activities will have a negligible impact on the affected species or stocks.

Impact on Availability of Affected Species or Stock for Taking for Subsistence Uses

There are no relevant subsistence uses of marine mammals implicated by this

action. Therefore, NMFS has determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act (ESA)

On February 5, 2007, NMFS concluded consultation with MARAD and the USCG, under section 7 of the ESA, on the proposed construction and operation of the Northeast Gateway LNG facility and issued a biological opinion. The finding of that consultation was that the construction and operation of the Northeast Gateway LNG terminal may adversely affect, but is not likely to jeopardize, the continued existence of northern right, humpback, and fin whales, and is not likely to adversely affect sperm, sei, or blue whales and Kemp's ridley, loggerhead, green or leatherback sea turtles. An incidental take statement (ITS) was issued following NMFS' issuance of the 2007 IHA.

On November 15, 2007, Northeast Gateway and Algonquin submitted a letter to NMFS requesting an extension for the LNG Port construction into December 2007. Upon reviewing Northeast Gateway's weekly marine mammal monitoring reports submitted under the previous IHA, NMFS recognized that the potential take of some marine mammals resulting from the LNG Port and Pipeline Lateral by Level B behavioral harassment likely had exceeded the original take estimates. Therefore, NMFS Northeast Region (NER) reinitiated consultation with MARAD and USCG on the construction and operation of the Northeast Gateway LNG facility. On November 30, 2007, NMFS NER issued a revised biological opinion, reflecting the revised construction time period and including a revised ITS. This revised biological opinion concluded that the construction and operation of the Northeast Gateway LNG terminal may adversely affect, but is not likely to jeopardize, the continued existence of northern right, humpback, and fin whales, and is not likely to adversely affect sperm, sei, or blue whales.

NMFS' Permits, Conservation and Education division has determined that the activities described in here are the same as those analyzed in the revised 2007 biological opinion. Therefore, a new consultation is not required for issuance of this IHA.

National Environmental Policy Act

MARAD and the USCG released a Final EIS/Environmental Impact Report (EIR) for the proposed Northeast Gateway Port and Pipeline Lateral. A notice of availability was published by MARAD on October 26, 2006 (71 FR 62657). The Final EIS/EIR provides detailed information on the proposed project facilities, construction methods and analysis of potential impacts on marine mammals.

NMFS was a cooperating agency (as defined by the Council on Environmental Quality (40 CFR 1501.6)) in the preparation of the Draft and Final EISs. NMFS reviewed the Final EIS and adopted it on May 4, 2007. NMFS issued a separate Record of Decision for issuance of authorizations pursuant to section 101(a)(5) of the MMPA for the construction and operation of the Northeast Gateway's LNG Port Facility in Massachusetts Bay.

Determinations

NMFS has determined that the operation and maintenance activities of the Northeast Gateway Port facility may result, at worst, in a temporary modification in behavior of small numbers of certain species of marine mammals that may be in close proximity to the Northeast Gateway LNG facility. These activities are expected to result in some local short-term displacement only of the affected species or stocks of marine mammals. Taking these two factors together, NMFS concludes that the activity will have no more than a negligible impact on the affected species or stocks, as there will be no expected effects on annual rates of survival and reproduction of these species or stocks. This determination is further supported by the required mitigation, monitoring, and reporting measures described in this document.

As a result of implementation of the described mitigation and monitoring measures, no take by injury or death would be requested, anticipated or authorized, and the potential for temporary or permanent hearing impairment is very unlikely due to the relatively low noise levels (and consequently small zone of impact relative to the size of Massachusetts Bay).

While the number of marine mammals that may be harassed will depend on the distribution and abundance of marine mammals in the vicinity of the LNG Port facility, the estimated numbers of marine mammals to be harassed are small relative to the affected species or stock sizes.

Authorization

NMFS has issued an IHA to Northeast Gateway for conducting LNG Port facility operations in Massachusetts Bay, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated.

Dated: October 4, 2011.

James H. Lecky,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2011–26200 Filed 10–7–11; 8:45 am]

BILLING CODE 3510–22–P

CONSUMER PRODUCT SAFETY COMMISSION

[CPSC Docket No. 12–C0001]

Nordica USA, Provisional Acceptance of a Settlement Agreement and Order

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: It is the policy of the Commission to publish settlements which it provisionally accepts under the Consumer Product Safety Act in the **Federal Register** in accordance with the terms of 16 CFR 1118.20(e). Published below is a provisionally-accepted Settlement Agreement with Nordica USA, containing a civil penalty of $214,000.00.

DATES: Any interested person may ask the Commission not to accept this agreement or otherwise comment on its contents by filing a written request with the Office of the Secretary by October 26, 2011.

ADDRESSES: Persons wishing to comment on this Settlement Agreement should send written comments to the Comment 12–C0001, Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Room 820, Bethesda, Maryland 20814–4408.

FOR FURTHER INFORMATION CONTACT: Dennis C. Kacoyanis, General Attorney, Division of Enforcement and Information, Office of the General Counsel, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814–4408; telephone (301) 504–7587.

SUPPLEMENTARY INFORMATION: The text of the Agreement and Order appears below.

Dated: October 4, 2011.

Todd A. Stevenson,

Secretary.

Settlement Agreement

1. In accordance with 16 CFR 1118.20, Nordica USA (''Nordica'') and staff of the United States Consumer Product Safety Commission (''Commission'') enter into this Settlement Agreement

(''Agreement'') under the Consumer Product Safety Act (''CPSC''). The Agreement and the incorporated attached Order (''Order'') resolve the allegations set forth below.

Parties

2. ''Staff'' is staff of the United States Consumer Product Safety Commission, an independent federal regulatory agency established pursuant to, and responsible for the enforcement of, the Consumer Product Safety Act, 15 U.S.C. 2051–2089 (''CPSA'').

3. Nordica is a corporation organized and existing under the laws of New Hampshire, with its principal corporate offices located in West Lebanon, New Hampshire. Nordica is a division of Tecnica Group USA.

Staff Allegations

4. From August 2006 through December 2008, Nordica imported and sold to ski retailers about 4,500 pairs of XBI ALU Skis (''Skis''). The binding plates on the skis could crack or break causing the skier to lose control or fall and suffer injuries.

5. The Skis are ''consumer products,'' and, at all relevant times, Nordica was a ''manufacturer'' of those consumer products, which were ''distributed in commerce,'' as those terms are defined or used in sections 3(a)(5), (8), and (11) of the CPSA, 15 U.S.C. 2052(a)(5), (8), and (11).

6. Beginning in December 2007, one of Nordica's retail customers advised Nordica that it had received calls with comments about the Skis' binding plates cracking and breaking. The retail customer requested replacement parts for the broken binding plates.

7. In March 2008, Nordica received a report from another retail customer about the Skis' binding plates breaking. Also in March 2008, Nordica employees identified numerous incidents of the Skis' binding plates cracking and breaking. Nordica advised the foreign manufacturer of the retail customers' claims of the Skis' binding plates cracking and breaking. Nordica asked the foreign manufacturer to provide Nordica with 25 pairs of replacement binding plates for the Skis.

8. Through April 2008, Nordica continued to receive reports of the Skis' binding plates breaking. By the end of April 2008, Nordica knew of at least 20 claims of broken Skis binding plates.

9. On or about Aug. 4, 2008, Nordica received an in-depth epidemiologic investigation report from the Commission about the Skis' binding plates breaking.

10. In September 2008, Nordica learned that the foreign manufacturer had redesigned the Ski's binding plate. Nordica did not ask the foreign manufacturer until December 2008, why it had redesigned the Ski's binding plate. At that time, Nordica learned that the foreign manufacturer had redesigned the Ski's binding plate because of the cracking and breakage problem.

11. Nordica continued to investigate the binding plate problem throughout the fall of 2008. Nordica discovered that it had about 200 reports of warranty claims related to the Skis' binding plates cracking and breaking.

12. Despite being aware of the information in paragraphs 7 through 12, Nordica did not report to the Commission until December 3, 2008. By that time, Nordica was aware of at least 200 reports of the Skis' binding plates cracking and breaking.

13. Nordica obtained information that reasonably supported the conclusion that the Skis' binding plates contained a defect that could create a substantial product hazard or that the Skis' binding plates created an unreasonable risk of serious injury or death. This knowledge required Nordica to immediately inform the Commission of the defect and risk associated with the Skis' binding plates, as required by section 15(b)(3) and (4) of the CPSA, 15 U.S.C. 2064(b)(3) and (4).

14. Nordica knowingly failed to inform the Commission immediately about the Skis' binding plates, as required by CPSA sections 15(b)(3) and (4), 15 U.S.C. 2064(b)(3) and (4), and as the term ''knowingly'' is defined in CPSA section 20(d), 15 U.S.C. 2069(d). This failure violated CPSA section 19(a)(4), 15 U.S.C. 2068(a)(4). Pursuant to CPSA section 20, 15 U.S.C. 2069, this failure subjected Nordica to civil penalties.

Nordica's Response

15. Nordica denies Staff's allegations that the Skis' binding plates contain defects that could create a substantial product hazard or create an unreasonable risk of serious injury or death, and further denies that it violated the reporting requirements of Section 15(b) of the CPSA, 15 U.S.C. 2064(b).

16. Nordica states that it is not aware of any reports of injury associated with cracking or breakage of the binding plates any time from the beginning of distribution (2006) up to and including the present date (2011).

17. On or about August 4, 2008, Nordica received a CPSC Incident Report that had been submitted by a consumer concerning breakage of an XBI Alu Ski. Nordica immediately began investigating whether cracking or breakage of the XBI Alu Ski presented a potential safety concern. Following extensive investigation, and based upon review of the available information—including, but not limited to, the absence of any reported injuries and test results provided by the manufacturer—Nordica did not and still does not believe that the XBI Alu binding plate ski contained a defect that could present a substantial product hazard or created an unreasonable risk of serious injury or death. Out of an abundance of caution, Nordica wished to replace any binding plates due to potential risk of cracking. Nordica therefore notified CPSC in December 2008 of its willingness to conduct a Fast Track recall in full cooperation with CPSC.

Agreement of the Parties

18. Under the CPSA, the Commission has jurisdiction over this matter and over Nordica.

19. The parties enter into the Agreement for settlement purposes only. The Agreement does not constitute an admission by Nordica, or a determination by the Commission, that Nordica knowingly violated the CPSA.

20. In settlement of Staff's allegations, Nordica must pay a civil penalty in the amount of two hundred-fourteen thousand dollars ($214,000.00). The civil penalty shall be paid within twenty (20) calendar days of receiving service of the Commission's final Order accepting the Agreement. The payment shall be made electronically to the CPSC via *http://www.pay.gov*.

21. The parties enter into this Agreement for settlement purposes. The Agreement does not constitute an admission by Nordica or a determination by the Commission that Nordica violated the CPSA's reporting requirements, or that the Skis' binding plates presented a substantial product hazard.

22. Upon provisional acceptance of the Agreement, the Agreement shall be placed on the public record and published in the **Federal Register** in accordance with the procedures set forth in 16 CFR 1118.20(e). Pursuant to 16 CFR 1118.20(f), if the Commission does not receive any written request not to accept the Agreement within fifteen (15) calendar days, the Agreement shall be deemed finally accepted on the sixteenth (16th) calendar day after the date it is published in the **Federal Register**, in accordance with 16 CFR 1118.20(f).

23. Upon the Commission's final acceptance of the Agreement and issuance of the final Order, Nordica knowingly, voluntarily, and completely waives any rights it may have in this matter to the following: (1) An

administrative or judicial hearing; (2) judicial review or other challenge or contest of the validity of the Order or of the Commission's actions; (3) a determination by the Commission of whether Nordica failed to comply with the CPSA and its underlying regulations; (4) a statement of findings of fact and conclusions of law; and (5) any claims under the Equal Access to Justice Act.

24. The Commission may publicize the terms of the Agreement and the Order.

25. The Agreement and the Order shall apply to, and be binding upon, Nordica and each of its successors and assigns.

26. The Commission issues the Order under the provisions of the CPSA, and a violation of the Order may subject Nordica and each of its successors and assigns to appropriate legal action.

27. The Agreement may be used in interpreting the Order. Understandings, agreements, representations, or interpretations apart from those contained in the Agreement and the Order may not be used to vary or contradict their terms. The Agreement cannot be waived, amended, modified, or otherwise altered without written agreement thereto, executed by the party against whom such waiver, amendment, modification, or alteration is sought to be enforced.

28. If any provision of the Agreement and the Order is held to be illegal, invalid, or unenforceable under present or future laws effective during the terms of the Agreement and the Order, such provision shall be fully severable. The balance of the provisions in the Agreement and the Order shall remain in full force and effect, unless the Commission and Nordica agree that the severed provision materially affects the purpose of the Agreement and the Order.

Nordica Usa

Dated: September 6, 2011.

By: _____

Willy Booker,

President, Nordica USA, 19 Technology Drive, West Lebanon, NH 03784.

Dated: September 12, 2011.

By: _____

Eric A. Rubel, Esquire,

Arnold & Porter, LLP, 555 Twelfth Street, NW., Washington, DC 20004–1206, Counsel for Nordica USA.

U.S. Consumer Product Safety Commission Staff.

Cheryl A. Falvey,

General Counsel.

Melissa V. Hampshire,

Assistant General Counsel, Office of the General Counsel.

Dated: September 22, 2011.

By: _____

Dennis C. Kacoyanis,

General Attorney, Division of Enforcement and Information, Office of the General Counsel.

Order

Upon consideration of the Settlement Agreement entered into between Nordica USA (''Nordica'') and U.S. Consumer Product Safety Commission (''Commission'') staff, and the Commission having jurisdiction over the subject matter and over Nordica, and it appearing that the Settlement Agreement and the Order are in the public interest, it is

Ordered, that the Settlement Agreement be, and hereby is, accepted; and it is

Further Ordered, that Nordica shall pay a civil penalty in the amount of two hundred-fourteen thousand dollars ($214,000.00) within twenty (20) calendar days of service of the Commission's final Order accepting the Agreement. The payment shall be made electronically to the CPSC via *http://www.pay.gov.* Upon the failure of Nordica to make the foregoing payment when due, interest on the unpaid amount shall accrue and be paid by Nordica at the federal legal rate of interest set forth at 28 U.S.C. 1961(a) and (b).

Provisionally accepted and provisional Order issued on the 4th day of October, 2011.

By Order of the Commission.

Todd A. Stevenson,

Secretary, U.S. Consumer Product Safety Commission.

[FR Doc. 2011–26162 Filed 10–7–11; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Meeting of the Department of Defense Military Family Readiness Council (MFRC); Change of Meeting Date and Time

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, Department of Defense.

ACTION: Notice.

SUMMARY: Pursuant to Section 10 (a), Public Law 92–463, on September 26, 2011 (76 FR 59388–59389) the Department of Defense Military Family Readiness Council (MFRC) announced a meeting to be held on October 17, 2011. This notice announces that the meeting date and time has been changed to November 21, 2011, from 2 p.m. to 4 p.m. All other information in the original notice remains the same.

The meeting is open to the public, subject to the availability of space. Persons desiring to attend may contact Ms. Melody McDonald at 571–256–1738 or e-mail *FamilyReadinessCouncil@osd.mil* no later than 5 p.m. on Tuesday, November 15, 2011 to arrange for parking and escort into the conference room inside the Pentagon.

Interested persons may submit a written statement for consideration by the Council. Persons desiring to submit a written statement to the Council must notify the point of contact listed below no later than 5 p.m., Wednesday, November 16, 2011.

ADDRESSES: Pentagon Conference Center M1 (escorts will be provided from the Pentagon Metro entrance).

FOR FURTHER INFORMATION CONTACT: Ms. Melody McDonald or Ms. Betsy Graham, Office of the Deputy Under Secretary (Military Community & Family Policy), 4000 Defense Pentagon, Room 2E319, Washington, DC 20301–4000. Telephones (571) 256–1738; (703) 697–9283 and/or *e-mail: FamilyReadinessCouncil@osd.mil.*

Dated: October 5, 2011.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2011–26166 Filed 10–7–11; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Air Force

Air University Board of Visitors Meeting

ACTION: Notice of Meeting of the Air University Board of Visitors.

SUMMARY: Under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150, the Department of Defense announces that the Air University Board of Visitors' meeting will take place on Monday, November 14th, 2011, from 1 p.m. to 5 p.m. and Tuesday, November 15th, 2011, from 8 a.m. to 5 p.m. The meeting will be held in the Air University Commander's Conference Room located in building 800. Please contact Mrs. Diana Bunch, 334–953–4547 for further details of the meeting location.

The purpose of this meeting is to provide independent advice and recommendations on matters pertaining to the educational, doctrinal, and research policies and activities of Air University. The agenda will include

topics relating to the policies, programs, and initiatives of Air University educational programs. Additionally, four subcommittees will meet to discuss issues relating to academic affairs; research; future learning and technology; and institutional advancement. Please contact Mrs. Diana Bunch, 334–953–4547 for further details of the subcommittees' meeting location.

Pursuant to 5 U.S.C. 552b, as amended, and 41 CFR 102–3.155 all sessions of the Air University Board of Visitors' meeting will be open to the public. Any member of the public wishing to provide input to the Air University Board of Visitors should submit a written statement in accordance with 41 CFR 102–3.140(c) and section 10(a)(3) of the Federal Advisory Committee Act and the procedures described in this paragraph. Written statements can be submitted to the Designated Federal Officer at the address detailed below at any time. Statements being submitted in response to the agenda mentioned in this notice must be received by the Designated Federal Officer at the address listed below at least five calendar days prior to the meeting which is the subject of this notice. Written statements received after this date may not be provided to or considered by the Air University Board of Visitors until its next meeting. The Designated Federal Officer will review all timely submissions with the Air University Board of Visitors' Board Chairperson and ensure they are provided to members of the Board before the meeting that is the subject of this notice. Additionally, any member of the public wishing to attend this meeting should contact either person listed below at least five calendar days prior to the meeting for information on base entry passes.

FOR FURTHER INFORMATION CONTACT: Mrs. Diana Bunch, Designated Federal Officer, Air University Headquarters, 55 LeMay Plaza South, Maxwell Air Force Base, Alabama 36112–6335, telephone (334) 953–4547.

Bao-Anh Trinh,

Air Force Federal Register Liaison Officer.

[FR Doc. 2011–26152 Filed 10–7–11; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2011–0024]

Privacy Act of 1974; System of Records; Correction

AGENCY: Department of the Army, Department of Defense (DoD).

ACTION: Notice to add a system of records; correction.

SUMMARY: On October 5, 2011 (76 FR 61680–61682), DoD published a notice announcing its intent to add a new Privacy Act System of Records. The Contesting Records category was inadvertently omitted. This notice corrects that error.

FOR FURTHER INFORMATION CONTACT: Mr. Leroy Jones, Department of the Army, Privacy Office, U.S. Army Records Management and Declassification Agency, 7701 Telegraph Road, Casey Building, Suite 144, Alexandria, VA 22325–3905, or by phone at (703) 428–6185.

SUPPLEMENTARY INFORMATION: On October 5, 2011, DoD published a notice announcing its intent to add a new system to its inventory of Privacy Act System of Records: A0350–20a TRADOC, Standardized Student Records System. Subsequent to the publication of that notice, DoD discovered that the Contesting Records category was inadvertently omitted.

Correction

In the notice published on October 5, 2011 (76 FR 61680–61682) make the following correction: On page 61682, in the third column, before the RECORD SOURCE CATEGORIES paragraph, add ''CONTESTING RECORDS PROCEDURES: The Army's rules for accessing records, and for contesting contents and appealing initial agency determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.''

Dated: October 5, 2011.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2011–26155 Filed 10–7–11; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Comment request.

SUMMARY: The Department of Education (the Department), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the reporting burden on the public and helps the public understand the Department's information collection requirements and provide the requested data in the desired format. The Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management, Office of Management, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before December 12, 2011.

ADDRESSES: Comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov* or mailed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202–4537. Please note that written comments received in response to this notice will be considered public records.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35) requires that Federal agencies provide interested parties an early opportunity to comment on information collection requests. The Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management, publishes this notice containing proposed information collection requests at the beginning of the Departmental review of the information collection. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: October 5, 2011.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

Office of Special Education and Rehabilitative Services

Type of Review: Extension.

Title of Collection: Quarterly Cumulative Caseload Report (RSA–113).

OMB Control Number: 1820–0013.

Agency Form Number(s): RSA–113.

Frequency of Responses: Quarterly, Annually.

Affected Public: State, Local or Tribal Government.

Total Estimated Number of Annual Responses: 80.

Total Estimated Annual Burden Hours: 320.

Abstract: State agencies that administer vocational rehabilitation programs provide key caseload data on this form, including numbers of persons who are applicants, determined eligible/ineligible, waiting for services, and their program outcomes. The Rehabilitative Services Administration collects this information quarterly from states and reports it in the Annual Report to Congress on the Rehabilitation Act.

Copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov,* by selecting the ''Browse Pending Collections'' link and by clicking on link number 4720. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–401–0920. Please specify the complete title of the information collection and OMB Control Number when making your request.

Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 2011–26240 Filed 10–7–11; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Comment Request.

SUMMARY: The Department of Education (the Department), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the reporting burden on the public and helps the public understand the Department's information collection requirements and provide the requested data in the desired format. The Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management, Office of Management, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before December 12, 2011.

ADDRESSES: Comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov* or mailed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202–4537. Please note that written comments received in response to this notice will be considered public records.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35) requires that Federal agencies provide interested parties an early opportunity to comment on information collection requests. The Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management, publishes this notice containing proposed information collection requests at the beginning of the Departmental review of the information collection. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: October 5, 2011.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

Office of Special Education and Rehabilitative Services

Type of Review: Extension.

Title of Collection: Annual Report on Appeals Process (RSA–722).

OMB Control Number: 1820–0563.

Agency Form Number(s): RSA–722.

Frequency of Responses: Annually.

Affected Public: State, Local or Tribal Government.

Total Estimated Number of Annual Responses: 80.

Total Estimated Annual Burden Hours: 160.

Abstract: Pursuant to Subsection 102(c)(8)(A) and (B) of the Rehabilitation Act of 1973, as amended, the RSA–722 is needed to meet specific data collection requirements on the number of requests for mediations, hearings, administrative reviews and other methods of dispute resolution requested and the manner in which they were resolved. The information collected is used to evaluate the types of complaints made by applicants and eligible individuals of the vocational rehabilitation program and the final resolution of appeals filed. Respondents are State agencies that administer the Federal/State Program for Vocational Rehabilition.

Copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov,* by selecting the ''Browse Pending Collections'' link and by clicking on link number 4733. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–401–0920. Please specify the complete title of the information collection and OMB Control Number when making your request.

Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 2011–26238 Filed 10–7–11; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP11–2607–000.
Applicants: CenterPoint Energy—Mississippi River Transmission, LLC.
Description: CenterPoint Energy—Mississippi River Transmission, LLC's Penalty Revenue Crediting Filing.
Filed Date: 09/28/2011.
Accession Number: 20110928–5088.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 11, 2011.

Docket Numbers: RP11–2608–000.
Applicants: Rager Mountain Storage Company LLC.
Description: Rager Mountain Storage Company LLC submits tariff filing per 154.203: Rager Mountain Storage Company LLC FERC Gas Tariff Volume No. 1 to be effective 11/1/2011.
Filed Date: 09/28/2011.
Accession Number: 20110928–5122.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 11, 2011.

Docket Numbers: RP11–2609–000.
Applicants: Transcontinental Gas Pipe Line Company, LLC.
Description: Transcontinental Gas Pipe Line Company, LLC submits tariff filing per 154.203: Compliance Filing—Commission Order in Docket Nos. RP10–608 and RP10–613, to be effective 10/29/2011.
Filed Date: 09/28/2011.
Accession Number: 20110928–5124.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 11, 2011.

Docket Numbers: RP11–2610–000.
Applicants: East Cheyenne Gas Storage, LLC.
Description: East Cheyenne Gas Storage, LLC submits tariff filing per 154.602: ECGS cancellation, to be effective 12/31/9998.
Filed Date: 09/28/2011.
Accession Number: 20110928–5136.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 11, 2011.

Docket Numbers: RP11–2611–000.
Applicants: Southern Star Central Gas Pipeline, Inc.
Description: Southern Star Central Gas Pipeline, Inc. submits tariff filing per 154.204: Scheduling Priorities—Restore Pre-10/1/11 Language (Related to RP11–2135) to be effective 10/1/2011.
Filed Date: 09/29/2011.
Accession Number: 20110929–5021.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 11, 2011.

Docket Numbers: RP11–2612–000.
Applicants: Gulf Crossing Pipeline Company LLC.
Description: Gulf Crossing Pipeline Company LLC submits tariff filing per 154.204: Antero 2 to Tenaska 209 Capacity Release Negotiated Rate Agreement Filing to be effective 10/1/2011 under RP11–2612 Filing Type: 570.
Filed Date: 09/29/2011.
Accession Number: 20110929–5029.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 11, 2011.

Docket Numbers: RP11–2613–000.
Applicants: Gulf Crossing Pipeline Company LLC.
Description: Gulf Crossing Pipeline Company LLC submits tariff filing per 154.204: Antero 3 to Tenaska 210 Capacity Release Negotiated Rate Agreement Filing to be effective 10/1/2011.
Filed Date: 09/29/2011.
Accession Number: 20110929–5030.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 11, 2011.

Docket Numbers: RP11–2614–000.
Applicants: Gulf South Pipeline Company, LP.
Description: Gulf South Pipeline Company, LP submits tariff filing per 154.204: CenterPoint 34682–6 Amendment to Negotiated Rate Agreement to be effective 10/1/2011.
Filed Date: 09/29/2011.
Accession Number: 20110929–5031.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 11, 2011.

Docket Numbers: RP11–2615–000.
Applicants: Gulf South Pipeline Company, LP.
Description: Gulf South Pipeline Company, LP submits tariff filing per 154.204: HK 37367 to Sequent 39121 Capacity Release Negotiated Rate Agreement Filing to be effective 9/29/2011.
Filed Date: 09/29/2011.
Accession Number: 20110929–5032.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 11, 2011.

Docket Numbers: RP11–2616–000.
Applicants: Williston Basin Interstate Pipeline Company.
Description: Williston Basin Interstate Pipeline Company submits tariff filing per 154.204: Non-Conforming Negotiated Rate Agreements—Bear Paw to be effective 10/1/2011.
Filed Date: 09/29/2011.
Accession Number: 20110929–5033.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 11, 2011.

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.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, and service 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 29, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–26077 Filed 10–7–11; 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 exempt wholesale generator filings:

Docket Numbers: EG11–129–000.
Applicants: Vasco Winds, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Vasco Winds, LLC.
Filed Date: 09/27/2011.
Accession Numbers: 20110927–5045.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 18, 2011.

Docket Numbers: EG11–130–000.
Applicants: NextEra Energy Montezuma II Wind, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of NextEra Energy Montezuma II Wind, LLC.
Filed Date: 09/27/2011.
Accession Numbers: 20110927–5046.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 18, 2011.

Docket Numbers: EG11–131–000.
Applicants: Richland-Stryker Generation LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Richland-Stryker Generation LLC .
Filed Date: 09/27/2011.
Accession Numbers: 20110927–5145.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 18, 2011.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–4254–002.
Applicants: New England Power Company.
Description: New England Power Company submits tariff filing per 35.17(b): Corrected Amendment to Filing of Interconnection Agreement with Lowell Cogen to be effective 10/1/2011.
Filed Date: 09/27/2011.
Accession Numbers: 20110927–5039.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 18, 2011.

Docket Numbers: ER11–4646–000.
Applicants: PJM Interconnection, L.L.C.
Description: PJM Interconnection, L.L.C. submits tariff filing per 35.13(a)(2)(iii: Queue No. W1–124; Original Service Agreement No. 3061 to be effective 8/30/2011.
Filed Date: 09/27/2011.
Accession Numbers: 20110927–5030.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 18, 2011.

Docket Numbers: ER11–4647–000.
Applicants: UP Power Marketing.
Description: UP Power Marketing submits tariff filing per 35.1: Market-Based Rate Tariff Baseline to be effective 9/27/2011.
Filed Date: 09/27/2011.
Accession Numbers: 20110927–5040.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 18, 2011.

Docket Numbers: ER11–4648–000.
Applicants: L'Anse Warden Electric Company.
Description: L'Anse Warden Electric Company submits tariff filing per 35.1: Market-Based Rate Tariff Baseline to be effective 9/27/2011.
Filed Date: 09/27/2011.
Accession Numbers: 20110927–5041.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 18, 2011.

Docket Numbers: ER11–4649–000.
Applicants: PacifiCorp.
Description: PacifiCorp submits tariff filing per 35.12: BPA Residential Exchange Settlement Implementation Agreement to be effective 10/1/2011.
Filed Date: 09/27/2011.
Accession Numbers: 20110927–5069.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 18, 2011.

Docket Numbers: ER11–4650–000.
Applicants: Avista Corporation.
Description: Avista Corporation submits tariff filing per 35.13(a)(2)(iii: Avista Corp FERC Rate Schedule No. 184 to be effective 10/1/2011.
Filed Date: 09/27/2011.
Accession Numbers: 20110927–5072.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 18, 2011.

Docket Numbers: ER11–4651–000.
Applicants: Ford Motor Company.
Description: Notice of Termination of Ford Motor Company.
Filed Date: 09/27/2011.
Accession Numbers: 20110927–5136.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 18, 2011.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES11–42–000.
Applicants: Interstate Power and Light Company.
Description: Interstate Power and Light Company submits Amendment to Form 523 Application for authorization to issue securities and request for waiver of competitive bidding requirements.
Filed Date: 09/23/2011.
Accession Numbers: 20110923–5102.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 5, 2011.

Docket Numbers: ES11–50–000.
Applicants: AEP Generating Company, AEP Texas North Company, AEP Texas Central Company, Appalachian Power Company, Indiana Michigan Power Company, Kentucky Power Company, Kingsport Power Company, Public Service Company of Oklahoma, Southwestern Electric Power Company, Wheeling Power Company.
Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of AEP Generating Company et al.
Filed Date: 09/27/2011.
Accession Numbers: 20110927–5132.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 18, 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 28, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–26076 Filed 10–7–11; 8:45 am]

BILLING CODE 6717–01–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: ER11–4525–001.
Applicants: Middletown Coke Company, LLC.
Description: Middletown Coke Company, LLC submits tariff filing per 35.17(b): Middletown Supplemental MBR to be effective 10/14/2011.
Filed Date: 09/28/2011.
Accession Number: 20110928–5120.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Docket Numbers: ER11–4652–000.
Applicants: PECO Energy Company.
Description: PECO Energy Company submits tariff filing per 35.1: Schedule No. 137 to be effective 10/1/2011.
Filed Date: 09/28/2011.
Accession Number: 20110928–5000.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Docket Numbers: ER11–4653–000.
Applicants: Idaho Power Company.
Description: Idaho Power Company submits tariff filing per 35.13(a)(2)(iii: BPA Residential Exchange Agreement to be effective 10/1/2011.
Filed Date: 09/28/2011.
Accession Number: 20110928–5001.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Docket Numbers: ER11–4654–000.
Applicants: AEP Texas Central Company.
Description: AEP Texas Central Company submits tariff filing per 35.13(a)(2)(iii: 20110928 TCC–Midway Farms Wind PDA to be effective 8/31/2011.
Filed Date: 09/28/2011.
Accession Number: 20110928–5040.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Docket Numbers: ER11–4655–000.
Applicants: Rensselaer Cogeneration LLC.
Description: Rensselaer Cogeneration LLC submits tariff filing per 35.1: Baseline MBR Tariff Filing to be effective 9/28/2011.
Filed Date: 09/28/2011.
Accession Number: 20110928–5041.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Docket Numbers: ER11–4656–000.
Applicants: AEP Texas North Company.
Description: AEP Texas North Company submits tariff filing per

35.13(a)(2)(iii: TNC–White Camp Solar PDA to be effective 9/19/2011.

Filed Date: 09/28/2011.

Accession Number: 20110928–5060.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Docket Numbers: ER11–4657–000.

Applicants: Apple Group.

Description: Apple Group submits tariff filing per 35.1: Apple Group Baseline Tariff to be effective 9/28/2011.

Filed Date: 09/28/2011.

Accession Number: 20110928–5072.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Docket Numbers: ER11–4658–000.

Applicants: E Minus LLC.

Description: E Minus LLC submits tariff filing per 35.1: E Minus LLC Baseline Tariff to be effective 9/28/2011.

Filed Date: 09/28/2011.

Accession Number: 20110928–5073.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Docket Numbers: ER11–4659–000.

Applicants: Raider Dog LLC.

Description: Raider Dog LLC submits tariff filing per 35.1: Raider Dog LLC Baseline Tariff to be effective 9/28/2011.

Filed Date: 09/28/2011.

Accession Number: 20110928–5078.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Docket Numbers: ER11–4660–000.

Applicants: Driftwood LLC.

Description: Driftwood LLC submits tariff filing per 35.1: Driftwood LLC Baseline Tariff to be effective 9/28/2011.

Filed Date: 09/28/2011.

Accession Number: 20110928–5082.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Docket Numbers: ER11–4661–000.

Applicants: Crafton LLC.

Description: Crafton LLC submits tariff filing per 35.1: Crafton LLC Baseline Tariff to be effective 9/28/2011.

Filed Date: 09/28/2011.

Accession Number: 20110928–5084.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Docket Numbers: ER11–4662–000.

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc.'s Notice of Cancellation of Large Generator Interconnection Agreement.

Filed Date: 09/28/2011.

Accession Number: 20110928–5087.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Docket Numbers: ER11–4664–000.

Applicants: New York Independent System Operator, Inc.

Description: New York Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: NYISO Proposed Revisions to Penalties for Voltage Service Suppliers to be effective 11/27/2011.

Filed Date: 09/28/2011.

Accession Number: 20110928–5104.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Docket Numbers: ER11–4665–000.

Applicants: North Branch Resources, LLC.

Description: North Branch Resources, LLC submits tariff filing per 35.1: NBR Baseline Tariff Filing to be effective 9/28/2011.

Filed Date: 09/28/2011.

Accession Number: 20110928–5105.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Docket Numbers: ER11–4666–000.

Applicants: NaturEner Glacier Wind Energy 1, LLC.

Description: NaturEner Glacier Wind Energy 1, LLC submits tariff filing per 35.1: Baseline Filing of Market Based Rate Tariff to be effective 9/28/2011.

Filed Date: 09/28/2011.

Accession Number: 20110928–5106.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Docket Numbers: ER11–4667–000.

Applicants: NaturEner Glacier Wind Energy 2, LLC.

Description: NaturEner Glacier Wind Energy 2, LLC submits tariff filing per 35.1: Baseline Filing of Market Based Rate Tariff to be effective 9/28/2011.

Filed Date: 09/28/2011.

Accession Number: 20110928–5107.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Docket Numbers: ER11–4668–000.

Applicants: NaturEner Montana Wind Energy 2, LLC.

Description: NaturEner Montana Wind Energy 2, LLC submits tariff filing per 35.1: Baseline Filing of Market Based Rate Tariff to be effective 9/28/2011.

Filed Date: 09/28/2011.

Accession Number: 20110928–5110.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Docket Numbers: ER11–4669–000.

Applicants: NaturEner Montana Wind Energy, LLC.

Description: NaturEner Montana Wind Energy, LLC submits tariff filing per 35.1: Baseline Filing of Market Based Rate Tariff to be effective 9/28/2011.

Filed Date: 09/28/2011.

Accession Number: 20110928–5114.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Docket Numbers: ER11–4670–000.

Applicants: NaturEner Power Watch, LLC.

Description: NaturEner Power Watch, LLC submits tariff filing per 35.1: Baseline Filing of Market Based Rate Tariff to be effective 9/28/2011.

Filed Date: 09/28/2011.

Accession Number: 20110928–5116.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Docket Numbers: ER11–4671–000.

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc. submits tariff filing per 35.13(a)(2)(iii: Implement Annual Updates to AEP Rate Formulas to be effective 7/1/2011.

Filed Date: 09/28/2011.

Accession Number: 20110928–5123.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Docket Numbers: ER11–4672–000.

Applicants: Griffiss Utility Services Corporation.

Description: Griffiss Utility Services Corporation submits tariff filing per 35.12: Application for MBR Authority to be effective 12/1/2011.

Filed Date: 09/28/2011.

Accession Number: 20110928–5126.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES11–51–000.

Applicants: PacifiCorp.

Description: Application for Authorization to Issue and Sell up to $1.5 Billion of Promissory Notes of Unsecured Short-Term Indebtedness of Pacificorp.

Filed Date: 09/27/2011.

Accession Number: 20110927–5157.

Comment Date: 5 p.m. Eastern Time on Tuesday, October 18, 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 28, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–26075 Filed 10–7–11; 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 corporate filings:

Docket Numbers: EC11–121–000.

Applicants: Alta Wind I, LLC, Alta Wind II, LLC, Alta Wind III, LLC, Alta Wind IV, LLC, Alta Wind V, LLC, Alta Wind VI, LLC, Alta Wind VIII, LLC, Alta Windpower Development, LLC.

Description: Application for Authorization for Disposition of Jurisdictional Facilities and Request for Expedited Action of Alta Wind I, LLC, et al.

Filed Date: 09/28/2011.

Accession Number: 20110928–5165.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2441–001.

Applicants: Central Vermont Public Service Corporation.

Description: Notice of Change in Status of Central Vermont Public Service Corporation.

Filed Date: 09/28/2011.

Accession Number: 20110928–5180.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Docket Numbers: ER11–3262–003.

Applicants: Trans Bay Cable LLC.

Description: Trans Bay Cable LLC submits tariff filing per 35: Compliance Filing for Corrected Title Page to be effective 9/28/2011.

Filed Date: 09/28/2011.

Accession Number: 20110928–5161.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Docket Numbers: ER11–4386–001.

Applicants: AmericaWide Energy, LLC.

Description: AmericaWide Energy, LLC submits tariff filing per 35.17(b): Amendment to Market-Based Rate Application to be effective 11/1/2011.

Filed Date: 09/29/2011.

Accession Number: 20110929–5040.

Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4673–000.

Applicants: Air Liquide Large Industries U.S. LP.

Description: Air Liquide Large Industries U.S. LP submits tariff filing per 35.1: Market-Based Rate Tariff to be effective 9/28/2011.

Filed Date: 09/28/2011.

Accession Number: 20110928–5127.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Docket Numbers: ER11–4674–000.

Applicants: Midwest Independent Transmission System Operator, Inc.

Description: Midwest Independent Transmission System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: Vectren-IMPA Facilities Connection Agreement to be effective 9/29/2011.

Filed Date: 09/28/2011.

Accession Number: 20110928–5146.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Docket Numbers: ER11–4675–000.

Applicants: Florida Power & Light Company

Description: Florida Power & Light Company submits tariff filing per 35.13(a)(2)(iii: FPL and City of Vero Beach First Revised Service Agreement No. 264 to be effective 10/1/2011.

Filed Date: 09/28/2011.

Accession Number: 20110928–5153.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Docket Numbers: ER11–4676–000.

Applicants: Puget Sound Energy, Inc.

Description: Puget Sound Energy, Inc. submits tariff filing per 35.12: Residential Exchange Program Settlement Implementation Agreemt Rate Schedule 620 to be effective 10/1/2011.

Filed Date: 09/28/2011.

Accession Number: 20110928–5156.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Docket Numbers: ER11–4677–000.

Applicants: NextEra Energy Montezuma II Wind, LLC.

Description: NextEra Energy Montezuma II Wind, LLC submits tariff filing per 35.12: NextEra Energy Montezuma II Wind, LLC Market-Based Rate Tariff to be effective 10/1/2011.

Filed Date: 09/28/2011.

Accession Number: 20110928–5160.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Docket Numbers: ER11–4678–000.

Applicants: Vasco Winds, LLC.

Description: Vasco Winds, LLC submits tariff filing per 35.12: Vasco Winds, LLC Market-Based Rate Tariff to be effective 10/1/2011.

Filed Date: 09/28/2011.

Accession Number: 20110928–5162.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Docket Numbers: ER11–4679–000.

Applicants: ITC Midwest LLC.

Description: ITC Midwest LLC submits tariff filing per 35.13(a)(2)(iii: Filing of Pole Attachment Agreement to be effective 9/28/2011.

Filed Date: 09/29/2011.

Accession Number: 20110929–5026.

Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4680–000.

Applicants: SIG Energy, LLLP.

Description: SIG Energy, LLLP submits tariff filing per 35.1: Baseline Filing to be effective 9/30/2011.

Filed Date: 09/29/2011.

Accession Number: 20110929–5046.

Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4681–000.

Applicants: Energy Consulting Services, LLC.

Description: Energy Consulting Services, LLC submits tariff filing per 35.12: ECS MBRA Baseline eTariff to be effective 9/30/2011.

Filed Date: 09/29/2011.

Accession Number: 20110929–5047

Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4682–000.

Applicants: Kuehne Chemical.

Description: Kuehne Chemical submits tariff filing per 35.12: Kuehne Chemical Company MBRA Baseline eTariff to be effective 9/30/2011.

Filed Date: 09/29/2011.

Accession Number: 20110929–5048.

Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4683–000.

Applicants: Elizabethtown Energy, LLC.

Description: Elizabethtown Energy, LLC submits tariff filing per 35.1: Elizabethtown Energy LLC Baseline MBR Filing to be effective 9/29/2011.

Filed Date: 09/29/2011.

Accession Number: 20110929–5050.

Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4684–000.

Applicants: Lumberton Energy, LLC

Description: Lumberton Energy, LLC submits tariff filing per 35.1: Lumberton Energy LLC Baseline MBR Filing to be effective 9/29/2011.

Filed Date: 09/29/2011.

Accession Number: 20110929–5051.

Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4685–000.

Applicants: KEB Trading LLC.

Description: KEB TRADING LLC submits a notice of cancellation.

Filed Date: 09/28/2011.

Accession Number: 20110928–0021.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 19, 2011.

Docket Numbers: ER11–4686–000.
Applicants: Goldfinch Capital Management, LP.
Description: Goldfinch Capital Management, LP submits tariff filing per 35.1: Goldfinch Capital Baseline Tariff Filing—Clone to be effective 9/29/2011.
Filed Date: 09/29/2011.
Accession Number: 20110929–5059.
Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4687–000.
Applicants: Arizona Public Service Company.
Description: Arizona Public Service Company submits tariff filing per 35.13(a)(2)(iii: Amendment to Service Agreement No. 215, Interconnection Agreement to be effective 9/12/2011.
Filed Date: 09/29/2011
Accession Number: 20110929–5062.
Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4688–000.
Applicants: Northeast Utilities Service Company, Western Massachusetts Electric Company.
Description: Northeast Utilities Service Company, on behalf of Western Massachusetts Electric Company Notification of Cancellation of Interconnection Operation and Maintenance Agreement between WMECO and MASSPOWER.
Filed Date: 09/29/2011.
Accession Number: 20110929–5066.
Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4689–000.
Applicants: Monarch Global Energy, Inc.
Description: Notice of Cancellation of Monarch Global Energy, Inc.
Filed Date: 09/29/2011.
Accession Number: 20110929–5068.
Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4690–000.
Applicants: Wisconsin Power and Light Company.
Description: Notice of Termination of Interconnection and Interchange Agreement between Northern States Power Companies and Wisconsin Power and Light Company.
Filed Date: 09/29/2011.
Accession Number: 20110929–5079.
Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4691–000.
Applicants: Icetec.com.
Description: Icetec.com submits tariff filing per 35.12: Icetec.com Baseline eTariff to be effective 9/30/2011.
Filed Date: 09/29/2011.
Accession Number: 20110929–5082.
Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4692–000.
Applicants: Vision Power Services, LLC.
Description: Vision Power Services, LLC submits tariff filing per 35.12: Vision Power Systems, LLC Baseline eTariff to be effective 9/30/2011.
Filed Date: 09/29/2011.
Accession Number: 20110929–5083.
Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4693–000.
Applicants: PJM Interconnection, LLC.
Description: PJM Interconnection, LLC submits tariff filing per 35.13(a)(2)(iii: Queue Position U1–059 & W1–056; Original Service Agreement Nos. 3071 & 3072 to be effective 8/30/2011.
Filed Date: 09/29/2011.
Accession Number: 20110929–5084.
Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES11–52–000.
Applicants: PPL Electric Utilities Corporation.
Description: Application under section 204 of PPL Electric Utilities Corporation.
Filed Date: 09/29/2011.
Accession Number: 20110929–5063.
Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 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 29, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–26073 Filed 10–7–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC11–124–000.
Applicants: Consolidated Edison Company of New York, Inc.
Description: Application of Consolidated Edison Company of New York, Inc. for an order pursuant to Section 203 of the Federal Power Act authorizing the purchase of short-term debt of Orange and Rockland Utilities, Inc.
Filed Date: 09/30/2011.
Accession Number: 20110930–5301.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–4048–001.
Applicants: Gratiot County Wind LLC.
Description: Gratiot County Wind LLC submits tariff filing per 35: Compliance Filing of Shared Facilities Agreement to be effective 9/28/2011.
Filed Date: 10/03/2011.
Accession Number: 20111003–5104.
Comment Date: 5 p.m. Eastern Time on Monday, October 24, 2011.

Docket Numbers: ER11–4049–001.
Applicants: Gratiot County Wind II LLC.
Description: Gratiot County Wind II LLC submits tariff filing per 35: Compliance Filing of Shared Facilities Agreement to be effective 9/28/2011.
Filed Date: 10/03/2011.
Accession Number: 20111003–5105.
Comment Date: 5 p.m. Eastern Time on Monday, October 24, 2011.

Docket Numbers: ER12–1–000.
Applicants: Energy Exchange Direct, LLC.
Description: Energy Exchange Direct, LLC submits tariff filing per 35.1: Energy Exchange Direct, LLC Electric Tariff Original Volume No 1 to be effective 10/1/2011.
Filed Date: 10/03/2011.
Accession Number: 20111003–5003.
Comment Date: 5 p.m. Eastern Time on Monday, October 24, 2011.

Docket Numbers: ER12–2–000.
Applicants: Major Lending, LLC.
Description: Major Lending, LLC submits tariff filing per 35.1: Major Lending, LLC Electric Tariff Original Volume No 1 to be effective 10/1/2011.
Filed Date: 10/03/2011.
Accession Number: 20111003–5004.

Comment Date: 5 p.m. Eastern Time on Monday, October 24, 2011.

Docket Numbers: ER12–3–000.
Applicants: PJM Interconnection, L.L.C.
Description: PJM Interconnection, L.L.C. submits tariff filing per 35.13(a)(2)(iii: Queue No. W3–145; Original Service Agreement No. 3064 to be effective 9/1/2011.
Filed Date: 10/03/2011.
Accession Number: 20111003–5063.
Comment Date: 5 p.m. Eastern Time on Monday, October 24, 2011.

Docket Numbers: ER12–4–000.
Applicants: PJM Interconnection, L.L.C.
Description: PJM Interconnection, L.L.C. submits tariff filing per 35.13(a)(2)(iii: Queue No. W3–146; Original Service Agreement No. 3065 to be effective 9/1/2011.
Filed Date: 10/03/2011.
Accession Number: 20111003–5081.
Comment Date: 5 p.m. Eastern Time on Monday, October 24, 2011.

Docket Numbers: ER12–5–000.
Applicants: Southwest Power Pool, Inc.
Description: Southwest Power Pool, Inc. submits tariff filing per 35.13(a)(2)(iii: 1154R6 Associated Electric Cooperative, Inc. NITSA NOA to be effective 9/1/2011.
Filed Date: 10/03/2011.
Accession Number: 20111003–5089.
Comment Date: 5 p.m. Eastern Time on Monday, October 24, 2011.

Docket Numbers: ER12–6–000.
Applicants: FirstEnergy Service Company, American Transmission Systems, Incorporation.
Description: Notice of Cancellation of ATSI Service Agreement No. 294 of FirstEnergy Service Company.
Filed Date: 10/03/2011.
Accession Number: 20111003–5094.
Comment Date: 5 p.m. Eastern Time on Monday, October 24, 2011.

Docket Numbers: ER12–7–000.
Applicants: ISO New England Inc., New England Power Pool Participants Committee.
Description: ISO New England Inc. submits tariff filing per 35.13(a)(2)(iii: Modify Tariff True-Up Provisions to be effective 1/1/2012.
Filed Date: 10/03/2011.
Accession Number: 20111003–5096.
Comment Date: 5 p.m. Eastern Time on Monday, October 24, 2011.

Docket Numbers: ER12–8–000.
Applicants: Invenergy Wind Development Michigan LLC.
Description: Invenergy Wind Development Michigan LLC submits tariff filing per 35.1: Compliance Filing of Facilities Use Agreement to be effective 9/27/2011.
Filed Date: 10/03/2011.
Accession Number: 20111003–5103.
Comment Date: 5 p.m. Eastern Time on Monday, October 24, 2011.

Docket Numbers: ER12–9–000.
Applicants: Invenergy Wind Development Michigan LLC.
Description: Invenergy Wind Development Michigan LLC submits tariff filing per 35.15: Cancellation of Tariff Identifier 62 to be effective 12/31/9998.
Filed Date: 10/03/2011.
Accession Number: 20111003–5106.
Comment Date: 5 p.m. Eastern Time on Monday, October 24, 2011.

Docket Numbers: ER12–10–000.
Applicants: Energy International Power Marketing.
Description: Energy International Power Marketing submits tariff filing per 35.1: EI Baseline Tariff to be effective 9/30/2011.
Filed Date: 10/03/2011.
Accession Number: 20111003–5140.
Comment Date: 5 p.m. Eastern Time on Monday, October 24, 2011.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES12–1–000.
Applicants: Northeast Utilities Service Company, The Connecticut Light and Power Company, Western Massachusetts Electric Company.
Description: Application of Northeast Utilities Service Company for The Connecticut Light and Power Company and WMECO Section 204 filing Form 523.
Filed Date: 10/03/2011.
Accession Number: 20111003–5107.
Comment Date: 5 p.m. Eastern Time on Monday, October 24, 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: October 3, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–26122 Filed 10–7–11; 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 exempt wholesale generator filings:

Docket Numbers: EG11–132–000.
Applicants: Pioneer Trail Wind Farm, LLC.
Description: Pioneer Trail Wind Farm, LLC, Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 09/29/2011.
Accession Number: 20110929–5120.
Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–4175–001.
Applicants: Arizona Public Service Company.
Description: Arizona Public Service Company submits tariff filing per 35: Compliance Filing to Add Title Page to Service Agreement No. 313 to be effective 8/31/2011.
Filed Date: 09/29/2011.
Accession Number: 20110929–5103.
Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4694–000.
Applicants: GSG 6, LLC.
Description: GSG 6, LLC submits tariff filing per 35.12: Market-Based Rate Application to be effective 12/1/2011.
Filed Date: 09/29/2011.
Accession Number: 20110929–5088.
Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4695–000.
Applicants: Hafslund Energy Trading LLC.
Description: Hafslund Energy Trading LLC submits tariff filing per 35.12: *Hafslund Baseline Tariff to be effective 9/29/2011.*
Filed Date: 09/29/2011.
Accession Number: 20110929–5092.
Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4696–000.
Applicants: NFI Solar, LLC.
Description: NFI Solar, LLC submits tariff filing per 35.1: Market-Based Rate Tariff Baseline to be effective 9/29/2011.
Filed Date: 09/29/2011.

Accession Number: 20110929–5093.
Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4697–000.
Applicants: PJM Interconnection, LLC.
Description: PJM Interconnection, LLC. submits tariff filing per 35.13(a)(2)(iii: Queue Position None—Original Service Agreement No. 3070 to be effective 8/30/2011.
Filed Date: 09/29/2011.
Accession Number: 20110929–5112.
Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4698–000.
Applicants: Somerset Power LLC.
Description: Somerset Power LLC submits tariff filing per 35.15: Cancellation of Market-Based Rate Tariff to be effective 9/30/2011.
Filed Date: 09/29/2011.
Accession Number: 20110929–5115.
Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4699–000.
Applicants: PJM Interconnection, LLC.
Description: PJM Interconnection, LLC submits tariff filing per 35.13(a)(2)(iii: Queue Position None—Original Service Agreement No. 3069 to be effective 8/30/2011.
Filed Date: 09/29/2011.
Accession Number: 20110929–5128.
Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4700–000.
Applicants: Southwest Power Pool, Inc.
Description: Southwest Power Pool, Inc. submits tariff filing per 35.13(a)(2)(iii: 2252 Cottonwood Wind Project GIA to be effective 8/31/2011.
Filed Date: 09/29/2011.
Accession Number: 20110929–5129.
Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4701–000.
Applicants: The Highlands Energy Group.
Description: The Highlands Energy Group submits tariff filing per 35.1: Market Based Rates to be effective 9/30/2011.
Filed Date: 09/29/2011.
Accession Number: 20110929–5147.
Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4702–000.
Applicants: PJM Interconnection, LLC.
Description: PJM Interconnection, LLC submits tariff filing per 35.13(a)(2)(iii: Quarterly Updates to PJM OA and RAA Membership Lists to be effective 9/23/2011.
Filed Date: 09/29/2011.
Accession Number: 20110929–5155.
Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4703–000.
Applicants: Avista Corporation.
Description: Avista Corporation submits tariff filing per 35.13(a)(2)(iii: Avista Corp OATT revisions Attachments F, G and I to be effective 10/1/2011.
Filed Date: 09/29/2011.
Accession Number: 20110929–5165.
Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4704–000.
Applicants: Black Hills Power, Inc.
Description: Black Hills Power, Inc. submits tariff filing per 35.13(a)(2)(iii: Revised BH Power, Inc., JOATT to Eliminate WAPA–RMR References to be effective 9/30/2011.
Filed Date: 09/29/2011.
Accession Number: 20110929–5177.
Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4705–000.
Applicants: Louisville Gas and Electric Company.
Description: Louisville Gas and Electric Company submits tariff filing per 35.13(a)(2)(iii: 09_29_11 Amended and Restated EKPC IA to be effective 11/30/2011.
Filed Date: 09/29/2011.
Accession Number: 20110929–5178.
Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4705–000.
Applicants: Louisville Gas and Electric Company.
Description: Louisville Gas and Electric Company submits tariff filing per 35.13(a)(2)(iii: 09_29_11 Amended and Restated EKPC IA to be effective 11/30/2011.
Filed Date: 09/29/2011.
Accession Number: 20110929–5179.
Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4706–000.
Applicants: Viridity Energy, Inc.
Description: Viridity Energy, Inc. submits tariff filing per 35.12: MBR Application of Viridity Energy, Inc. to be effective 11/28/2011.
Filed Date: 09/29/2011.
Accession Number: 20110929–5180.
Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4707–000.
Applicants: Kentucky Utilities Company.
Description: Kentucky Utilities Company submits tariff filing per 35.13(a)(2)(iii): LGE and KU Joint Rate Schedule FERC No. 500 to be effective 11/30/2011.
Filed Date: 09/29/2011.
Accession Number: 20110929–5181.
Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4708–000.
Applicants: Arizona Public Service Company.
Description: Arizona Public Service Company submits tariff filing per 35.13(a)(2)(iii: Filing To Remove RMS Requirement From Multiple Service Agreements to be effective 9/21/2011.
Filed Date: 09/29/2011.
Accession Number: 20110929–5182.
Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4714–000.
Applicants: Niagara Mohawk Power Corporation.
Description: Notice of Termination of Service Agreement No. 309 by Niagara Mohawk Power Corporation.
Filed Date: 09/29/2011.
Accession Number: 20110929–5188.
Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

Docket Numbers: ER11–4715–000.
Applicants: Puget Sound Energy, Inc.
Description: Termination of the Short-Term Bridge Residential Purchase and Sale Agreement, Rate Schedule FERC No. 448.
Filed Date: 09/29/2011.
Accession Number: 20110929–5226.
Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 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 30, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–26080 Filed 10–7–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC11–122–000.
Applicants: TPW Petersburg, LLC.
Description: Application for Authorization for Disposition of Jurisdictional Facilities and Request for Expedited Action of TPW Petersburg, LLC.
Filed Date: 09/30/2011.
Accession Numbers: 20110930–5139.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2869–002.
Applicants: Midwest Independent Transmission System Operator, Inc.
Description: Midwest Independent Transmission System Operator, Inc. submits tariff filing per 35: 9–30–11 Module B, Cross Border Out Compliance II to be effective 11/22/2010.
Filed Date: 09/30/2011.
Accession Numbers: 20110930–5088.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Docket Numbers: ER11–2657–001.
Applicants: Milford Wind Corridor Phase II, LLC.
Description: Notification of Non-Material Change in Status by Milford Wind Corridor Phase II, LLC.
Filed Date: 09/30/2011.
Accession Numbers: 20110930–5193.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Docket Numbers: ER11–4709–000.
Applicants: Texzon Utilities, Ltd.
Description: Texzon Utilities, Ltd. submits tariff filing per 35.1: Texzon Utilities Baseline Tariff Filing to be effective 9/29/2011.
Filed Date: 09/30/2011.
Accession Numbers: 20110930–5000.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Docket Numbers: ER11–4710–000.
Applicants: Avista Corporation.
Description: Avista Corporation submits tariff filing per 35.12: Avista Corp NITSA filing to be effective 10/1/2011.
Filed Date: 09/30/2011.
Accession Numbers: 20110930–5004.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Docket Numbers: ER11–4711–000.
Applicants: R&R Energy, Inc.
Description: R&R Energy, Inc. submits tariff filing per 35.1: R & R Baseline Tariff to be effective 9/29/2011.
Filed Date: 09/30/2011.
Accession Numbers: 20110930–5005.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Docket Numbers: ER11–4712–000.
Applicants: GGBB Energy, Inc.
Description: GGBB Energy, Inc. submits tariff filing per 35.1: GGBB Baseline Tariff to be effective 9/29/2011.
Filed Date: 09/30/2011.
Accession Numbers: 20110930–5007.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Docket Numbers: ER11–4713–000.
Applicants: NCSU Energy, Inc.
Description: NCSU Energy, Inc. submits tariff filing per 35.1: NCSU Energy Baseline Tariff to be effective 9/29/2011.
Filed Date: 09/30/2011.
Accession Numbers: 20110930–5008.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Docket Numbers: ER11–4716–000.
Applicants: Energy Alternatives, Inc.
Description: Energy Alternatives, Inc. submits tariff filing per 35.1: FERC Baseline Electric Tariff to be effective 9/30/2011.
Filed Date: 09/30/2011.
Accession Numbers: 20110930–5080.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Docket Numbers: ER11–4717–000.
Applicants: International Paper Company.
Description: International Paper Company submits tariff filing per 35.1: International Paper Company MBR Filing 2011–09–30 to be effective 9/30/2011.
Filed Date: 09/30/2011.
Accession Numbers: 20110930–5083.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Docket Numbers: ER11–4718–000.
Applicants: Gateway Energy Marketing.
Description: Gateway Energy Marketing submits tariff filing per 35.1: Gateway Market-Based Rate Baseline Filing to be effective 9/30/2011.
Filed Date: 09/30/2011.
Accession Numbers: 20110930–5108.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Docket Numbers: ER11–4719–000.
Applicants: Continental Electric Cooperative Service
Description: Continental Electric Cooperative Services, Inc. submits tariff filing per 35.1: CCS Market Based Rate Filing to be effective 9/30/2011.
Filed Date: 09/30/2011.
Accession Numbers: 20110930–5124.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Docket Numbers: ER11–4720–000.
Applicants: PacifiCorp.
Description: PacifiCorp submits tariff filing per 35.13(a)(2)(iii: BPA Agreement for Work at Hat Rock Switching Station to be effective 11/30/2011.
Filed Date: 09/30/2011.
Accession Numbers: 20110930–5137.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Docket Numbers: ER11–4721–000.
Applicants: New Hope Power Partnership.
Description: New Hope Power Partnership submits tariff filing per 35.1: New Hope FERC Electric Tariff Baseline Filing to be effective 9/30/2011.
Filed Date: 09/30/2011.
Accession Numbers: 20110930–5141.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Docket Numbers: ER11–4722–000.
Applicants: Allied Energy Resources Corporation.
Description: Allied Energy Resources Corporation submits tariff filing per 35.1: Base line filing to be effective 10/3/2011.
Filed Date: 09/30/2011.
Accession Numbers: 20110930–5142.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Docket Numbers: ER11–4723–000.
Applicants: Southern California Edison Company.
Description: Southern California Edison Company submits tariff filing per 35.13(a)(2)(iii: LGIA WDAT SERV AG SCE-Wellhead Power Delano LLC, Wellhead Power Delano Proj to be effective 10/3/2011.
Filed Date: 09/30/2011.
Accession Numbers: 20110930–5144.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Docket Numbers: ER11–4724–000.
Applicants: Northern States Power Company, a Minnesota.
Description: Northern States Power Company, a Minnesota corporation submits tariff filing per 35.13(a)(2)(iii: 2011–09–30_CAPX_Fargo_Phase-2_CMA_306_0.1.0 to be effective 8/12/2011.
Filed Date: 09/30/2011.
Accession Numbers: 20110930–5145.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Docket Numbers: ER11–4725–000.
Applicants: APN Starfirst, LP.
Description: APN Starfirst, LP submits tariff filing per 35.1: APN Starfirst, LP,

Rate Schedule FERC No. 1 to be effective 9/30/2011.

Filed Date: 09/30/2011.

Accession Numbers: 20110930–5150.

Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Docket Numbers: ER11–4726–000.

Applicants: PJM Interconnection, L.L.C.

Description: PJM Interconnection, L.L.C. submits tariff filing per 35.13(a)(2)(iii: Queue No. W3–078; Original Service Agreement No. 3063 to be effective 9/1/2011.

Filed Date: 09/30/2011.

Accession Numbers: 20110930–5156.

Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES11–43–000.

Applicants: El Paso Electric Company.

Description: Supplement to Application of El Paso Electric Company.

Filed Date: 09/30/2011.

Accession Numbers: 20110930–5095.

Comment Date: 5 p.m. Eastern Time on Tuesday, October 11, 2011.

Take notice that the Commission received the following qualifying facility filings:

Docket Numbers: QF11–515–000.

Applicants: Air Products and Chemicals, Inc.

Description: Form 556 of Air Products LLC.

Filed Date: 09/29/2011.

Accession Numbers: 20110929–5017.

Comment Date: 5 p.m. Eastern Time on Thursday, October 20, 2011.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

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Dated: September 30, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–26079 Filed 10–7–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP11–2531–000.

Applicants: Stingray Pipeline Company, LLC.

Description: Stingray Pipeline Company, LLC submits tariff filing per 154.206: motion filing to be effective 10/1/2011.

Filed Date: 09/30/2011.

Accession Number: 20110930–5001.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2617–000.

Applicants: Midcontinent Express Pipeline LLC.

Description: Midcontinent Express Pipeline LLC submits tariff filing per 154.204: Filing to Remove Expired Tenaska Agreement to be effective 11/1/2011.

Filed Date: 09/29/2011.

Accession Number: 20110929–5078.

Comment Date: 5 p.m. Eastern Time on Tuesday, October 11, 2011.

Docket Numbers: RP11–2618–000.

Applicants: Williston Basin Interstate Pipeline Company.

Description: Williston Basin Interstate Pipeline Company submits tariff filing per 154.204: Mutual Contract Extension to be effective 10/30/2011.

Filed Date: 09/29/2011.

Accession Number: 20110929–5080.

Comment Date: 5 p.m. Eastern Time on Tuesday, October 11, 2011.

Docket Numbers: RP11–2619–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: Transcontinental Gas Pipe Line Company, LLC submits tariff filing per 154.501: Annual Cash-Out Report Period Ending July 31, 2011 to be effective N/A.

Filed Date: 09/29/2011.

Accession Number: 20110929–5102.

Comment Date: 5 p.m. Eastern Time on Tuesday, October 11, 2011.

Docket Numbers: RP11–2620–000.

Applicants: Maritimes & Northeast Pipeline, LLC.

Description: Maritimes & Northeast Pipeline, LLC submits tariff filing per 154.403(d)(2): MNUS FRQ 2011 to be effective 11/1/2011.

Filed Date: 09/29/2011.

Accession Number: 20110929–5104.

Comment Date: 5 p.m. Eastern Time on Tuesday, October 11, 2011.

Docket Numbers: RP11–2621–000.

Applicants: Natural Gas Pipeline Company of America LLC.

Description: Natural Gas Pipeline Company of America LLC submits tariff filing per 154.204: Remove Expired/Expiring Agreements to be effective 11/1/2011.

Filed Date: 09/29/2011.

Accession Number: 20110929–5118.

Comment Date: 5 p.m. Eastern Time on Tuesday, October 11, 2011.

Docket Numbers: RP11–2622–000.

Applicants: CenterPoint Energy Gas Transmission Company, LLC.

Description: CenterPoint Energy Gas Transmission Company, LLC submits tariff filing per 154.204: CEGT LLC—Material Deviations Filing—September 2011 to be effective 10/30/2011.

Filed Date: 09/29/2011.

Accession Number: 20110929–5152.

Comment Date: 5 p.m. Eastern Time on Tuesday, October 11, 2011.

Docket Numbers: RP11–2623–000.

Applicants: Gas Transmission Northwest LLC.

Description: Gas Transmission Northwest LLC submits tariff filing per 154.204: Medford Extension Rate Increase to be effective 11/1/2011.

Filed Date: 09/30/2011.

Accession Number: 20110930–5033.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2624–000.

Applicants: Big Sandy Pipeline, LLC.

Description: Big Sandy Pipeline, LLC submits tariff filing per 154.204: Revised EQT Energy Negotiated Rate Agreement to be effective 10/1/2011.

Filed Date: 09/30/2011.

Accession Number: 20110930–5035.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2625–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: Transcontinental Gas Pipe Line Company, LLC submits tariff filing per 154.402: GSS LSS SS–2 S–2 2011 TGPL ACA Tracker Filing to be effective 10/1/2011.

Filed Date: 09/30/2011.

Accession Number: 20110930–5036.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2626–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: Transcontinental Gas Pipe Line Company, LLC submits tariff

filing per 154.403(d)(2): LNG Fuel Tracker Filing to be effective 11/1/2011.
Filed Date: 09/30/2011.
Accession Number: 20110930–5048.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2627–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: Algonquin Gas Transmission, LLC submits tariff filing per 154.204: Non-conforming Agreement with Nextera to be effective 10/1/2011.
Filed Date: 09/30/2011.
Accession Number: 20110930–5053.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2628–000.
Applicants: Kern River Gas Transmission Company.
Description: Kern River Gas Transmission Company submits tariff filing per 154.204: 2011 Pooling, Ivanpah to be effective 11/1/2011.
Filed Date: 09/30/2011.
Accession Number: 20110930–5054.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2629–000.
Applicants: Texas Gas Transmission, LLC.
Description: Texas Gas Transmission, LLC submits tariff filing per 154.403(d)(2): 2011 Fuel Tracker Filing to be effective 11/1/2011.
Filed Date: 09/30/2011.
Accession Number: 20110930–5058.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2630–000.
Applicants: Texas Gas Transmission, LLC.
Description: Texas Gas Transmission, LLC submits tariff filing per 154.204: ProLiance Negotiated Rate Agreements Filing to be effective 10/1/2011.
Filed Date: 09/30/2011.
Accession Number: 20110930–5063.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2631–000.
Applicants: Colorado Interstate Gas Company.
Description: Colorado Interstate Gas Company submits tariff filing per 154.204: Totem Withdrawal/ Deliverability Curve Change to be effective 11/1/2011.
Filed Date: 09/30/2011.
Accession Number: 20110930–5067.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2632–000.
Applicants: Texas Gas Transmission, LLC.
Description: Texas Gas Transmission, LLC submits tariff filing per 154.204: NICOR Amendment to Negotiated Rate Agreement to be effective 10/1/2011.
Filed Date: 09/30/2011.
Accession Number: 20110930–5071.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2633–000.
Applicants: Iroquois Gas Transmission System, L.P.
Description: Iroquois Gas Transmission System, L.P. submits tariff filing per 154.403: 09/30/11 DAS Termination to be effective 11/1/20110.
Filed Date: 09/30/2011.
Accession Number: 20110930–5075.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2634–000.
Applicants: Williston Basin Interstate Pipeline Company.
Description: Williston Basin Interstate Pipeline Company submits tariff filing per 154.204: 2011 Account 191 Filing to be effective 9/30/2011.
Filed Date: 09/30/2011.
Accession Number: 20110930–5094.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2635–000.
Applicants: CenterPoint Energy Gas Transmission Company, LLC.
Description: CenterPoint Energy Gas Transmission Company, LLC submits tariff filing per 154.204: CEGT LLC—October 2011 Negotiated Rate Filing to be effective 10/1/2011.
Filed Date: 09/30/2011.
Accession Number: 20110930–5101.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2636–000.
Applicants: Dauphin Island Gathering Partners.
Description: Dauphin Island Gathering Partners submits tariff filing per 154.204: Negotiated Rates 2011–09–30 to be effective 10/1/2011.
Filed Date: 09/30/2011.
Accession Number: 20110930–5102.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2637–000.
Applicants: Williston Basin Interstate Pipeline Company.
Description: Williston Basin Interstate Pipeline Company submits tariff filing per 154.204: Non-Conforming Service Agreements—Baker Expansion to be effective 11/1/2011.
Filed Date: 09/30/2011.
Accession Number: 20110930–5106.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2638–000.
Applicants: Midwestern Gas Transmission Company.
Description: Midwestern Gas Transmission Company submits tariff filing per 154.204: NonConforming Agreements—BP, et al to be effective 11/1/2011.
Filed Date: 09/30/2011.
Accession Number: 20110930–5107.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2639–000.
Applicants: Northern Border Pipeline Company.
Description: Northern Border Pipeline Company submits tariff filing per 154.601: Ameren Non-conforming Agreement to be effective 12/31/9998.
Filed Date: 09/30/2011.
Accession Number: 20110930–5109.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2640–000.
Applicants: Kinder Morgan Interstate Gas Transmission LLC.
Description: Kinder Morgan Interstate Gas Transmission LLC submits tariff filing per 154.204: Negotiated Rate 2011–09–30 Enserco to be effective 10/1/2011.
Filed Date: 09/30/2011.
Accession Number: 20110930–5116.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2641–000.
Applicants: Williston Basin Interstate Pipeline Company.
Description: Annual Report of Penalty Revenue Credits of Williston Basin Interstate Pipeline Company.
Filed Date: 09/30/2011.
Accession Number: 20110930–5143.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2642–000.
Applicants: Columbia Gas Transmission, LLC.
Description: Columbia Gas Transmission, LLC submits tariff filing per 154.204: Service Agreements—Non-Conforming Clean Up to be effective 11/1/2011.
Filed Date: 09/30/2011.
Accession Number: 20110930–5146.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2643–000.
Applicants: Panhandle Eastern Pipe Line Company, LP.
Description: Panhandle Eastern Pipe Line Company, LP submits tariff filing per 154.204: Fuel Filing on 9–30–2011 to be effective 11/1/2011.
Filed Date: 09/30/2011.
Accession Number: 20110930–5147.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2644–000.
Applicants: Carolina Gas Transmission Corporation.
Description: Carolina Gas Transmission Corporation submits tariff

filing per 154.204: 2011 FRQ & TDA Filing to be effective 11/1/2011.

Filed Date: 09/30/2011.

Accession Number: 20110930–5148.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2645–000.

Applicants: Southwest Gas Storage Company.

Description: Southwest Gas Storage Company submits tariff filing per 154.204: Fuel Filing on 9–30–2011 to be effective 11/1/2011.

Filed Date: 09/30/2011.

Accession Number: 20110930–5149.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2646–000.

Applicants: Trunkline Gas Company, LLC.

Description: Trunkline Gas Company, LLC submits tariff filing per 154.204: Fuel Filing on 9–30–11 to be effective 11/1/2011.

Filed Date: 09/30/2011.

Accession Number: 20110930–5160.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2647–000.

Applicants: Trunkline Gas Company, LLC.

Description: Trunkline Gas Company, LLC submits tariff filing per 154.203: Annual Report of Flow Through filed on 9–30–11 to be effective N/A.

Filed Date: 09/30/2011.

Accession Number: 20110930–5168.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2648–000.

Applicants: PetroLogistics Natural Gas Storage, LLC.

Description: PetroLogistics Natural Gas Storage, LLC submits tariff filing per 154.204: Revision to Adopt Section for the Operational Purchase and Sale of Gas to be effective 10/31/2011.

Filed Date: 09/30/2011.

Accession Number: 20110930–5179.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2649–000.

Applicants: Tennessee Gas Pipeline Company.

Description: Tennessee Gas Pipeline Company submits tariff filing per 154.204: 300 Line Project Recourse Rate to be effective 11/1/2011.

Filed Date: 09/30/2011.

Accession Number: 20110930–5225.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2650–000.

Applicants: Dominion Transmission, Inc.

Description: Dominion Transmission, Inc. submits tariff filing per 154.403: DTI—2011 Annual EPCA to be effective 11/1/2011.

Filed Date: 09/30/2011.

Accession Number: 20110930–5231.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2651–000.

Applicants: Dominion Transmission, Inc.

Description: Dominion Transmission, Inc. submits tariff filing per 154.403(d)(2): DTI—2011 Annual TCRA to be effective 11/1/2011.

Filed Date: 09/30/2011.

Accession Number: 20110930–5236.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2652–000.

Applicants: ANR Pipeline Company.

Description: ANR Pipeline Company submits tariff filing per 154.601: Wisconsin Non-Conforming Agreements to be effective 11/1/2011.

Filed Date: 09/30/2011.

Accession Number: 20110930–5251.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2653–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: Algonquin Gas Transmission, LLC submits tariff filing per 154.204: GDF SUEZ Agreements to be effective 10/1/2011.

Filed Date: 09/30/2011.

Accession Number: 20110930–5262.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2654–000.

Applicants: Columbia Gulf Transmission Company.

Description: Columbia Gulf Transmission Company submits tariff filing per 154.204: Service Agreements—Non-Conforming Clean Up to be effective 11/1/2011.

Filed Date: 09/30/2011.

Accession Number: 20110930–5266.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Docket Numbers: RP11–2655–000.

Applicants: Tennessee Gas Pipeline Company.

Description: Tennessee Gas Pipeline Company submits tariff filing per 154.204: Negotiated Non-Conforming ETQ Energy—Line 300 Project to be effective 11/1/2011.

Filed Date: 09/30/2011.

Accession Number: 20110930–5268.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

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.

Filings in Existing Proceedings

Docket Numbers: RP11–1957–002.

Applicants: Stingray Pipeline Company, LLC.

Description: Stingray Pipeline Company, LLC submits tariff filing per 154.203: Motion to Place Rates into Effect to be effective 10/1/2011.

Filed Date: 09/29/2011.

Accession Number: 20110929–5151.

Comment Date: 5 p.m. Eastern Time on Tuesday, October 11, 2011.

Docket Numbers: RP11–2611–001.

Applicants: Southern Star Central Gas Pipeline, Inc.

Description: Southern Star Central Gas Pipeline, Inc. submits tariff filing per 154.205(b): Scheduling Priorities—November 1 Effective Date (Related to RP11–2135) to be effective 11/1/2011.

Filed Date: 09/29/2011.

Accession Number: 20110929–5049.

Comment Date: 5 p.m. Eastern Time on Tuesday, October 11, 2011.

Docket Numbers: RP11–1957–003.

Applicants: Stingray Pipeline Company, LLC.

Description: Stingray Pipeline Company, LLC submits tariff filing per 154.203: Motion to Place Rates Into Effect to be effective 10/1/2011.

Filed Date: 09/30/2011.

Accession Number: 20110930–5151.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, and service 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: October 3, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–26078 Filed 10–7–11; 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 corporate filings:

Docket Numbers: EC11–123–000.
Applicants: MidAmerican Energy Company.
Description: Section 203 Application of MidAmerican Energy Company.
Filed Date: 09/30/2011.
Accession Number: 20110930–5291.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG11–133–000.
Applicants: GSG 6, LLC.
Description: Notice of GSG 6, LLC of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 09/30/2011.
Accession Number: 20110930–5175.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–4423–001.
Applicants: Lockport Energy Associates, LP.
Description: Second triennial market power analysis of Lockport Energy Associates, LP.
Filed Date: 09/30/2011.
Accession Number: 20110930–5290.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Docket Numbers: ER11–4727–000.
Applicants: Celerity Energy Partners San Diego LLC.
Description: Celerity Energy Partners San Diego LLC submits tariff filing per 35.1: Celerity Energy Partners San Diego LLC MBR Tariff to be effective 9/30/2011.
Filed Date: 09/30/2011.
Accession Number: 20110930–5184.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Docket Numbers: ER11–4728–000.
Applicants: Massachusetts Electric Company.
Description: Massachusetts Electric Company submits tariff filing per 35.13(a)(2)(iii: Rate Update Filing for Massachusetts Electric Borderline Sales Agreement to be effective 3/5/2011.
Filed Date: 09/30/2011.
Accession Number: 20110930–5186.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Docket Numbers: ER11–4729–000.
Applicants: APN Starfirst, LP.
Description: APN Starfirst, LP submits tariff filing per 35: APN Starfirst LP, Rate Schedule FERC No. 1 to be effective N/A.
Filed Date: 09/30/2011.
Accession Number: 20110930–5208.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Docket Numbers: ER11–4730–000.
Applicants: Las Vegas Power Company, LLC.
Description: Las Vegas Power Company, LLC submits tariff filing per 35.13(a)(2)(iii: Reactive Service Rate Schedule to be effective 10/1/2011.
Filed Date: 09/30/2011.
Accession Number: 20110930–5219.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Docket Numbers: ER11–4731–000.
Applicants: Xcel Energy Services Inc., Northern States Power Company, a Minnesota corporation, Northern States Power Company, a Wisconsin corporation.
Description: Xcel Energy Services, Inc. on behalf of Northern States Power Companies, submits a Notice of Termination of FERC Electric Rate Schedule No. 4.
Filed Date: 09/30/2011.
Accession Number: 20110930–5232.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Docket Numbers: ER11–4732–000.
Applicants: California Independent System Operator Corporation
Description: California Independent System Operator Corporation submits tariff filing per 35.13(a)(2)(iii: 2011–09–30 Pseudo PGA with Mesquite Solar 1 to be effective 11/1/2011.
Filed Date: 09/30/2011.
Accession Number: 20110930–5255.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Docket Numbers: ER11–4733–000.
Applicants: California Independent System Operator Corporation.
Description: California Independent System Operator Corporation submits tariff filing per 35.13(a)(2)(iii: 2011–09–30 SCP–QF Forced Outage Amendment to be effective 12/1/2011.
Filed Date: 09/30/2011.
Accession Number: 20110930–5264.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Docket Numbers: ER11–4734–000.
Applicants: New England Power Pool Participants Committee.
Description: New England Power Pool Participants Committee submits tariff filing per 35.13(a)(2)(iii: Oct 2011 Membership Filing to be effective 9/1/2011.
Filed Date: 09/30/2011.
Accession Number: 20110930–5265.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Docket Numbers: ER11–4735–000.
Applicants: Pacific Gas and Electric Company.
Description: Pacific Gas and Electric Company submits tariff filing per 35.13(a)(2)(iii: Western USBR TFA for Red Bluff Pumping Plant to be effective 10/3/2011.
Filed Date: 09/30/2011.
Accession Number: 20110930–5267.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Docket Numbers: ER11–4736–000.
Applicants: Centaurus Energy Master Fund, LP.
Description: Notice of Cancellation of Market-Based Rate FERC Tariff of Centaurus Energy Master Fund, LP.
Filed Date: 09/30/2011.
Accession Number: 20110930–5287.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Docket Numbers: ER11–4737–000.
Applicants: Patriot Partnership, LLC.
Description: Notice of Cancellation of Patriot Partnership LLC.
Filed Date: 09/30/2011.
Accession Number: 20110930–5288.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Docket Numbers: ER11–4738–000.
Applicants: California Independent System Operator Corporation.
Description: Petition for Distribution of Forfeited Funds Collected in Connection with Processing Generator Interconnection Requests of the California Independent System Operator Corporation.
Filed Date: 09/30/2011.
Accession Number: 20110930–5297.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 2011.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES11–53–000.
Applicants: System Energy Resources, Inc.
Description: Application for Authority under FPA Section 204 of System Energy Resources, Inc.
Filed Date: 09/30/2011.
Accession Number: 20110930–5286.
Comment Date: 5 p.m. Eastern Time on Friday, October 21, 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: October 3, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–26123 Filed 10–7–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12715–003]

Fairlawn Hydroelectric Company, LLC; Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's regulations, 18 CFR part 380, the Office of Energy Projects has reviewed the application for an original license for the proposed 14,000-kilowatt (kW) Jennings Randolph Hydroelectric Project located on the North Branch Potomac River in Garrett County, Maryland and Mineral County, West Virginia, at the U.S. Army Corps of Engineers' (Corps) Jennings Randolph Dam and has prepared an environmental assessment (EA). In the EA, Commission staff assess the potential environmental effects of licensing the project and conclude that issuing a license for the project, with appropriate environmental measures, would not constitute a major Federal action significantly affecting the quality of the human environment.

A copy of the EA is on file with the Commission and is available for public inspection. The final EA may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or for TTY, (202) 502–8659.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Comments on the EA should be filed within 30 days from the issuance date of this notice, and should be addressed to the Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Room 1–A, Washington, DC 20426. Please affix ''Jennings Randolph Hydroelectric Project No. 12715–003'' to all comments. Comments may be filed electronically via Internet in lieu of paper. The Commission strongly encourages electronic filings.

See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''eFiling'' link. For further information contact Allyson Conner at (202) 502–6082.

Dated: October 3, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–26117 Filed 10–7–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RC11–6–000]

North American Electric Reliability Corporation; Notice of Filing

Take notice that on September 30, 2011, the North American Electric Reliability Corporation (NERC) filed a petition requesting Federal Energy Regulatory Commission (Commission) approval of new enforcement mechanisms and submitted initial informational filing regarding NERC's efforts to refocus implementation of its compliance monitoring and enforcement program.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on October 21, 2011.

Dated: October 3, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–26116 Filed 10–7–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER11–4672–000]

Griffiss Utility Services Corporation; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Griffiss Utility Services Corporation's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard

to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is October 18, 2011.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: September 28, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–26074 Filed 10–7–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER11–4706–000]

Viridity Energy, Inc.; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Viridity Energy, Inc.'s application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is October 24, 2011.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: October 4, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–26124 Filed 10–7–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER11–4694–000]

GSG 6, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of GSG 6, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is October 24, 2011.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: October 4, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–26121 Filed 10–7–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2503–147]

Duke Energy Carolinas, LLC; Notice of Meetings To Discuss Resource Issues Related to the Relicensing of the Keowee-Toxaway Hydroelectric Project

a. *Dates and Times of Meetings:*

Duke Energy Carolinas, LLC (Duke) Water Quantity and Operations Resource Committee: Thursday, October 13, 2011, 10 a.m. to 1 p.m.

Duke Stakeholder Team and Shoreline Management Resource Committee: Wednesday, October 26, 2011, 10 a.m. to 3 p.m.

b. *Place:* Duke Energy Carolina, LLC's—Wenwood Operations Center*, 425 Fairforest Way, Greenville, SC 29607.

c. *FERC Contact:* Stephen Bowler at (202) 505–6861 or *stephen.bowler@ferc.gov.*

d. *Purpose of Meetings:* Duke is holding regular meetings of its resource committees and stakeholder team as part of its consultation effort under the Integrated Licensing Process. Commission staff will attend the meetings (in person and by telephone) for the purpose of establishing an open dialogue regarding Commission procedures for addressing resource and settlement issues.

e. *Discussion of Proposed Agendas:*

Duke Energy Carolinas, LLC (Duke) Water Quantity and Operations Resource Committee: Operations models.

Duke Stakeholder Team and Shoreline Management Resource Committee: Summary of Commission Policy on Settlement Agreements; Presentation Regarding the Comparison of Historic Aerial Photography to More Recent Photography to Assess Erosion of the Islands in Lake Keowee.

g. All local, state, and federal agencies, Indian tribes, and other interested parties are invited to participate. Please e-mail Elana Kimbrell at ekimbrell@kearnswest.com to register to participate.

Dated: October 3, 2011,

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–26119 Filed 10–7–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of FERC Staff Attendance at the Entergy Regional State Committee Work Group and Stakeholder Meeting

The Federal Energy Regulatory Commission hereby gives notice that members of its staff may attend the meeting noted below. Their attendance is part of the Commission's ongoing outreach efforts.

Entergy Regional State Committee Work Group and Stakeholder Meeting

October 19, 2011 (9 a.m.–3 p.m.)

This meeting will be held at the Pan American Life Center, 601 Poydras Street, New Orleans, LA 70130.

The discussions may address matters at issue in the following proceedings:

Docket No. OA07–32	Entergy Services, Inc.
Docket No. EL00–66	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL01–88	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL07–52	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL08–51	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL08–60	*Ameren Services Co.* v. *Entergy Services, Inc.*
Docket No. EL09–43	*Arkansas Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL09–50	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL09–61	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL10–55	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL10–65	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL11–34	Midwest Independent System Transmission Operator, Inc.
Docket No. ER05–1065	Entergy Services, Inc.
Docket No. ER07–682	Entergy Services, Inc.
Docket No. ER07–956	Entergy Services, Inc.
Docket No. ER08–1056	Entergy Services, Inc.
Docket No. ER09–833	Entergy Services, Inc.
Docket No. ER09–1224	Entergy Services, Inc.
Docket No. ER10–794	Entergy Services, Inc.
Docket No. ER10–1350	Entergy Services, Inc.
Docket No. ER10–1676	Entergy Services, Inc.
Docket No. ER10–2001	Entergy Arkansas, Inc.
Docket No. ER10–2161	Entergy Texas, Inc.
Docket No. ER10–2748	Entergy Services, Inc.
Docket No. ER10–3357	Entergy Arkansas, Inc.
Docket No. ER11–2131	Entergy Arkansas, Inc.
Docket No. ER11–2132	Entergy Gulf States, Louisiana, LLC.
Docket No. ER11–2133	Entergy Gulf States, Louisiana, LLC.
Docket No. ER11–2134	Entergy Mississippi, Inc.
Docket No. ER11–2135	Entergy New Orleans, Inc.
Docket No. ER11–2136	Entergy Texas, Inc.
Docket No. ER11–2161	Entergy Texas, Inc.
Docket No. ER11–3156	Entergy Arkansas, Inc.
Docket No. ER11–3157	Entergy Arkansas, Inc.
Docket No. ER11–3274	Entergy Arkansas, Inc.
Docket No. ER11–3728	Midwest Independent Transmission System Operator, Inc.
Docket No. ER11–3657	Entergy Arkansas, Inc.
Docket No. ER11–3658	Entergy Arkansas, Inc.

* Registration is required. Please see item g. below.

These meetings are open to the public.

For more information, contact Patrick Clarey, Office of Energy Market Regulation, Federal Energy Regulatory Commission at (317) 249–5937 or *patrick.clarey@ferc.gov.*

Dated: October 3, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–26120 Filed 10–7–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PR11–131–000]

Public Service Company of Colorado; Notice of Rate Election

Take notice that on September 30, 2011, Public Service Company of Colorado (PSCo) filed a Rate Election pursuant to section 284.123(b)(1) of the Commission's regulations. PSCo proposes to utilize rates that are the same as those contained in PSCo's transportation rate schedules for comparable intrastate service on file with the Colorado Public Utilities Commission, as more fully detailed in the petition.

Any person desiring to participate in this rate filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 7 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on Monday, October 17, 2011.

Dated: October 3, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–26118 Filed 10–7–11; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2011–0207; FRL–9477–7]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; NESHAP for Pesticide Active Ingredient Production (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. The ICR which is abstracted below describes the nature of the collection and the estimated burden and cost.

DATES: Additional comments may be submitted on or before November 10, 2011.

ADDRESSES: Submit your comments, referencing docket ID number EPA–HQ–OECA–2011–0207, to: (1) EPA online using *http://www.regulations.gov* (our preferred method), or by e-mail to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center (EPA/DC), Environmental Protection Agency, Enforcement and Compliance Docket and Information Center, mail code 2822IT, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *Attention:* Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Learia Williams, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2223A, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; *telephone number:* (202) 564–4113; *fax number:* (202) 564–0050; *e-mail address: williams.learia@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On May 9, 2011 (76 *FR* 26900), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments. Any additional comments on this ICR should be submitted to both EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under docket ID number EPA–HQ–OECA–2011–0207, which is available for public viewing online at *http://www.regulations.gov*, or in person viewing at the Enforcement and Compliance Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Avenue, NW., Washington, DC The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Enforcement and Compliance Docket is (202) 566–1752.

Use EPA's electronic docket and comment system at *http://www.regulations.gov* to either submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in the system, select ''docket search,'' then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at *http://www.regulations.gov* as EPA receives them and without change, unless the comment contains copyrighted material, Confidential Business Information (CBI), or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to *http://www.regulations.gov*.

Title: NESHAP for Pesticide Active Ingredient Production (Renewal).

ICR Numbers: EPA ICR Number 1807.05, OMB Control Number 2060–0370.

ICR Status: This ICR is scheduled to expire on December 31, 2011. Under OMB regulations, the Agency may

continue to conduct or sponsor the collection of information while this submission is pending at OMB.

Abstract: The National Emissions Standards for Hazardous Air Pollutants (NESHAP) for Pesticide Active Ingredient Production were proposed on November 10, 1997 (62 *FR* 60579), and promulgated on June 23, 1999, (64 *FR* 33550).

Owners or operators of pesticide active ingredient (PAI) production facilities to which this regulation applies must choose one of the compliance options that are described in the rule or install and monitor a specific control system that reduces hazardous air pollutant (HAP) emissions to the compliance level. The respondents are subject to sections of subpart A of 40 CFR part 63 relating to NESHAP. These requirements include those associated with the applicability determination; the notification that the facility is subject to the rule; the notification of testing [control device performance test and continuous monitoring system (CMS) performance evaluation]; the results of performance testing and CMS performance evaluations; startup, shutdown, and malfunction reports; semiannual or quarterly summary reports, and/or excess emissions reports; and CMS performance reports. In addition to the requirements of subpart A, many respondents are required to submit pre-compliance plan and leak detection and repair (LDAR) reports; and plants that wish to implement emissions averaging provisions must submit an emission-averaging plan.

Respondents electing to comply with the emission limit or emission reduction requirements for process vents, storage tanks, or wastewater must record the values of equipment operating parameters as specified in 40 CFR 63.1367 of the rule.

Owners or operators of PAI production facilities subject to the rule must maintain a file of these measurements, and retain the file for at least five years following the date of such measurements, maintenance reports, and records. All reports are sent to the delegated state or local authority. In the event that there is no such delegated authority, the reports are sent directly to the EPA regional office. This information is being collected to assure compliance with 40 CFR part 63, subpart MMM, as authorized in section 112 and 114(a) of the Clean Air Act. The required information consists of emissions data and other information that have been determined to be private.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB Control Number. The OMB Control Number for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15, and are identified on the form and/or instrument, if applicable.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 57 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Pesticide active ingredient production.

Estimated Number of Respondents: 15.

Frequency of Response: Initially, quarterly, and semiannually.

Estimated Total Annual Hour Burden: 3,666.

Estimated Total Annual Cost: $366,098, which includes $346,223 in labor costs, no capital/startup costs, and $19,875 in operation and maintenance (O&M) costs.

Changes in the Estimates: The adjustment decrease in burden from the most recently approved ICR is due to a more accurate estimate of existing and anticipated new sources. After consulting with the EPA Office of Air Quality Planning and Standards (OAQPS), and a number of trade associations, our data indicates that there are approximately fifteen sources subject to the rule, as compared with the active ICR that shows eighty-eight sources. There are no new facilities expected to be constructed over the next three years of this ICR. The decline in the number of sources is due to: (1) Plant closures, including the cost to retrofit aging facilities increased due to the down turn in the economy; (2) corporate mergers; and (3) foreign competition. Therefore, there is a net decrease in the burden to industry.

Because there are no new sources with reporting requirements, no capital/startup costs are incurred. The only cost that is incurred is for the operation and maintenance (O&M) of the monitoring equipment, which have decreased by $333,125 due to the decline in the number of sources, as explained above.

Dated: October 4, 2011.

John Moses,

Director, Collection Strategies Division.

[FR Doc. 2011–26237 Filed 10–7–11; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System, Federal Reserve System.

SUMMARY: Notice is hereby given of the final approval of a proposed information collection by the Board of Governors of the Federal Reserve System (Board) under OMB delegated authority, as per 5 CFR 1320.16 (OMB Regulations on Controlling Paperwork Burdens on the Public). Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the Paperwork Reduction Act Submission, supporting statements and approved collection of information instrument(s) are placed into OMB's public docket files. The Federal Reserve may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

FOR FURTHER INFORMATION CONTACT: *Federal Reserve Board Clearance Officer*—Cynthia Ayouch—Division of Research and Statistics, Board of Governors of the Federal Reserve System, Washington, DC 20551 (202–452–3829). Telecommunications Device for the Deaf (TDD) users may contact (202–263–4869), Board of Governors of the Federal Reserve System, Washington, DC 20551.

OMB Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street, NW., Washington, DC 20503.

Final approval under OMB delegated authority of the extension for three years, without revision, of the following report:

Report title: The Recordkeeping, Reporting and Disclosure Requirements in Connection with Regulation BB (Community Reinvestment Act (CRA)).

Agency form number: Reg BB.

OMB control number: 7100–0197.

Frequency: Annually.

Reporters: State member banks (SMBs).

Annual reporting hours: 52,127 hours.

Estimated average hours per response: Recordkeeping Requirement, small business and small farm loan register, 219 hours. Optional Recordkeeping Requirements, consumer loan data, 326 hours and other loan data, 25 hours. Reporting Requirements, assessment area delineation, 2 hours; small business and small farm loan data, 8 hours; community development loan data, 13 hours; and Home Mortgage Disclosure Act (HMDA) out of Metropolitan Statistical Areas (MSA) loan data, 253 hours. Optional Reporting Requirements, data on lending by a consortium or third party, 17 hours; affiliate lending data, 38 hours; strategic plan, 275 hours; and request for designation as a wholesale or limited purpose bank, 4 hours. Disclosure Requirement, public file, 10 hours.

Number of respondents: Recordkeeping Requirement, small business and small farm loan register, 72. Optional Recordkeeping Requirements, consumer loan data, 24 and other loan data, 4. Reporting Requirements, assessment area delineation, 72; small business and small farm loan data, 72; community development loan data, 72; and HMDA out of MSA loan data, 72. Optional Reporting Requirements, data on lending by a consortium or third party, 6; affiliate lending data, 4; strategic plan, 1; and request for designation as a wholesale or limited purpose bank, 1. Disclosure Requirement, public file, 803.

General description of report: This information collection is authorized by section 806 of the CRA which permits the board to issue regulations to carry out the purpose of CRA (12 U.S.C. 2905), Section 11 of the Federal Reserve Act (FRA), which permits the Board to require such statements as reports of SMBs as it deems necessary (12 U.S.C. 248(a)(1)), and section 9 of the FRA, which permits the Board to examine SMBs (12 U.S.C. 325). The requirements are generally mandatory, depending on bank size and other factors. The data that are reported to the Federal Reserve are not considered confidential.

Abstract: This submission covers an extension of the Federal Reserve's currently approved information collections in their CRA regulations (12 CFR part 228). The submission involves no change to the regulation or to the information collection. The Federal Reserve System needs the information collected to fulfill their obligations under the CRA to evaluate and assign ratings to the performance of institutions in connection with helping to meet the credit needs of their communities, including low- and moderate-income neighborhoods, consistent with safe and sound banking practices. The Federal Reserve System uses the information in the examination process and in evaluating applications for mergers, branches, and certain other corporate activities. Financial institutions maintain and provide the information to the Federal Reserve System.

Current Actions: On July 21, 2011, the Federal Reserve published a notice in the **Federal Register** (76 FR 43686) requesting public comment for 60 days on the extension, without revision, of the recordkeeping, reporting and disclosure requirements in connection with Regulation BB. The comment period for this notice expired on September 19, 2011. The Federal Reserve did not receive any comments.

Board of Governors of the Federal Reserve System, October 4, 2011.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 2011–26085 Filed 10–7–11; 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 November 4, 2011.

A. Federal Reserve Bank of Dallas (E. Ann Worthy, Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *SHB Bancorp, Inc.,* Jonesville, Louisiana; to become a bank holding company by acquiring 100 percent of the voting shares of Southern Heritage Bank, Jonesville, Louisiana.

Board of Governors of the Federal Reserve System, October 5, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–26156 Filed 10–7–11; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Shamarendra Sanyal, PhD Duke University: Based on an inquiry conducted by Duke University (Duke), admissions by the Respondent, and additional analysis conducted by ORI in its oversight review, ORI and Duke found that Dr. Shamarendra Sanyal, former postdoctoral scholar, Duke, engaged in research misconduct by falsifying data in a grant application submitted to the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH).

Specifically, ORI found that the Respondent falsified Figure 2C of grant application 1 R01 HL107901–01, ''Store-operated calcium entry in airway inflammation,'' by altering the gain settings in the instrument used to measure store-operated current (SOC) densities in a whole cell patch clamp experiment comparing Stim $1^{+/-}$ mouse airway cells and wild type mouse airway cells. Respondent also

falsified the calcium response data in Figure 5A (right panel) of the grant application referenced above by adding ATP as a reagent to the mouse airway epithelial cells to sharpen the results purported to be caused by PGN without disclosing that ATP had been added and without disclosing that ATP was not added to the control sample.

The questioned research was not submitted for publication.

Dr. Sanyal has entered into a Voluntary Settlement Agreement with ORI and Duke, in which he voluntarily agreed to the administrative actions set forth below. The administrative actions are required for two (2) years beginning on the date of Dr. Sanyal's employment in a research position in which he receives or applies for PHS support on or after the effective date of the Agreement (September 16, 2011); however, if he has not obtained employment in a research position in which he receives or applies for PHS support within three (3) years of the effective date of the Agreement, the administrative actions set forth below will no longer apply. Dr. Sanyal has voluntarily agreed:

(1) To have his research supervised as described below and to notify his employer(s)/institutions(s) of the terms of this supervision; Respondent agrees to ensure that prior to the submission of an application for PHS support for a research project on which Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS supported research, the institution employing him will submit a plan for supervision of Respondent's duties to ORI for approval; the plan for supervision must be designed to ensure the scientific integrity of Respondent's research contribution; Respondent agrees that he will not participate in any PHS supported research from the effective date of this Agreement until a plan for supervision is submitted to and approved by ORI; Respondent agrees to be responsible for maintaining compliance with the agreed upon plan for supervision;

(2) that any institution employing him must submit, in conjunction with each application for PHS funds, or report, manuscript, or contract involving PHS supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract; and

(3) to exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8800.

John Dahlberg,

Director, Division of Investigative Oversight, Office of Research Integrity.

[FR Doc. 2011–26127 Filed 10–7–11; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS–3180–N2]

Food and Drug Administration

[Docket No. FDA–2010–N–0308]

Pilot Program for Parallel Review of Medical Products

AGENCY: Food and Drug Administration, Centers for Medicare and Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) (the Agencies) are soliciting nominations from sponsors of innovative device technologies to participate in a pilot program for concurrent review of certain FDA premarket review submissions and CMS national coverage determinations. The Agencies announced the intention to initiate a pilot program in the **Federal Register** of September 17, 2010. The Agencies are now providing notice of the procedures for voluntary participation in the pilot program, as well as the guiding principles the Agencies intend to follow.

DATES: *Effective Date:* November 10, 2011.

FOR FURTHER INFORMATION CONTACT:

For device sponsors interested in requesting voluntary parallel review:

Markham C. Luke, Center for Devices and Radiological Health, Food and Drug Administration, 301–796–5550, *e-mail: markham.luke@fda.hhs.gov.*

For General questions about parallel review:

Peter Beckerman, Office of Policy, Food and Drug Administration, 301–796–4830, *e-mail: peter.beckerman@fda.hhs.gov* or Tamara Syrek Jensen, Centers for Medicare and Medicaid Services, 410–786–3529, *e-mail: Tamara.Syrekjensen@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. Parallel Review Proposal

As discussed in the September 17, 2010, **Federal Register** notice (75 FR 57045), parallel review is intended to reduce the time between FDA marketing approval and CMS national coverage determinations, thereby improving the quality of patient health care by facilitating earlier access to innovative medical products for Medicare beneficiaries. In the notice of September 17, 2010, we solicited comments on parallel review of submissions to FDA and CMS for regulated medical products. We also stated our intention to initiate a pilot program for parallel review of devices. The Agencies received 36 comments before the comment period closed on December 16, 2010. The public comments can be found at: *http://www.regulations.gov,* identified by docket number FDA–2010–N–0308. Major themes of the comments included, among others: Parallel review should be sponsor/requester initiated, voluntary, and include an option to opt out of a national coverage determination (NCD); agencies should clarify the confidentiality standards for data sharing between the Agencies; and agencies should establish clear and concise guidelines on the procedures and a timeline for parallel review. These comments have informed the parallel review pilot program for medical devices we are announcing in this notice. We also intend to seek input and feedback from candidate sponsor/requesters who participate in the pilot. Current information describing the FDA–CMS Parallel Review Pilot Program for Medical Devices can be found at the following Web site: *http://www.parallel-review.fda.gov.*

B. Expected Benefits of Parallel Review

The expected benefits of an FDA–CMS parallel review program were discussed in the September 17, 2010, notice. The anticipated benefits include facilitating development of innovative new products and increased efficiency in the Agencies' review processes.

It has come to our attention that innovators have generally focused solely on obtaining FDA approval, only to later realize that Medicare payment may not automatically be forthcoming.

As stated in the notice of September 17, 2010, parallel review will serve the

public interest by providing the possibility of reducing the time between FDA marketing approval or clearance decisions and Medicare NCDs. The efficiencies gained by parallel review are expected to benefit all interested parties. Patients are expected to gain quicker access to innovative medical technologies if they are covered. The sponsor/requester gains timely insight to the information needs of CMS with respect to pursuing a positive NCD as well as a potentially shortened time to payment due to a streamlined multi-review process. The Agencies gain enhanced channels of communication. Specifically with regard to CMS, its early involvement will streamline the decision making process. It will also focus attention on health outcomes of importance to Medicare, and provide early awareness of any remaining evidence gaps. If there are evidence gaps, CMS may address them by implementing coverage with evidence development (CED) or other policy vehicles. For example, if FDA approval or clearance is conditioned on a post-approval study, CMS could decide to cover the device within the parameters of the post-approval study under CED.

II. Parallel Review Pilot Program for Medical Devices

The Agencies have developed a pilot program that reflects our review of the comments received on the September 17, 2010, notice and our interest in creating a streamlined process with minimal additional burden to interested sponsor/requesters. This document outlines the: (1) Guiding principles underlying the pilot program; (2) appropriate candidates for the pilot program; (3) procedures FDA and CMS intend to follow in conducting parallel product reviews; and (4) general roles and responsibilities of the sponsor/requester, FDA, and CMS.

A. Guiding Principles

In response to comments received, the Agencies have identified basic principles underlying the parallel review pilot program described in this document. The following principles are intended to create a common understanding among the sponsor/requester, FDA, and CMS about the goals and parameters of the parallel review pilot program:

1. Participation in parallel review will not affect the review standard for device approval by FDA or for a coverage determination by CMS.

2. The Agencies will adhere to all statutory and regulatory requirements as stipulated in the memorandum of understanding between FDA and CMS, available at *http://www.fda.gov/aboutfda/partnershipscollaborations/memorandaofunderstandingmous/domesticmous/ucm217585.htm.*

3. A sponsor/requester may withdraw from, and FDA and CMS may terminate, parallel review up until the time of CMS's public posting of an NCD tracking sheet.

4. The Agencies will not publicly disclose participation of a sponsor/requester in parallel review prior to CMS's posting of an NCD tracking sheet, unless the sponsor/requester consents or has already made this information public or disclosure is required by law. If a sponsor/requester does not wish the information that would be revealed by the posting of the NCD tracking sheet to become public, it must withdraw from parallel review prior to this point.

5. Due to Agency resource issues the pilot program expects to accept no more than three to five candidates per year.

B. Appropriate Candidates

During its pilot phase, the Agencies believe parallel review should focus on truly innovative technologies that are most likely to benefit from the efficiencies of parallel review. Accordingly, appropriate candidates for the parallel review pilot are medical devices which each use the following:

1. New technologies for which the sponsor/requester has had sufficient pre-investigational device exemption (IDE) interaction with FDA or approved IDE application.

2. New technologies for which an original or supplemental application for premarket approval (PMA) or petition for de novo review would be required.

3. New technologies that fall within the scope of a Part A or Part B Medicare benefit category and are not subject to an NCD.

The agencies encourage any interested sponsors who believe their devices are appropriate candidates and would like to explore the use of the pilot program to contact FDA by e-mail at: *parallel-review@fda.gov,* before initiating the procedures referenced under section II.C of this document entitled ''C. Procedures.''

C. Procedures

For sponsor/requesters of devices that have already had contact with FDA through the pre-IDE or IDE process, much of the information necessary to assess the suitability of a candidate technology should already be in FDA's possession. The Agencies have developed the following procedures to ensure adequate information to assess a candidate's suitability for parallel review without creating a burdensome new application process:

1. *Nomination.* The sponsor/requester of an innovative therapeutic or diagnostic device may nominate its device for participation in parallel review by following the instructions posted on the *http://www.parallel-review.fda.gov* web page. FDA intends to acknowledge receipt of nominations by e-mail. The following information will assist FDA in processing and responding to nominations:

- Name of the sponsor/requester and relevant contact information;
- Pre-IDE/IDE/PMA/De Novo reference number;
- Name of the product;
- Succinct description of the technology and disease or condition the device is intended to diagnose or treat;
- Stage of development of the technology (that is, in preclinical testing, in clinical trials, currently undergoing premarket review by FDA);
- Brief statement explaining why the device is an appropriate candidate for the pilot program as described under the section II.B of this document entitled: ''B. Appropriate Candidates.''

2. *FDA/CMS Consideration.* The Agencies intend to meet to consider a nomination within 30 days of receiving a complete nomination containing the information described previously. The Agencies may contact the sponsor/requester to request supplemental information.

3. *Sponsor/requester Notification.* Upon completion of the consideration meeting, the Agencies will notify the sponsor/requester whether the product is an appropriate candidate for the parallel review pilot program.

4. *Acceptance Meeting.* If deemed an appropriate candidate, the Agencies will meet with the product sponsor/requester, either in person or by phone.

5. *FDA Review.* Parallel review candidates will be reviewed according the normal FDA review process. Participation in parallel review will not affect user fees, review timeframes or procedures, or the FDA standard of approval, which is reasonable assurance of safety and effectiveness.

6. *CMS NCD Review and Timing.* CMS will begin its informal review process sometime after submission of the PMA or de novo petition. For PMAs, this will typically begin after the PMA-specific Panel meeting of the FDA Medical Devices Advisory Committee.

D. Roles and Responsibilities

The Agencies have outlined the general roles and responsibilities of each participant in the parallel review process to ensure clarity and shared

understandings. These roles and responsibilities are as follows:

1. *Sponsor/requester.* The sponsor/requester initiates consideration for parallel review by submitting a complete nomination as outlined previously under ''1. Nomination,'' of section II.C of this document entitled ''Procedures.''. Once a nomination has been submitted, the sponsor/requester should comply with all requirements necessary for FDA review of a PMA or de novo petition and CMS issuance of an NCD including the submission of a formal request for an NCD. The Agencies request that a sponsor/requester who wishes to withdraw from the parallel review process notify the FDA and CMS in writing before CMS' formal opening of an NCD by the posting of the NCD tracking sheet.

2. *The FDA.* FDA will provide a secure and confidential nomination and review process as outlined previously in section II.C of this document. FDA will initiate review of nominations for parallel review by retrieving applications from the secure mailbox, and coordinating with CMS, on the planning and implementation of the parallel review process. FDA will review PMAs and de novo petitions for products that have been selected by the Agencies for parallel review according to the usual timeframes, procedures, and review standards for PMA approval and de novo classification.

3. *The CMS.* In addition to the coverage review, CMS's parallel review roles include participating in the nomination process as well as coordinating with FDA regarding the planning and implementation of the parallel review process. During the parallel review, CMS is responsible for maintaining open communication channels with FDA and the sponsor/requester and for fulfilling its statutory obligations concerning the NCD process.

E. Duration of the Pilot

The Agencies intend to accept requests for participation in the pilot program for parallel review for 2 years. The Agencies may terminate the pilot program before the close of the 2-year period, or may extend the pilot program beyond 2 years. The decisions will be announced in the **Federal Register.**

F. Evaluation

The Agencies intend to use their experience with the pilot program to develop a parallel review program not only for devices but also for drugs and biological products. The Agencies anticipate their experience with the parallel review program for devices and feedback from participants in the program will inform guidance for a broader program applicable to all medical products. The Agencies may also determine that they should extend or modify the parallel review pilot program to continue their evaluation.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program) (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 21, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Dated: September 21, 2011.

Margaret A. Hamburg,

Commissioner of Food and Drugs.

[FR Doc. 2011–25907 Filed 10–6–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0263]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experiment To Evaluate Risk Perceptions of Produce Growers, Food Retailers, and Consumers After a Food Recall Resulting From a Foodborne Illness Outbreak

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by November 10, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–New and title ''Experiment to Evaluate Risk Perceptions of Produce Growers, Food Retailers, and Consumers After a Food Recall Resulting From a Foodborne Illness Outbreak.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Experiment To Evaluate Risk Perceptions of Produce Growers, Food Retailers, and Consumers After a Food Recall Resulting From a Foodborne Illness Outbreak—(OMB Control Number 0910—NEW)

I. Background

This proposed collection of information entitled ''Experiment to Evaluate Risk Perceptions of Produce Growers, Food Retailers, and Consumers After a Food Recall Resulting From a Foodborne Illness Outbreak'' will be conducted under a cooperative agreement between the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) and the Center for Risk Communication Research (CRCR) at the University of Maryland. JIFSAN was established in 1996 and is a public and private partnership between FDA and the University of Maryland. The CRCR will design and administer the study.

FDA is requesting OMB approval under the PRA for the CRCR to conduct research with produce growers, food retailers, and consumers to gain information about these groups' risk perceptions associated with produce that has recently been subject to a food recall resulting from a foodborne illness outbreak. The purpose of this research is to help FDA better understand whether the magnitude and duration of the decline in commodity consumption following food recalls can be partly explained by grower and retailer speculations and projections about consumers' attitudes toward food recalls resulting from foodborne illness outbreaks. This research will be used to assess how grower, retailer, and consumer perceptions, attitudes, knowledge, and beliefs affect market recovery after a hypothetical fresh spinach recall.

Epidemiologists define foodborne illness outbreaks as two or more cases of a similar illness resulting from the ingestion of a common food (Ref. 1). Because many foodborne illness cases are mild, most outbreaks are never

recognized or brought to the attention of public health authorities. When the outbreaks are large in scale or cause hospitalization, serious illness, or death, public health officials will inform the public in order to try to stop the spread of disease. A food recall can occur when a particular food in the marketplace is found to have a known contaminant because either people have become sickened by it or pathogen testing has revealed contamination (Ref. 2). The purpose of a food recall is to rid retail establishments of the product and to inform consumers that they should discard the product if they have it in their homes. Although the purpose of a food recall is to keep consumers from becoming ill, food recalls can be costly to all sectors of the food distribution chain (Ref. 3). The goal of the proposed project is to test, by experimental study, whether the psychological tendency called ''attribution error,'' contributes to unnecessarily prolonging the economic effects of a food recall. ''Attribution error'' is the tendency people have of overestimating others' negative response to situations compared to their own response. If industry decisionmakers' measures of consumer response are biased by ''attribution error,'' industry could be contributing to its own slow recovery after a food recall.

When a widespread foodborne illness outbreak results in a food recall, the product can be out of the marketplace for an extended period of time; this occurred when fresh, bagged spinach was recalled in 2006 (Ref. 3). Tomatoes were also less available following the *Salmonella* Saintpaul outbreak in 2008 (Ref. 4). Although growers and retailers want to provide safe foods, decisions surrounding production, wholesale, and retail sales forecasting in response to a food recall affects how quickly the food is again available for consumption. We hypothesize that industry's overattribution of consumers' fear of the food after such a food recall would result in the food being kept off of the market longer than necessary.

The CRCR plans to conduct an experiment using a Web-based questionnaire. The center will use a convenience sample of 900 participants (180 growers, 180 retailers, 540 consumers) drawn from industry networks (for the growers and retailers), and a Web-based panel of U.S. households (for the consumers). Participation in the study is voluntary.

This study will help FDA better understand the reasons for the time between a food recall resulting from a foodborne illness outbreak and market recovery. In order to understand the complexities of market recovery process, the CRCR will compare understandings and reactions of growers, retailers, and consumers to a hypothetical food recall resulting from a hypothetical foodborne illness outbreak. To make this comparison, individuals in each group will be assigned to one of the following experimental conditions (consisting of vignettes in the form of news articles on a hypothetical food recall): An ''anger'' scenario, a ''fear'' scenario, or a ''control'' scenario. After reading the news article, participants will complete a questionnaire assessing their emotional response; appraisals; attribution of responsibility; perceptions about the safety of the affected produce; intentions to grow, sell, or buy the affected produce; perceived probability of a repeat event; and a measure of their innate ability to effectively respond to the information in the article.

To help design and refine the questionnaire, we will recruit 25 participants in order to conduct 10 cognitive interviews. We estimate cognitive interview recruitment will take 5 minutes (0.083 hours), for a total of 2 hours. The cognitive interviews are estimated at 1 hour per response for a total of 10 hours for the cognitive interview activities. We expect to send screeners to 800 members of a consumer panel, each taking 2 minutes (0.03 hours) to complete, for a total of 24 hours for the consumer panel screener activity. We also expect to administer 360 screeners to growers and retailers, each taking 2 minutes (0.03 hours) to complete, for a total of 22 hours (11 + 11 = 22). Twenty-four participants (20 consumers, 2 growers, 2 retailers) will complete the pretest. Each pretest will take 10 minutes (0.17 hours) for a total of 5 hours for the pretest activity. We estimate that 900 individuals (540 consumers, 180 growers, and 180 retailers) will complete the questionnaire for the experiment, each taking 10 minutes (0.17 hours) for a total of 153 hours for the experimental study activities. The estimated total hour burden of the collection of information is 216 hours.

In the **Federal Register** of April 15, 2011 (76 FR 21379), FDA published a 60-day notice requesting public comment on the proposed collection of information. The Agency received two comments. The comments, and the Agency's responses, are discussed in the following paragraphs.

(Comment 1) One comment suggested that FDA should include the foodservice distributor community in the study.

(Response) FDA disagrees. FDA is not including the foodservice distributor community as a study sample because the foodservice distributor community is responsive to retail's demands for product. The retail sector is included in the study.

(Comment 2) One comment questioned the need for FDA to apply government resources toward the research question, which was characterized in the comment as a survey of consumers' reactions to food recalls.

(Response) FDA disagrees that the research data are not needed. The proposed study utilizes an experimental design to assess how well industry predicts consumer reaction to a food recall. This information will help FDA in their risk management role during and following a food recall. Risk management involves communicating both with industry and consumers about the important health and economic consequences related to the recall.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cognitive Interview Recruitment.	25	1	25	0.08 (5 min.)	2
Cognitive Interviews	10	1	10	1 (60 min.)	10
Consumer Panel Screener	800	1	800	0.03 (2 min.)	24
Grower Screener	360	1	360	0.03 (2 min.)	11
Retailer Screener	360	1	360	0.03 (2 min.)	11
Pretests	24	1	24	0.17 (10 min.)	5

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Experiment	900	1	900	0.17 (10 min.)	153
Total					216

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

II. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Olsen, S., L. MacKinnon, J.S. Goulding, et al., ''Surveillance for Foodborne Disease Outbreaks—United States, 1993 to 1997,'' *Morbidity and Mortality Weekly Report,* vol. 49, pp. 1–51, 2000.
2. ''FDA 101: Product Recalls—From First Alert to Effectiveness Checks,'' (*http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049070.htm*).
3. Calvin, L., ''Outbreak Linked to Spinach Forces Reassessment of Food Safety Practices,'' *Amber Waves,* vol. 5, pp. 24–31, 2007.
4. Lucier, G. and R. Dettmann, ''Vegetables and Melons Outlook: A Report From the United States Department of Agriculture, Economic Research Service,'' VGS–327, June 26, 2008.

Dated: October 4, 2011.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2011–26131 Filed 10–7–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0509]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Appeals of Science-Based Decisions Above the Division Level at the Center for Veterinary Medicine

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by November 10, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, *Fax:* 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0566. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *juanmanuel.vilela@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Appeals of Science-Based Decisions Above the Division Level at the Center for Veterinary Medicine—21 CFR Part 10.75 (OMB Control Number 0910–0566)—Extension

Respondents: Respondents to this collection of information are applicants that wish to submit a request for review of a scientific dispute.

The Center for Veterinary Medicine's Guidance for Industry #79 ''Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine'' describes the process by which the Center for Veterinary Medicine (CVM) formally resolves disputes relating to scientific controversies. A scientific controversy involves issues concerning a specific product regulated by CVM related to matters of technical expertise and requires specialized education, training, or experience to be understood and resolved. Further, the guidance details information on how the Agency intends to interpret and apply provisions of the existing regulations regarding internal Agency review of decisions. In addition, the guidance outlines the established procedures for persons who are sponsors, applicants, or manufacturers, for animal drugs or other products regulated by CVM, that wish to submit a request for review of a scientific dispute. When a sponsor, applicant, or manufacturer has a scientific disagreement with a written decision by CVM, they may submit a request for a review of that decision by following the established Agency channels of supervision for review.

In the **Federal Register** of July 13, 2011 (76 FR 41264), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
10.75	1	3	3	10	30

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

This estimated annual reporting burden is based on CVM's experience over the past 3 years in handling formal appeals for scientific disputes. The number of respondents multiplied by the number of responses per respondent equals the total annual responses. The average burden per response (in hours) is based on discussions with industry and may vary depending on the complexity of the issue(s) involved and the duration of the appeal process.

Dated: October 4, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–26132 Filed 10–7–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0281]

Pilot Program To Evaluate Proposed Proprietary Name Submissions; Public Meeting on Pilot Program Results Will Not Be Held

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it will not hold a public meeting to discuss the results of a 2-year voluntary pilot program that enabled participating pharmaceutical firms to evaluate proposed proprietary names and submit the data generated from those evaluations for FDA to review. FDA anticipated holding a public meeting at the end of fiscal year 2011 to discuss the results of the pilot program, but the Agency did not receive sufficient pilot submissions to form a basis for discussion. Interested parties may submit to the docket any additional comments on the pilot program. As previously announced, FDA plans to publish a draft guidance describing the best test methods for proprietary name evaluation.

DATES: Submit either electronic or written comments by November 10, 2011.

ADDRESSES: Submit electronic comments on the pilot program or this document 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: *Regarding human drug products:* Carol Holquist, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4416, Silver Spring, MD 20993–0002.

Regarding human biological products: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration (HFM–17), 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In Title I of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), Congress reauthorized and expanded the Prescription Drug User Fee program for fiscal years 2008 to 2012 (PDUFA IV). In performance goals agreed to in conjunction with the reauthorization of PDUFA IV, FDA agreed to publish a concept paper on and implement a pilot program to enable pharmaceutical firms to evaluate proposed proprietary names and submit the data generated from those evaluations to FDA for review. (See IX.B at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119243.htm.*).

In June 2008, FDA held a public technical meeting (see 73 FR 27001, May 12, 2008) to discuss a draft concept paper describing the pilot program and FDA's thinking about how pharmaceutical firms could participate in the pilot program to evaluate proposed proprietary names and submit the data generated to FDA for review. After considering comments from the meeting and the public docket, FDA announced the availability of the concept paper entitled ''PDUFA Pilot Project Proprietary Name Review'' in the **Federal Register** of October 7, 2008 (73 FR 58604). As stated in the concept paper, the goals of the pilot program were to minimize the use of names that are misleading or that are likely to lead to medication errors, to make FDA's application review more efficient, and to make regulatory decisions more transparent.

In the **Federal Register** of October 1, 2009 (74 FR 50806), FDA announced the opportunity for firms to register for and submit data to the voluntary pilot program. FDA stated that at the end of fiscal year 2011, or after accruing 2 years experience with pilot program submissions, the Agency would evaluate the results to determine whether the model of industry conducting reviews, submitting the results to FDA, and FDA reviewing the data is feasible and whether it is a better model than FDA conducting de novo reviews of proprietary names. FDA planned to hold a public meeting to discuss the results of the pilot program and recommended additions and/or changes to methods based on the report results. FDA also stated that, following the meeting, FDA would publish draft guidance on best test practices for proprietary name review.

FDA began accepting requests to participate in the pilot program on October 1, 2009, and the pilot program ended on September 30, 2011. Although three applicants registered to participate during the 2-year period, FDA received only one complete submission for pilot program review, which is not a sufficient number to assess the feasibility of industry conducting reviews of proposed proprietary names. Therefore, the public meeting that was anticipated to occur at the end of fiscal year 2011 to assess the pilot program for evaluation of proposed proprietary names will not be held because of insufficient participation. The pilot program docket (docket number FDA–2008–N–0281) has remained open for comment during the 2-year pilot program, and FDA has invited comments on human factor testing. In lieu of a public meeting, interested persons may submit any additional comments to the docket. After the close of the public comment period, FDA intends to publish a draft guidance

describing the best test methods for proprietary name evaluation.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding the pilot project or 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: October 4, 2011.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2011–26099 Filed 10–7–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council on Blood Stem Cell Transplantation; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), notice is hereby given of the following meeting:

Name: Advisory Council on Blood Stem Cell Transplantation (ACBSCT).

Date and Time: November 08, 2011, 10 am to 4 pm EDT.

Place: The meeting will be via audio conference call and Adobe Connect Pro.

Status: The meeting will be open to the public.

Purpose: Pursuant to Public Law 109–129, 42 U.S.C. 274k (section 379 of the Public Health Service Act, as amended,) the Advisory Council on Blood Stem Cell Transplantation (ACBSCT) advises the Secretary of HHS and the Administrator, HRSA, on matters related to the activities of the C.W. Bill Young Cell Transplantation Program (Program) and the National Cord Blood Inventory (NCBI) Program.

Agenda: The Council will hear reports from five ACBSCT Work Groups: Cord Blood Bank Collections, Realizing the Potential of Cord Blood, Scientific Factors Necessary to Define a Cord Blood Unit as High Quality, Cord Blood Thawing and Washing, and Access to Transplantation. The Council also will hear presentations and discussions, which may include the following topics: CAO study and report; FDA licensure and unmet need.

The public can join the meeting by:

1. Calling Conference Phone Number: 888–790–3527 and providing Participant Code: 8064893, for the audio portion, *AND*

2. Connecting to the ACBSCT Adobe Connect Pro Meeting for the visual portion using the following URL: *https://hrsa.connectsolutions.com/acbsct/* (*if the link does not work, copy and paste it into your browser*). The conference call leader is Patricia A. Stroup.

Call (301) 443–0437 or send an e-mail to ptongele@hrsa.com if you are having trouble connecting to the meeting site.

Participants should call no later than 9:45 am EDT in order for logistics to be set up.

If you have never attended an Adobe Pro Connect Meeting, please test your connection using the following URL: https://hrsa.connectsolutions.com/common/help/en/support/meeting_test.htm.

For quick overview, please access: *http://www.adobe.com/go/connectpro_overview.* Those planning to participate are asked to complete and submit an online registration form by visiting our Web site at *http://www.ACBSCT.com* and selecting the tab titled ''Registration.'' Individuals with no Internet access should request the registration form by contacting Gabrielle Kardolus at (301) 585–1261 or at Gabrielle.Kardolus@luxcg.com and fax the registration form to Gabrielle Kardolus at (301) 585–7741. The registration deadline is November 2, 2011. The next face-to-face ACBSCT meeting is planned for Spring 2012. Details regarding the next meeting will be published in a subsequent **Federal Register** notice.

Public Comment: Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Passy Tongele, DoT, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 12C–06, 5600 Fishers Lane, Rockville, Maryland 20857 or *e-mail: ptongele@hrsa.gov.* Requests should contain the name, address, telephone number, e-mail address, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the public comment period. Public participation and ability to comment will be limited to space and time as it permits.

For Further Information Contact: Patricia Stroup, Executive Secretary, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 12C–06, Rockville, Maryland 20857; telephone (301) 443–1127.

Dated: October 3, 2011.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2011–26168 Filed 10–7–11; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center For Research Resources; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Special Emphasis Panel.

Date: November 9, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Martha F. Matocha, PhD, Scientific Review Officer, Office of Review, National Center for Research Resources, National Institutes of Health, 6701 Democracy Blvd., 1 Democracy Plaza, Rm. 1070, Bethesda, MD 20892, 301–435–0813, *matocham@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93.333; 93.702, ARRA Related Construction Awards., National Institutes of Health, HHS)

Dated: October 4, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–26218 Filed 10–7–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections

552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel, 2012–01 NIBIB R13 Conference Grant Review.

Date: November 14, 2011.

Time: 11 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health/NIBIB, DEM II, 6707 Democracy Blvd., 223, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Ruixia Zhou, PhD, Scientific Review Officer, 6707 Democracy Boulevard, Democracy Two Building, Suite 957, Bethesda, MD 20892, 301–496–4773, *zhour@mail.nih.gov.*

Dated: October 4, 2011.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–26219 Filed 10–7–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy And Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, NIH/PEPFAR Collaboration for Implementation Science and Impact Evaluation.

Date: December 5, 2011.

Time: 9 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Dharmendar Rathore, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Rm 3134, Bethesda, MD 20892–7616, 301–435–2766, *rathored@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: October 4, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–26212 Filed 10–7–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel, MBRS Score.

Date: November 7, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Saraswathy Seetharam, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12C, Bethesda, MD 20892, 301–594–2763, *seetharams@nigms.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: October 4, 2011.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–26210 Filed 10–7–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Initial Review Group, Minority Programs Review Subcommittee B.

Date: November 7, 2011.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Courtyard Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Rebecca H. Johnson, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN18C, Bethesda, MD 20892, 301–594–2771, *johnsonrh@nigms.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: October 4, 2011.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–26206 Filed 10–7–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Biotechnology Activities; Recombinant DNA Research: Action Under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)

AGENCY: National Institutes of Health (NIH), Public Health Services (PHS), Department of Health and Human Services, (DHHS).

ACTION: Notice of Final Action under the *NIH Guidelines.*

SUMMARY: The Office of Biotechnology Activities (OBA) is updating Appendix B of the *NIH Guidelines* to specify the risk group (RG) classification for several common attenuated strains of bacteria and viruses that are frequently used in recombinant DNA research. OBA is also specifying the risk group for several viruses not previously listed in Appendix B. In addition, a reference to Appendix B will be added to Section II–A of the *NIH Guidelines,* which addresses the risk assessment for research with recombinant DNA.

Background: The *NIH Guidelines* provide guidance to investigators and local Institutional Biosafety Committees (IBCs) for setting containment for recombinant DNA research. Section II–A, Risk Assessment, instructs investigators and IBCs to make an initial risk assessment based on the RG of the agent (see Appendix B, Classification of Human Etiologic Agents on the Basis of Hazard). The RG of the agent often correlates with the minimum containment level required for experiments subject to the *NIH Guidelines.*

The classification of agents into various RG categories is based largely on their ability to cause human disease and the availability of treatments for that disease. For the most part, the organisms listed in Appendix B are wild-type, non-attenuated strains and a distinction is not made between the RG classification for the wild-type organism and a corresponding attenuated strain. A few attenuated strains are classified in Appendix B at a lower RG than that of the wild-type organism. However, there are a number of well-established attenuated strains commonly employed in research that are not specifically listed and thus by default are included in the same RG as the wild-type organism. Therefore, the biosafety level (BL) specified for research subject to the *NIH Guidelines* may be identical for experimentation with either the attenuated or the wild-type strain.

OBA has conducted an evaluation of certain attenuated strains, focusing on those for which a risk assessment had been undertaken and containment recommendations determined in the Centers for Disease Control and Prevention (CDC)/NIH publication *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) (5th edition). In addition, the NIH Recombinant DNA Advisory Committee (RAC) discussed the appropriate containment for two attenuated strains of *Yersinia pestis* (*lcr*$^{(-)}$ and *pgm*$^{(-)}$ mutants) at its meeting on June 16, 2010. (A webcast of that discussion is available at *http://oba.od.nih.gov/rdna_rac/rac_past_meetings_2010.html.*)

Specifying the risk groups for attenuated strains in Appendix B of the *NIH Guidelines* will lead to more uniform containment recommendations that are commensurate with the biosafety risk. In addition, OBA has identified several RG3 viruses that are not currently specified in Appendix B or are a member of a family of viruses otherwise classified as RG2. Therefore, Appendix B is being updated to address these viruses as well.

OBA consulted the NIH RAC as well as other subject matter experts from NIH, CDC, and academia. These proposed changes were published in the **Federal Register** (76 FR 44339) on July 25, 2011, and one comment was received. This comment, from the American Biological Safety Association (ABSA), suggested that ''OBA should consider adding additional information to Section II–A–3 covering the assignment of Risk Group to commonly used attenuated strains.'' Section II–A of the *NIH Guidelines* provides a framework for conducting a comprehensive risk assessment. These proposed changes to Appendix B and ABSA's comment were discussed at the September 13, 2011, meeting of the RAC. OBA and the RAC appreciated ABSA's comments and will add a reference to Appendix B to the last sentence of the first paragraph of Section II–A–3. The last sentence of the first paragraph of Section II–A–3 currently reads: ''Certain attenuated strains or strains that have been demonstrated to have irreversibly lost known virulence factors may qualify for a reduction of the containment level compared to the Risk Group assigned to the parent strain (see Section V–B, *Footnotes and References of Sections I–IV*).'' It will be amended to read:

Certain attenuated strains or strains that have been demonstrated to have irreversibly lost known virulence factors may qualify for a reduction of the containment level compared to the Risk Group assigned to the parent strain (see Appendix B, *Classification of Human Etiologic Agents on the Basis of Hazard* and Section V–B, *Footnotes and References of Sections I–IV*).

In addition to the change to the first paragraph of Section II–A–3, the following additions will be made to *Appendix B–II–A. Risk Group 2 (RG2)—Bacterial Agents Including Chlamydia:*

Coxiella burnetii, Nine Mile strain, plaque purified, clone 4.

**Francisella tularensis* subspecies *novicida* (also referred to as *Francisella novicida*) strain, Utah 112.

**Francisella tularensis* subspecies *holartica* LVS.

**Francisella tularensis* biovar tularensis strain ATCC 6223 (also known as strain B38).

Yersinia pestis pgm$^{(-)}$ (lacking the 102 kb pigmentation locus).

Yersinia pestis lcr$^{(-)}$ (lacking the LCR plasmid).

The following footnote will be added regarding research with attenuated strains of *Francisella:*

*For research involving high concentrations, BL3 practices should be considered (See Appendix G–II–C–2).

The following changes/additions will be made to *Appendix B–II–D Risk Group 2 (RG2)—Viruses:*

Alphaviruses (Togaviruses)—Group A Arboviruses:

''Venezuelan equine encephalomyelitis vaccine strain TC–83'' will be changed to:

Venezuelan equine encephalomyelitis vaccine strains TC–83 and V3526.

Alphaviruses (Togaviruses)—Group A Arboviruses:

Add: Chikungunya vaccine strain 181/25.

Arenaviruses:

Add: Junin virus candid #1 vaccine strain.

Flaviviruses (Togaviruses)—Group B Arboviruses:

Add: Japanese encephalitis virus strain SA 14–14–2.

Rhabdoviruses:

''Vesicular stomatitis virus—laboratory adapted strains including VSV—Indiana, San Juan, and Glasgow'' will be changed to:

Vesicular stomatitis virus non-exotic strains: VSV—Indiana 1 serotype strains (*e.g.* Glasgow, Mudd-Summers, Orsay, San Juan) and VSV—New Jersey serotype strains (*e.g.* Ogden, Hazelhurst).

The following additions will be made to *Appendix B–III–D Risk Group 3 (RG3)—Viruses and Prions:*

Add: Coronaviruses:

Add: SARS-associated coronavirus

(SARS—CoV).
Alphaviruses (Togaviruses)—Group A Arboviruses:
Add: Chikungunya.
Flaviviruses (Togaviruses)—Group B Arboviruses:
Add: West Nile virus (WNV).

Dated: October 3, 2011.

Jacqueline Corrigan-Curay,

Acting Director, Office of Biotechnology Activities, National Institutes of Health.

[FR Doc. 2011–26224 Filed 10–7–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2011–0877]

National Offshore Safety Advisory Committee

AGENCY: United States Coast Guard.

ACTION: Committee Management; Notice of Federal Advisory Committee Meeting.

SUMMARY: The National Offshore Safety Advisory Committee (NOSAC) will meet on November 15, 2011, in Houston, Texas to discuss various issues related to safety of operations and other matters affecting the oil and gas offshore industry. The meeting will be open to the public.

DATES: NOSAC will meet Tuesday, November 15, 2011, from 9 a.m. to 4 p.m. Please note that the meeting may close early if the committee has completed its business or be extended based on the level of public comments.

ADDRESSES: The meeting will be held at Hilton Houston NASA Clear Lake, Discovery Ballroom, 3000 NASA Road One, Houston, Texas, 77058–4322.

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact the person listed in ''**FOR FURTHER INFORMATION CONTACT**'' as soon as possible.

To facilitate public participation, we are inviting public comment on the issues to be considered by the committee as listed in the ''Agenda'' section below. Comments must be submitted in writing no later than November 1, 2011, and must be identified by USCG–2011–0877 and may be submitted by *one* of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001.
- *Hand Delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

Instructions: All submissions received must include the words ''Department of Homeland Security'' and the docket number for this action. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided. You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the Federal Register (73 FR 3316).

Docket: For access to the docket to read documents or comments related to this Notice, go to *http://www.regulations.gov.*

A public comment period will be held during the meeting on November 15, 2011, and speakers are requested to limit their comments to 3 minutes. Please note that the public comment period may end before the time indicated, following the last call for comments. Contact the individual listed below to register as a speaker.

FOR FURTHER INFORMATION CONTACT: Commander Rob Smith, Designated Federal Officer of NOSAC, Commandant (CG–5222), U.S. Coast Guard, 2100 Second Street, SW., Stop 7126, Washington, DC 20593–0001 or Mr. Kevin Pekarek, Alternate Designated Federal Officer of NOSAC, Commandant (CG–5222), U.S. Coast Guard, 2100 Second Street, SW., Stop 7126, Washington, DC 20593–0001; telephone (202) 372–1386, fax (202) 372–1926. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. (Pub. L. 92–463). The National Offshore Safety Advisory Committee (NOSAC) provides advice and recommendations to the Department of Homeland Security on matters and actions concerning activities directly involved with or in support of the exploration of offshore mineral and energy resources insofar as they relate to matters within Coast Guard jurisdiction.

Agenda

The NOSAC will meet, review and discuss reports and recommendations received from the Medical Evacuation of Injured Divers subcommittee and the Mississippi Canyon Incident Report subcommittee. The Committee will then use this information to formulate recommendations to the agency.

A complete agenda is as follows:

(1) Roll call of committee members and determination of a quorum.

(2) Approval of minutes from the May 19, 2011, meeting.

(3) Committee Administration.

a. Introduction of new members.

b. Nominations for Committee Chair and Vice Chair for presentation to the Commandant.

c. Discussion of Committee By-Laws.

d. DFO announcements.

(4) Presentation and discussion of reports and recommendations from the subcommittees on:

(a) Medical Evacuation of Injured Divers.

(b) Mississippi Canyon Incident Reports subcommittee, to include the appointment of a Co-chairman.

(5) Establishment of a sub-committee to work on the task to evaluate the requirements for licensing mariners who will man and operate large OSVs.

(6) Offshore Operators Committee (OOC) update regarding medical evacuations from the OCS.

(7) An update on USCG regulations and Federal Register notices.

(8) USCG Briefing on Joint Investigation Team for DEEPWATER HORIZON drilling rig explosion and sinking.

(9) Update from the Bureau of Ocean Energy Management Regulation and Enforcement concerning their reorganization, rules and regulations, etc. Discussion to include USCG/BOEMRE Memorandum of Agreement OCS–06 and contracting of the National Research Council's Marine Board to conduct a study on regulating worker safety in connection with the development of offshore renewable energy on the Outer Continental Shelf (OCS).

(10) EO 13580—Domestic Energy Development and Permitting in Alaska; USCG and BOEMRE processes involved.

(11) Updates on International Maritime Organization (IMO) activities of interest to the OCS community.

(12) Briefing on the activities of Ocean Energy Safety Advisory Committee.

(13) Use of Liquefied Natural Gas (LNG) as fuel for internal engines.

(14) Period for Public comment.

(15) Adjournment of meeting.

A copy of each report is available at the *https://www.fido.gov* Web site or by contacting Kevin Y Pekarek. Use ''code 68'' to identify NOSAC when accessing this material. Once you have accessed the Committee page, click on the

meetings tab and then the ''View'' button for the meeting dated November 15, 2011, to access the information for this meeting. Minutes will be available approximately 30 days after this meeting. Both minutes and documents applicable for this meeting can also be found at an alternative site using the following web address: *https://homeport.uscg.mil* and use these key strokes: Missions>Port and Waterways>Safety Advisory Committee>NOSAC and then use the event key.

The meeting will be recorded by a court reporter. A transcript of the meeting and any material presented at the meeting will be made available through the *https://www.fido.gov* Web site.

The committee will review the information presented on each issue, deliberate on any recommendations presented in the subcommittees' reports, and formulate recommendations for the Department's consideration. The committee will also receive tasking from CDR Rob Smith, Designated Federal Officer, on evaluating the various requirements for licensing mariners who will man and operate large OSVs, and to make recommendations on same.

Dated: October 3, 2011.

F. J. Sturm,

Deputy Director of Commercial Regulations and Standards.

[FR Doc. 2011–26126 Filed 10–7–11; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Extension of Agency Information Collection Activity Under OMB Review: Critical Facility Information of the Top 100 Most Critical Pipelines

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-day Notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652–0050, abstracted below to OMB for review and approval of an extension of the currently approved collection under the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. TSA published a **Federal Register** notice, with a 60-day comment period, soliciting comments of the following collection of information on June 16, 2011, 76 FR 35229. The 9/11 Act required TSA to develop and implement a plan to inspect critical pipeline systems.

DATES: Send your comments by November 10, 2011. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, OMB. Comments should be addressed to Desk Officer, Department of Homeland Security/TSA, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Joanna Johnson, TSA PRA Officer, Office of Information Technology (OIT), TSA–11, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598–6011; telephone (571) 227–3651; e-mail *TSAPRA@dhs.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), 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. The ICR documentation is available at *http://www.reginfo.gov.* Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement 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;

(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 using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

Title: Critical Facility Information of the Top 100 Most Critical Pipelines.

Type of Request: Revision of a currently approved collection.

OMB Control Number: 1652–0050.

Forms(s): Critical Facility Security Review (CFSR).

Affected Public: Pipeline companies.

Abstract: Section 1557(b) of the Implementing the Recommendations of the 9/11 Commission Act of 2007 specifically tasked TSA to develop and implement a plan for inspecting critical facilities of the 100 most critical pipeline systems. See Public Law 110–53, 121 Stat. 266, 475 (Aug. 3, 2007). Operators determined their critical facilities based on guidance and criteria set forth in the Department of Transportation's (DOT) September 5, 2002, ''Pipeline Security Information Circular'' and June 2002 ''Pipeline Security Contingency Planning Guidance.'' With OMB approval (OMB Control Number 1652–0050), TSA reached out to the operators of the top 125 critical pipeline systems and requested they submit a listing of their critical facilities to TSA. This critical facility information was submitted to TSA between November 2008 and August 2009. In April 2011, TSA updated the ''Pipeline Security Guidelines'' in consultation with stakeholders and DOT. TSA is now seeking to renew its OMB approval to request critical facility information from the top 125 pipeline operators. TSA anticipates that each operator will report, on average, a total of 5 critical facilities on their system, for a total of approximately 600 critical facilities across the top 125 operators.

Once updated critical facility information is obtained, TSA intends to visit critical pipeline facilities and collect site-specific information from pipeline operators on facility security policies, procedures, and physical security measures. Information obtained on the visits will be collected on a Critical Facility Security Review (CFSR) Form. The CFSR will differ from TSA's Corporate Security Review (CSR) in that a CSR looks at corporate or company-wide security management plans and practices while the CFSR will look at individual pipeline facility security measures and procedures. TSA is seeking OMB approval to utilize the CFSR document during critical facility reviews in order to collect facility security information. Information collected from the reviews would be analyzed and used to determine strengths and weaknesses at the nation's critical pipeline facilities, areas to target for risk reduction strategies, pipeline industry implementation of the voluntary guidelines, and the need for regulations in accordance with Section 1557(d) of the Implementing the Recommendations of the 9/11 Commission Act of 2007. TSA anticipates visiting 120 critical facilities each year.

As part of this collection process, TSA intends to follow-up with pipeline operators on their implementation of security improvements and recommendations made during facility visits. During critical facility visits, TSA documents and provides recommendations to improve the security posture of the facility. TSA intends to follow-up with pipeline operators via email on their status toward implementation of the recommendations made during the critical facility visits. The follow-up will be conducted between approximately 12 and 24 months after the facility visit.

TSA will use the information collected to determine to what extent the pipeline industry is implementing the 2011 guidance document and security improvement recommendations made during critical facility visits. The information provided by owners or operators for each information collection is Sensitive Security Information (SSI), and it will be protected in accordance with procedures meeting the transmission, handling and storage requirements of SSI set forth in 49 CFR parts 15 and 1520.

Number of Respondents: 125 for the renewal of the critical facility information and 590 for the critical facility security reviews and recommendations follow-up.

Estimated Annual Burden Hours: An estimated 2,730 hours in the first year and 1,080 hours annually in subsequent years.

Issued in Arlington, Virginia, on October 4, 2011.

Joanna Johnson,

TSA Paperwork Reduction Act Officer, Office of Information Technology.

[FR Doc. 2011–26188 Filed 10–7–11; 8:45 am]

BILLING CODE 9110–05–P

DEPARTMENT OF INTERIOR

Bureau of Land Management

[LLCOF03000 L16100000.DU0000]

Notice of Intent To Amend the Resource Management Plan for the San Luis Resource Area, Colorado, and Associated Environmental Assessment

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Intent.

SUMMARY: In compliance with the National Environmental Policy Act of 1969 (NEPA), as amended, and the Federal Land Policy and Management Act of 1976 (FLPMA), as amended, the Bureau of Land Management (BLM) San Luis Valley Public Lands Center, Monte Vista, Colorado, intends to prepare a Resource Management Plan (RMP) Amendment with an associated Environmental Assessment (EA) and by this notice is announcing the beginning of the scoping process to solicit public comments and identify issues.

DATES: This notice initiates the public scoping process for the RMP amendment and associated EA. Comments on issues and planning criteria may be submitted in writing by November 10, 2011. The date(s) and location(s) of any scoping meetings will be announced at least 15 days in advance through local media and newspapers. In order to be included in the RMP amendment and associated EA, all comments must be received prior to the close of the 30 day scoping period or 30 days after the last public meeting, whichever is later. We will provide additional opportunities for public participation upon publication of the Draft RMP amendment and associated EA.

ADDRESSES: You may submit comments related to the proposed RMP amendment by any of the following methods:

- *E-mail: slvplc_comments@blm.gov.*
- *Fax:* 719-852-6250
- *Mail:* BLM, La Jara Field Office, 15571, County Road T–5, La Jara, Colorado 81140–9579.

Documents pertinent to this plan amendment and associated EA may be examined at the La Jara Field Office.

FOR FURTHER INFORMATION CONTACT: For further information and/or to have your name added to our mailing list, contact Jill Lucero, Interdisciplinary Team Lead, (719) 274–6327; see address above; e-mail *jlucero@blm.gov.* 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: This document provides notice that the BLM La Jara Field Office La Jara, Colorado, intends to prepare an RMP amendment and associated EA for the San Luis Valley Public Lands Center, announces the beginning of the scoping process, and seeks public input on issues and planning criteria. The EA will analyze the BLM proposal to amend the San Luis Resource Area (SLRA) Resource Management Plan (RMP) of September 1991, to expand the Blanca Wetlands Area of Critical Environmental Concern (ACEC) and to analyze the terms, along with the compatibility and suitability, of three grazing allotments—one allotment within the Blanca Wetlands ACEC (Blanca allotment) and two allotments adjacent to the current ACEC (Lakes and Dry Lakes allotments). The purpose of the public scoping process is to determine relevant issues that will influence the scope of the environmental analysis, including alternatives, and guide the process for amending the RMP. The RMP amendment and associated EA will specifically address resources in the project area that may be affected. The BLM welcomes public comments concerning the RMP amendment and associated EA and on the following proposed planning criteria:

1. The BLM intends to continue to manage the SLRA in accordance with FLPMA, (43 U.S.C. 1701. *et seq.*), other applicable laws and regulations, and all existing public land laws.

2. The BLM intends to use a collaborative, multi-jurisdictional approach with local, state, tribal and Federal agencies to jointly determine the desired future condition of public lands and provide consistency with existing plans and policies to the extent that those plans and policies are consistent with Federal law governing the administration of public land.

3. The BLM intends to limit its RMP amendment to enlarging the Blanca Wetlands ACEC and analyzing the three range allotments (Lakes, Dry Lakes and Blanca).

4. The BLM intends to address the socioeconomic impacts of the alternatives.

5. The amendment process will follow the NEPA planning process and will include an EA. If a Finding of No Significant Impact cannot be reached, an EIS will follow.

At present, the BLM has identified the following preliminary issues concerning the RMP amendment and associated EA. The BLM welcomes public comments on potential issues in addition to those identified here:

1. Compatibility of grazing with wetland habitat and waterbird production;

2. Need for restoration and connectivity of wetland habitat;

3. Impacts to cultural resources;

4. Impacts to mineral resource production;

5. Potential for recreational development and conflicts in priorities between recreation and wildlife.

The BLM will use and coordinate the NEPA commenting process to help fulfill the public involvement process under Section 106 of the National Historic Preservation Act (16 U.S.C. 470f) as provided for in 36 CFR 800.2(d)(3). Native American tribal consultations will be conducted in accordance with policy, and tribal concerns will be given due consideration, including impacts on Indian trust assets. Federal, state and local agencies, and tribes—along with other stakeholders that may be interested or affected by the BLM's decision on this project—are invited to participate in the scoping process and, if eligible, may request or be contacted by the BLM to participate as a cooperating agency. You may submit comments on issues and planning criteria in writing to the BLM at any public scoping meeting, or you may submit them to the BLM using one of the methods listed in the **ADDRESSES** section above. To be most helpful, you should submit comments by the close of the 30 day scoping period or within 30 days after the last public meeting, whichever is later. 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.

The BLM will use an interdisciplinary approach to develop the RMP amendment in order to consider the resource issues and concerns identified during public scoping. The planning process will include specialists with expertise in rangeland management, minerals and geology, forestry, outdoor recreation, archaeology, botany, wildlife, fisheries, lands and realty, hydrology, soils, vegetation and fire.

Authority: 40 CFR 1501.7 and 43 CFR 1610.2.

John Mehlhoff,

Acting Colorado State Director.

[FR Doc. 2011–26183 Filed 10–7–11; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNVS03000.L5101.ER0000. LVRWF1104400; NVN–089669; 11–08807; MO# 4500023114; TAS: 14X5017]

Notice of Intent To Prepare an Environmental Impact Statement for the Proposed Valley Electric Association Hidden Hills Transmission Project, Clark and Nye Counties, NV

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Intent.

SUMMARY: In compliance with the National Environmental Policy Act of 1969, as amended, and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) Southern Nevada District, Las Vegas Field Office, intends to prepare an Environmental Impact Statement (EIS) and by this notice is announcing the beginning of the scoping process to solicit public comments and identify issues.

DATES: This notice initiates the public scoping process for the EIS. Comments on issues may be submitted in writing until December 12, 2011. The date(s) and location(s) of any scoping meetings will be announced at least 15 days in advance through local news media, newspapers, and the BLM Web site at: *http://www.blm.gov/nv/st/en/fo/lvfo.html.* Comments must be received prior to the close of the scoping period or 15 days after the last public meeting, whichever is later, to be included in the Draft EIS. We will provide additional opportunities for public participation upon publication of the Draft EIS.

ADDRESSES: You may submit comments related to the Valley Electric Association Hidden Hills Transmission Project by any of the following methods:

- *E-mail: ValleyElec_HiddenHillsEIS@blm.gov.*
- *Fax:* (702) 515–5010 (*attention:* Gregory Helseth).
- *Mail:* Gregory Helseth, BLM Southern Nevada District Office, 4701 North Torrey Pines Drive, Las Vegas, Nevada 89130–2301.
- *In Person:* At any EIS public scoping meeting.

Documents pertinent to this proposal may be examined at the BLM Southern Nevada District Office.

FOR FURTHER INFORMATION CONTACT: Gregory Helseth, Renewable Energy Project Manager, (702) 515–5173; or e-mail *ValleyElec_HiddenHillsEIS@blm.gov.* You may also use this contact information to request that your name be added to the project mailing list. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at (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: The applicant, Valley Electric Association (VEA), has requested a right-of-way authorization for the construction, operation, maintenance, and termination of transmission infrastructure improvements in Pahrump and Sandy Valleys to Jean, Nevada, and terminating at Eldorado Substation near McCullough Pass. The proposed project will support the delivery of 500 megawatts into the VEA transmission system through the development of a solar electric generating facility to be located on private land in Inyo County, California. The proposed improvements may also support the development of additional renewable resource generation facilities in Nevada.

The proposed transmission upgrades would consist of the following new or expanded facilities on BLM managed land:

- A new 10-acre Tap 230/500 kilovolt (kV) Substation (Tap Substation) located immediately northeast of the existing VEA 138 kV and VEA 230 kV transmission line alignments adjacent to Highway 160.
- Approximately 53.7 miles of new 500 kV single-circuit transmission line from the Tap Substation to the existing Eldorado Substation.
- Approximately 9.7 miles of new 230 kV single-circuit transmission line from the solar electric generating facility site in Inyo County, California to the new Tap Substation.
- Improvement of existing VEA facilities to accommodate the necessary interconnections at Pahrump Substation, Vista Substation, Gamebird Substation, Charleston Substation, and Eldorado Substation.
- Installation of a buried 9.3 mile, 12-inch natural gas pipeline, which would extend from the solar electric generating facility site in Inyo County, California, to the existing VEA 230 kV transmission line. From this location, a 36-inch line would turn southeast and continue 26 miles to where it intersects the existing Kern River Gas Transmission pipeline.
- Construction and operation of new and improved existing access roads

along each of the proposed transmission alignments.

• Temporary work areas associated with construction activities, material storage, and staging.

The proposed transmission project is in conformance with the 1998 Las Vegas Resource Management Plan and does not require a land use plan amendment.

The purpose of the public scoping process is to ascertain the relevant issues that will influence the scope of the environmental analysis, including alternatives, and guide the process for developing the EIS. At present, the BLM has identified the following preliminary issues: threatened and endangered species, visual resource impacts (including visual effects to the Old Spanish Trail National Historic Trail), recreation impacts, socioeconomic effects, and connected and cumulative actions.

The BLM will utilize and coordinate the NEPA commenting process to satisfy the public involvement process for Section 106 of the National Historic Preservation Act (NHPA) (16 U.S.C. 470f) as provided for in 36 CFR 800.2(d)(3). Native American tribal consultations will be conducted in accordance with policy, and tribal concerns will be given due consideration, including impacts on Indian trust assets. Federal, State, and local agencies, as well as individuals, organizations, or tribes that may be interested or affected by the BLM's decision on this project are invited to participate in the scoping process and, if eligible, may request or be requested by the BLM to participate as a cooperating agency.

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.

Mary Jo Rugwell,

District Manager, Southern Nevada District Office.

[FR Doc. 2011–26192 Filed 10–7–11; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLAZ956000.L14200000.BJ0000.241A]

Notice of Filing of Plats of Survey; Arizona

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Filing of Plats of Survey; Arizona.

SUMMARY: The plats of survey of the described lands were officially filed in the Arizona State Office, Bureau of Land Management, Phoenix, Arizona, on dates indicated.

SUPPLEMENTARY INFORMATION:

The Gila and Salt River Meridian, Arizona

The plat representing the dependent resurvey of a portion of the east boundary and a portion of the subdivisional lines, Township 1 North, Range 4 East, accepted September 26, 2011, and officially filed September 30, 2011, for Group 1076, Arizona.

This plat was prepared at the request of the Bureau of Indian Affairs, Western Regional Office.

The plat representing the dependent resurvey of a portion of the north boundary, a portion of the subdivisional lines, a portion of the subdivision of section 8 and portions of a metes-and-bounds survey of the south boundary of the Salt River Pima-Maricopa Indian Community and the subdivision of section 3, Township 1 North, Range 5 East, accepted September 26, 2011, and officially filed September 30, 2011, for Group 1076, Arizona.

This plat was prepared at the request of the Bureau of Indian Affairs, Western Regional Office.

The plat representing the dependent resurvey of a portion of the subdivisional lines and a portion of the subdivision of section 34, Township 2 North, Range 5 East, accepted September 26, 2011, and officially filed September 30, 2011, for Group 1076, Arizona.

This plat was prepared at the request of the Bureau of Indian Affairs, Western Regional Office.

A person or party who wishes to protest against any of these surveys must file a written protest with the Arizona State Director, Bureau of Land Management, stating that they wish to protest.

A statement of reasons for a protest may be filed with the notice of protest to the State Director, or the statement of reasons must be filed with the State Director within thirty (30) days after the protest is filed.

FOR FURTHER INFORMATION CONTACT: These plats will be available for inspection in the Arizona State Office, Bureau of Land Management, One North Central Avenue, Suite 800, Phoenix, Arizona 85004–4427. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

Dated: October 4, 2011.

Danny A. West,

Chief Cadastral Surveyor of Arizona.

[FR Doc. 2011–26216 Filed 10–7–11; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCON03000–L12200000–PA0000]

Notice of Final Supplementary Rules for Public Lands in Colorado: North Fruita Desert Management Area

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of final supplementary rules.

SUMMARY: The Bureau of Land Management (BLM) Grand Junction Field Office (GJFO) is implementing supplementary rules to regulate conduct on public lands within the North Fruita Desert Management Area (NFDMA). These supplementary rules are needed to implement decisions found in the 2004 North Fruita Desert Management Plan (NFDMP) to protect public lands, resources, and public health, and provide for public safety.

DATES: *Effective Date:* These rules are effective December 12, 2011.

ADDRESSES: You may send inquiries to the Bureau of Land Management, 2815 H Road, Grand Junction, Colorado 81506, or email comments to *gjfo_webmail@blm.gov, Attn:* ''North Fruita.''

FOR FURTHER INFORMATION CONTACT: Bryce Stewart, BLM Ranger, Bureau of Land Management, Grand Junction Field Office, at the address listed above or by telephone at 970–244–3070.

SUPPLEMENTARY INFORMATION:

I. Authority
II. Background
III. Discussion of the Public Comments

IV. Procedural Matters
V. Final Supplementary Rules

I. Authority

43 U.S.C. 1740, 43 U.S.C. 315a, and 43 CFR 8365.1–6.

II. Background

Recreation resource management decisions for the GJFO were detailed in the Grand Junction Resource Area (GJRA) Resource Management Plan (RMP) in 1987. The Grand Valley, including the North Fruita Desert, was designated as an Intensive Recreation Management Area (IRMA) in the RMP. The RMP recommended additional planning for the IRMA due to its distinguishing characteristics and significant opportunities for recreation. The NFDMP and the supporting environmental assessment (EA) approved in 2004 fulfill the obligation of the GJFO to complete a site-specific recreation plan for this area. They establish management objectives and identify management strategies to achieve those objectives. The final rules published today are consistent with direction for recreation actions in the BLM's National Mountain Bicycling Strategic Action Plan (2002) and the BLM's National Management Strategy for Motorized Off-Highway Vehicle Use on Public Lands (2001). The BLM has added definitions in the final rule to clarify the meaning of camping, day-use areas, designated trails, firearms, vehicles, mechanized vehicles, off-road vehicles, and Special Recreation Management Areas. The BLM revised proposed rule number six to clarify allowable uses on roads and trails. That proposed rule was broken into four separate rules for clarification. The BLM revised proposed rule eight to clarify access to day-use areas for hunting. Possession of an off-road vehicle was inadvertently left out of proposed rule number four and was added in the final rule for consistency with rule numbers five and six. The BLM also clarified penalties under the Taylor Grazing Act of 1934. Otherwise, with the exception of minor non-substantive grammatical and formatting changes, the final rules remain as proposed.

III. Discussion of Public Comments

The BLM GJFO proposed these supplementary rules in the **Federal Register** (74 FR 39100) on August 5, 2009. Public comments were accepted for a period of 60 days, ending on October 5, 2009. The BLM received one comment from the Colorado Division of Wildlife (CDOW). The CDOW asked the BLM to consider revising proposed supplementary rule number eight, which addresses areas designated as ''day-use only.'' The CDOW noted that CDOW Rule 202(A) provides ''Big game may be taken from one-half (½) hour before sunrise to one-half (½) hour after sunset.''

The BLM agrees with this comment and has made changes in final rule number nine.

IV. Procedural Matters

Executive Order 12866, Regulatory Planning and Review

These supplementary rules are not significant regulatory actions and are not subject to review by the Office of Management and Budget under Executive Order 12866. These supplementary rules will not have an annual effect of $100 million or more on the economy. They will not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities. These supplementary rules will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency. The supplementary rules do not materially alter the budgetary effects of entitlements, grants, user fees, or loan programs or the rights or obligations of their recipients; nor do they raise any novel legal or policy issues. These supplementary rules merely establish rules of conduct for public use of a limited area of public lands.

Clarity of the Regulations

Executive Order 12866 requires each agency to write regulations that are simple and easy to understand. The BLM invites public comments on how to make these supplementary rules easier to understand, including answers to questions such as the following:

1. Are the requirements in the supplementary rules clearly stated?
2. Do the supplementary rules contain technical language or jargon that interferes with their clarity?
3. Does the format of the supplementary rules (grouping and order of sections, use of headings, paragraphing, *etc.*) aid or reduce clarity?
4. Is the description of the supplementary rules in the **SUPPLEMENTARY INFORMATION** section of this preamble helpful in understanding the supplementary rules? How could this description be more helpful in making the supplementary rules easier to understand?

Please send any comments you have on the clarity of the rules to the address specified in the **ADDRESSES** section.

National Environmental Policy Act (NEPA)

The NFDMP amends the GJRA RMP and supports BLM policies. In 2002, an EA (CO–130–02–008–EA) was initiated to provide the environmental analysis necessary to implement these final supplementary rules, and the Decision Record (DR) was signed in 2004. These supplementary rules would give the BLM the tools to enforce the measures approved in the 2004 DR by allowing the BLM to enforce decisions developed to protect public health and safety and improve the protection of recreational and public land resources. These rules do not change any of the NEPA analysis or decisions in the 2004 DR. These rules are established for the purpose of enforcing the actions and protecting the resources identified in CO–130–02–008–EA.

The BLM reviewed CO–130–02–008–EA and found that the supplementary rules do not constitute a major Federal action significantly affecting the quality of the human environment under Section 102(2)(C) of NEPA, 42 U.S.C. 4332(2)(C). The DR and Finding of No Significant Impact (FONSI) were signed on November 8, 2004 (CO–130–02–008–EA, p. 74). The BLM placed the EA, DR and FONSI on file in the BLM Administrative Record, and invites the public to review these documents at the address specified in the **ADDRESSES** section.

Regulatory Flexibility Act

Congress enacted the Regulatory Flexibility Act (RFA) of 1980, as amended (5 U.S.C. 601–612), to ensure that government regulations do not unnecessarily or disproportionately burden small entities. The RFA requires a regulatory flexibility analysis if a rule would have a significant economic impact, either detrimental or beneficial, on a substantial number of small entities. These supplementary rules merely establish rules of conduct for public use of a limited area of public lands. Therefore, the BLM has determined under the RFA that these supplementary rules would not have a significant economic impact on a substantial number of small entities.

Small Business Regulatory Enforcement Fairness Act

These supplementary rules are not considered a ''major rule'' as defined under 5 U.S.C. 804(2). The supplementary rules merely establish rules of conduct for public use of a limited area of public lands.

Unfunded Mandates Reform Act

These supplementary rules do not impose an unfunded mandate on state, local, or tribal governments in the aggregate, or the private sector, of more than $100 million per year; nor do they have a significant or unique effect on small governments. The rules have no effect on governmental or tribal entities and would impose no requirements on any of these entities. The supplementary rules merely establish rules of conduct for public use of a limited area of public lands. Therefore, the BLM is not required to prepare a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*).

Executive Order 12630, Governmental Actions and Interference With Constitutionally Protected Property Rights (Takings)

These supplementary rules do not have significant takings implications, nor are they capable of interfering with Constitutionally-protected property rights. The supplementary rules merely establish rules of conduct for public use of a limited area of public lands. Therefore, the BLM has determined that these rules will not cause a ''taking'' of private property or require preparation of a Takings Assessment under this Executive Order.

Executive Order 13132, Federalism

These supplementary rules will not have a substantial direct effect on the states, the relationship between the national government and the states, or the distribution of power and responsibilities among the various levels of government. These supplementary rules do not come into conflict with any state law or regulation. Therefore, in accordance with Executive Order 13132, the BLM has determined that these supplementary rules do not have sufficient Federalism implications to warrant preparation of a Federalism Assessment.

Executive Order 12988, Civil Justice Reform

Under Executive Order 12988, the BLM has determined that these rules will not unduly burden the judicial system and that they meet the requirements of Sections 3(a) and 3(b)(2) of Executive Order 12988.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

In accordance with Executive Order 13175, the BLM has found that these supplementary rules do not include policies that have tribal implications. The supplementary rules merely establish rules of conduct for public use of a limited area of public land and do not affect land held for the benefit of Indians or Alaska Natives or impede their rights.

Paperwork Reduction Act

These final supplementary rules do not directly provide for any information collection that the Office of Management and Budget must approve under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* Any information collection that may result from Federal criminal investigations or prosecutions conducted under these final supplementary rules is exempt from the provisions of the Paperwork Reduction Act of 1995, as provided at 44 U.S.C. 3518(c)(1).

Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

Under Executive Order 13211, the BLM has determined that these supplementary rules are not a significant energy action, and would not have an adverse effect on energy supplies, production, or consumption.

V. Final Supplementary Rules

Author

The principal author of these supplementary rules is Eric Boik, Field Staff Ranger, Bureau of Land Management, Grand Junction Field Office, 2815 H Road, Grand Junction, Colorado 81506.

For the reasons stated in the preamble, and under the authorities for supplementary rules found at 43 U.S.C. 1740, 43 U.S.C. 315a, and 43 C.F.R. 8365.1–6, the Colorado State Director, issues final supplementary rules for public lands within the NFDMA, Colorado, to read as follows:

Supplementary Rules for North Fruita Desert Management Area

Definitions

Camping means the erecting of a tent or shelter of natural or synthetic material, preparing a sleeping bag or other bedding material for use, parking a motor vehicle, motor home, or trailer, or mooring of a vessel for the apparent purpose of overnight occupancy.

Day-Use Area means any area open for public access during daylight hours, between sunrise and sunset, or where specific hours of operation have been identified. Overnight use in these areas is specifically prohibited.

Designated Trail means a trail developed, maintained, and explicitly identified for public use by the BLM. All designated trails will be identified by a combination of trailhead maps and on-site signage listing allowable uses.

Firearm or Other Projectile Shooting Device means all firearms, air rifles, pellet and BB guns, spring guns, bows and arrows, slings, paint ball markers, other instruments that can propel a projectile (such as a bullet, dart, or pellet) by combustion, air pressure, gas pressure, or other means, or any instrument that can fire blank cartridges.

Mechanized Vehicle means mechanical transport by way of any vehicle, device, or contrivance for moving people or material in or over land, water, snow, or air that has moving parts. This includes but is not limited to sailboats, sailboards, hang gliders, parachutes, bicycles, game carriers, carts, or wagons. The term does not include wheelchairs, nor does it include horses or other pack stock, skis, snowshoes, non-motorized river craft including, but not limited to, drift boats, rafts, and canoes, or sleds, travois, or similar devices without moving parts. (See 43 CFR 6301.5).

Off-road Vehicle means any motorized vehicle capable of, or designed for, travel on or immediately over land, water, or other natural terrain excluding:

(1) Any non-amphibious registered motorboat;

(2) Any military, fire, emergency, or law enforcement vehicle while being used for emergency purposes;

(3) Any vehicle whose use is expressly authorized by the authorized officer, or otherwise officially approved;

(4) Vehicle in official use; and

(5) Any combat or combat support vehicle when used in times of national defense emergencies. (See 43 CFR 8340.0–5).

Special Recreation Management Area means an administrative unit where the existing or proposed recreation opportunities and recreation setting characteristics are recognized for their unique value, importance, and/or distinctiveness, especially as compared to other areas used for recreation.

Vehicle means every device in, upon, or by which a person or property is or may be transported from one place to another.

Prohibited Acts

Unless otherwise authorized, the following acts are prohibited on public lands within the North Fruita Desert Management Area:

1. You must not start or maintain a fire outside of a metal fire ring at sites or areas where fire rings are provided by

the BLM. Mechanical stoves or other appliances fueled by gas and equipped with a valve that allows the operator to control the flame are exempt from this rule.

2. You must not start or maintain a fire in sites or areas not designated as open for such use by a BLM sign or map. Mechanical stoves or other appliances fueled by gas and equipped with a valve that allows the operator to control the flame are exempt from this rule.

3. You must not cut, collect, or use live, dead, or down wood except in areas designated as open to such use by a BLM sign or map.

4. You must not operate or be in possession of an off-road vehicle or mechanized vehicle on any road which is not designated as open to such use by a BLM sign or map.

5. You must not operate or be in possession of an off-road vehicle or mechanized vehicle on any trail which is not designated as open to such use by a BLM sign or map.

6. You must not ride or be in possession of horses or other pack animals on any trail which is not designated as open to such use by a BLM sign or map.

7. Where pedestrian travel is restricted to a designated trail or route, you must not travel cross-country off the designated trail or route.

8. You must not discharge a firearm or other projectile shooting device of any kind, including those used for target shooting or paintball, where a BLM sign or map indicates a no-shooting area. Licensed hunters in pursuit of game during a legal hunting season with appropriate firearms, as defined by the Colorado Division of Wildlife, are exempt from this rule.

9. You must not enter or remain in a designated day-use area after sunset or before sunrise. Licensed hunters in pursuit of game during the proper season, as defined by the Colorado Division of Wildlife, are exempt from this rule.

10. You must not enter an area that is designated as closed by a BLM sign or map.

11. You must not camp in sites or areas not designated as open to camping by a BLM sign or map.

12. You must not burn wood or other material containing nails, glass, or any metal.

13. You must not park a vehicle in areas not designated for parking by a BLM sign or map.

14. You must not bring any dog into the NFDMA that is not controlled by visual, audible, or physical means.

15. You must remove and properly dispose of solid dog waste as indicated by a BLM sign or map.

16. You must properly dispose of solid human waste as indicated by a BLM sign or map.

17. You must not operate or be in possession of an off-road vehicle that produces sound exceeding 96 decibels.

Exemptions

The following persons are exempt from these supplementary rules: Any Federal, state, local, and/or military persons acting within the scope of their official duties; members of any organized rescue or fire-fighting force in performance of an official duty; and persons, agencies, municipalities, or companies holding an existing special-use permit inside the NFDMA and operating within the scope of their permit.

Penalties

Under the Taylor Grazing Act of 1934, 43 U.S.C. 315a, any willful violation of these supplementary rules on public lands within a grazing district shall be punishable by a fine of not more than $500.

Under section 303(a) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1733(a) and 43 CFR 8360.0–7, any person who knowingly and willfully violates any of these supplementary rules on public lands within the NFDMA may be tried before a United States Magistrate and fined no more than $1,000, imprisoned for no more than 12 months, or both. Such violations may also be subject to the enhanced fines provided for by 18 U.S.C. 3571.

Helen M. Hankins,

State Director.

[FR Doc. 2011–26190 Filed 10–7–11; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCON03000–L12200000–PA0000]

Notice of Final Supplementary Rules for Public Lands in Colorado: Bangs Canyon Special Recreation Management Area

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of final supplementary rules.

SUMMARY: The Bureau of Land Management (BLM) Grand Junction Field Office (GJFO) is implementing supplementary rules to regulate conduct on public lands within Bangs Canyon Special Recreation Management Area (BCSRMA). These supplementary rules are needed to implement decisions found in the 1999 Bangs Canyon Special Recreation Management Area Management Plan (BCSRMAMP) and the Grand Junction Resource Management Plan (GJRMP). These rules are needed to protect natural resources located within the BCSRMA and provide for public health and safety.

DATES: *Effective Date:* These rules are effective December 12, 2011.

ADDRESSES: You may send inquiries to the Bureau of Land Management, Grand Junction Field Office, 2815 H Road, Grand Junction, Colorado 81506, or e-mail comments to *gjfo_webmail@blm.gov,* Attn: ''Bangs Canyon.''

FOR FURTHER INFORMATION CONTACT: Bryce Stewart, Ranger, Bureau of Land Management, Grand Junction Field Office, at the address listed above or by telephone at (970) 244–3070.

SUPPLEMENTARY INFORMATION:

I. Authority
II. Background
III. Discussion of Public Comments
IV. Procedural Matters
V. Final Supplemental Rules

I. Authority

43 U.S.C. 1740, 43 U.S.C. 315a, and 43 CFR 8365.1–6

II. Background

Recreation resource management decisions for the GJFO were detailed in the GJRMP in 1987. The Grand Valley, including the Bangs Canyon area, was designated as an Intensive Recreation Management Area (IRMA) in the GJRMP. The plan recommended additional planning for the IRMA due to its distinguishing characteristics and significant recreation opportunities. The BCSRMAMP was approved in 1999 and the subsequent BCSRMA implementation plan and environmental assessment (EA) were approved in 2006, fulfilling the GJFO obligation to complete site-specific plans for this area. The BCSRMAP establishes management objectives and identifies management strategies to achieve those objectives while the BCSRMA implementation plan provides site-specific direction and analysis of management actions. The final rules are consistent with the BLM's National Management Strategy for Motorized Off-Highway Vehicle Use on Public Lands (2001). The BLM has added definitions to the final rule to clarify the meaning of camping, day-use areas, designated trails, firearms, vehicles, mechanized

vehicles, off-road vehicles, and Special Recreation Management Areas. The BLM revised proposed rule number 8 to clarify allowable uses on roads and trails. The proposed rule was broken into four separate rules for clarification. The BLM revised proposed rule 17 to clarify access to day-use areas for hunting. Possession of an off-road vehicle was inadvertently left out of proposed rule numbers 6, 10, and 11 and was added in the final rule for consistency with rule numbers 7 and 8. The BLM also clarified penalties under the Taylor Grazing Act of 1934. Otherwise, with the exception of minor non-substantive grammatical and formatting changes, the final rules remain as proposed.

III. Discussion of Public Comments

The BLM proposed these supplementary rules in the **Federal Register** (74 FR 36506) on July 23, 2009. Public comments were accepted for a period of 60 days ending on September 21, 2009. The BLM received one comment from the Colorado Division of Wildlife (CDOW). The CDOW asked the BLM to consider revising proposed supplementary rule 17, which addresses areas designated as ''day-use only.'' The CDOW noted that CDOW Rule 202(A) provides ''Big game may be taken from one-half (½) hour before sunrise to one-half (½) hour after sunset.'' The BLM agrees with this comment and has made changes in final rule number 18.

IV. Procedural Matters

Executive Order 12866, Regulatory Planning and Review

These supplementary rules are not significant regulatory actions and are not subject to review by the Office of Management and Budget under Executive Order 12866. These supplementary rules will not have an annual effect of $100 million or more on the economy. They will not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities. These supplementary rules will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency. The supplementary rules do not materially alter the budgetary effects of entitlements, grants, user fees, or loan programs or the rights or obligations of their recipients, nor do they raise novel legal or policy issues. These supplementary rules merely establish rules of conduct for public use of a limited area of public lands.

Clarity of the Regulations

Executive Order 12866 requires each agency to write regulations that are simple and easy to understand. The BLM invites public comments on how to make these supplementary rules easier to understand, including answers to questions such as the following:

1. Are the requirements in the supplementary rules clearly stated?
2. Do the supplementary rules contain technical language or jargon that interferes with their clarity?
3. Does the format of the supplementary rules (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce clarity?
4. Is the description of the supplementary rules in the **SUPPLEMENTARY INFORMATION** section of this preamble helpful in understanding the supplementary rules? How could this description be more helpful in making the supplementary rules easier to understand?

Please send any comments you have on the clarity of the rules to the address specified in the **ADDRESSES** section.

National Environmental Policy Act (NEPA)

Between 1995 and 1999, the Bangs Canyon Citizens Advisory Group formed and convened a series of public meetings, working group meetings, and field trips to accomplish additional planning outlined in the GJRMP, eventually developing recommendations on how the Bangs Canyon area should be managed. These recommendations were endorsed by the Northwest Resource Advisory Council and compiled into a non-NEPA document known as the BCSRMAMP. In December 2003, environmental assessment CO–130–04–018–EA was initiated to provide the environmental analysis necessary to implement these recommendations, and a Decision Record (DR) was signed in 2006. These supplementary rules would allow the BLM to implement the measures approved in the 2006 DR by allowing the BLM to enforce decisions developed to protect public health and safety and improve the protection of recreational and public lands resources. These rules do not change any of the NEPA analysis or recommendations from the DR signed in 2006. These rules are established for the purpose of enforcing the actions and protecting the resources identified in CO–130–04–018–EA.

The BLM reviewed CO–130–04–018–EA and found that the supplementary rules do not constitute a major Federal action significantly affecting the quality of the human environment under Section 102(2)(C) of NEPA, 42 U.S.C. 4332(2)(C). The DR and Finding of No Significant Impact (FONSI) were signed on April 5, 2006 (CO–130–04–018–EA, p. 11). The BLM placed the EA, DR and FONSI on file in the BLM Administrative Record, and invites the public to review these documents at the address specified in the **ADDRESSES** section.

Regulatory Flexibility Act

Congress enacted the Regulatory Flexibility Act (RFA) of 1980, as amended (5 U.S.C. 601–612), to ensure that government regulations do not unnecessarily or disproportionately burden small entities. The RFA requires a regulatory flexibility analysis if a rule would have a significant economic impact, either detrimental or beneficial, on a substantial number of small entities. These supplementary rules merely establish rules of conduct for public use of a limited area of public lands. Therefore, the BLM has determined under the RFA that these supplementary rules would not have a significant economic impact on a substantial number of small entities.

Small Business Regulatory Enforcement Fairness Act

These supplementary rules are not considered a ''major rule'' as defined under 5 U.S.C. 804(2). The supplementary rules merely establish rules of conduct for public use of a limited area of public lands.

Unfunded Mandates Reform Act

These supplementary rules do not impose an unfunded mandate on state, local, or tribal governments in the aggregate, or the private sector, of more than $100 million per year; nor do they have a significant or unique effect on small governments. The rules have no effect on governmental or tribal entities and would impose no requirements on any of these entities. The supplementary rules merely establish rules of conduct for public use of a limited area of public lands. Therefore, the BLM is not required to prepare a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*).

Executive Order 12630, Governmental Actions and Interference With Constitutionally Protected Property Rights (Takings)

These supplementary rules do not have significant takings implications, nor are they capable of interfering with Constitutionally-protected property rights. The supplementary rules merely establish rules of conduct for public use

of a limited area of public lands. Therefore, the Department of the Interior has determined that these rules will not cause a ''taking'' of private property or require preparation of a Takings Assessment under this Executive Order.

Executive Order 13132, Federalism

These supplementary rules will not have a substantial direct effect on the states, the relationship between the national government and the states, or the distribution of power and responsibilities among the various levels of government. These supplementary rules do not come into conflict with any state law or regulation. Therefore, in accordance with Executive Order 13132, the BLM has determined that these supplementary rules do not have sufficient Federalism implications to warrant preparation of a Federalism Assessment.

Executive Order 12988, Civil Justice Reform

Under Executive Order 12988, the BLM has determined that these rules will not unduly burden the judicial system and that they meet the requirements of Sections 3(a) and 3(b)(2) of Executive Order 12988.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

In accordance with Executive Order 13175, the BLM has found that these supplementary rules do not include policies that have tribal implications. The supplementary rules merely establish rules of conduct for public use of a limited area of public land and do not affect land held for the benefit of Indians or Alaska Natives or impede their rights.

Paperwork Reduction Act

These final supplementary rules do not directly provide for any information collection that the Office of Management and Budget must approve under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* Any information collection that may result from Federal criminal investigations or prosecutions conducted under these supplementary rules is exempt from the provisions of the Paperwork Reduction Act of 1995, as provided at 44 U.S.C. 3518(c)(1).

Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

Under Executive Order 13211, the BLM has determined that these supplementary rules are not a significant energy action, and that they would not have an adverse effect on energy supplies, production, or consumption.

V. Final Supplementary Rules

Author

The principal author of these supplementary rules is Eric Boik, Field Staff Ranger, Bureau of Land Management, Grand Junction Field Office, 2815 H Road, Grand Junction, Colorado 81506.

For the reasons stated in the preamble, and under the authorities for supplementary rules found at 43 U.S.C. 1740, 43 U.S.C. 315a, and 43 CFR 8365.1–6, the Colorado State Director issues these final supplementary rules for public lands within the BCSRMA, Colorado, to read as follows:

Supplementary Rules for Bangs Canyon Special Recreation Management Area

Definitions

Camping means the erecting of a tent or shelter of natural or synthetic material, preparing a sleeping bag or other bedding material for use, parking a motor vehicle, motor home or trailer, or mooring of a vessel for the apparent purpose of overnight occupancy.

Day-Use Area means any area open for public access during daylight hours, between sunrise and sunset, or where specific hours of operation have been identified. Overnight use in these areas is specifically prohibited.

Designated Trail means a trail developed, maintained, and explicitly identified for public use by the BLM. All designated trails will be identified by a combination of trailhead maps and on-site signage listing allowable uses.

Firearm or Other Projectile Shooting Device means all firearms, air rifles, pellet and BB guns, spring guns, bows and arrows, slings, paint ball markers, other instruments that can propel a projectile (such as a bullet, dart, or pellet) by combustion, air pressure, gas pressure, or other means, or any instrument that can fire blank cartridges.

Mechanized Vehicle means mechanical transport by means of any vehicle, device, or contrivance for moving people or material in or over land, water, snow, or air that has moving parts. This includes but is not limited to sailboats, sailboards, hang gliders, parachutes, bicycles, game carriers, carts, or wagons. The term does not include wheelchairs, nor does it include horses or other pack stock, skis, snowshoes, non-motorized river craft including, but not limited to, drift boats, rafts, and canoes, or sleds, travois, or similar devices without moving parts. (See 43 CFR 6301.5)

Off-road Vehicle means any motorized vehicle capable of, or designed for, travel on or immediately over land, water, or other natural terrain excluding:

(1) Any non-amphibious registered motorboat;

(2) Any military, fire, emergency, or law enforcement vehicle while being used for emergency purposes;

(3) Any vehicle whose use is expressly authorized by the authorized officer, or otherwise officially approved;

(4) Vehicle in official use; and

(5) Any combat or combat support vehicle when used in times of national defense emergencies. (See 43 CFR 8340.0–5)

Special Recreation Management Area means an administrative unit where the existing or proposed recreation opportunities and recreation setting characteristics are recognized for their unique value, importance, and/or distinctiveness, especially as compared to other areas used for recreation.

Vehicle means every device in, upon, or by which a person or property is or may be transported from one place to another.

Prohibited Acts

Unless otherwise authorized, the following acts are prohibited on public lands within the BCSRMA:

1. You must not start or maintain a fire in sites or areas not designated as open for such use by a BLM sign or map. Mechanical stoves or other appliances fueled by gas and equipped with a valve that allows the operator to control the flame are exempt from this rule.

2. You must not start or maintain a fire outside of a metal fire ring at sites or areas where fire rings are provided by the BLM. Mechanical stoves or appliances fueled by gas and equipped with a valve that allows the operator to control the flame are exempt from this rule.

3. You must not cut, collect, or use live, dead, or down wood except in areas designated as open to such use by a BLM sign or map.

4. You must not camp in sites or areas not designated as open to camping by a BLM sign or map.

5. You must properly dispose of solid human waste as indicated by a BLM sign or map.

6. You must not operate or be in possession of an off-road vehicle or mechanized vehicle on any road which is not designated as open to such use by a BLM sign or map.

7. You must not operate or be in possession of an off-road vehicle or

mechanized vehicle on any trail which is not designated as open to such use by a BLM sign or map.

8. You must not ride or be in possession of horses or other pack animals on any trail which is not designated as open to such use by a BLM sign or map.

9. Where pedestrian travel is restricted to a designated trail or route, you must not travel cross-country off the designated trail or route.

10. You must not operate or be in possession of an off-road vehicle or mechanized vehicle in violation of vehicle width and/or vehicle type restrictions as indicated by a BLM sign or map.

11. You must not operate or be in possession of an off-road vehicle that produces sound exceeding 96 decibels.

12. You must not discharge a firearm or other projectile shooting device of any kind, including those used for target shooting or paintball, where a BLM sign or map indicates a no-shooting area. Licensed hunters in pursuit of game during a legal hunting season with appropriate firearms, as defined by the Colorado Division of Wildlife, are exempt from this rule.

13. You must not enter an area that is designated as closed by a BLM sign or map.

14. You must remove and properly dispose of solid dog waste as indicated by a BLM sign or map.

15. You must not bring any dog into the BCSRMA that is not controlled by visual, audible, or physical means.

16. You must not park a vehicle in areas not designated for parking by a BLM sign or map.

17. You must not burn wood or other material containing nails, glass, or any metal.

18. You must not enter or remain in a designated day-use area after sunset or before sunrise. Licensed hunters in pursuit of game during a legal hunting season, as defined by the Colorado Division of Wildlife, are exempt from this rule.

Exemptions

The following persons are exempt from these supplementary rules: any Federal, state, local, and/or military persons acting within the scope of their official duties; members of any organized rescue or fire-fighting force in the performance of an official duty; and persons, agencies, municipalities, or companies holding an existing special-use permit inside the BCSRMA and operating within the scope of their permit.

Penalties

Under the Taylor Grazing Act of 1934, 43 U.S.C. 315a, any willful violation of these supplementary rules on public lands within a grazing district shall be punishable by a fine of not more than $500.

Under Section 303(a) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1733(a) and 43 CFR 8360.0–7, any person who knowingly and willfully violates any of these supplementary rules on public lands within the BCSRMA may be tried before a United States Magistrate and fined no more than $1,000, imprisoned for no more than 12 months, or both. Such violations may also be subject to the enhanced fines provided for by 18 U.S.C. 3571.

Helen M. Hankins,

State Director.

[FR Doc. 2011–26186 Filed 10–7–11; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCON01000 L12200000.PN0000]

Notice of Final Supplementary Rules for Public Lands in Routt County, CO: Emerald Mountain Special Recreation Management Area

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Final Supplementary Rules.

SUMMARY: The Bureau of Land Management (BLM) Little Snake Field Office is issuing final supplementary rules to regulate conduct on specific public lands within Routt County, Colorado. The rules apply to the Emerald Mountain Special Recreation Management Area (SRMA), also known as Emerald Mountain. The BLM determined these rules are necessary to protect Emerald Mountain's natural resources and provide for public health and safety.

DATES: These rules are effective November 10, 2011.

ADDRESSES: You may submit inquiries by the following methods: Mail or hand-delivery: BLM, Little Snake Field Office, 455 Emerson Street, Craig, Colorado 81625.

FOR FURTHER INFORMATION CONTACT: Gina Robison, Outdoor Recreation Planner, BLM Little Snake Field Office (see **ADDRESSES** listed above); or by phone at (970) 826–5000. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at (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:

I. Background
II. Discussion of Public Comments and Final Supplementary Rules
III. Procedural Matters
IV. Final Supplementary Rules

I. Background

Prior to the BLM's ownership on February 22, 2007, the Emerald Mountain parcel was owned by the Colorado State Land Board and closed to the general public with the exception of permitted agriculture and hunting. Since 2007 the area has been managed as a day use area and has remained closed to motorized vehicle use. A wide variety of recreational uses are allowed and occur on the parcel including biking, hiking, hunting, horseback riding, sightseeing, and wildlife viewing. This wide variety of use has resulted in user conflicts and the need for additional management actions to address user conflicts, impacts to natural resources, and public safety concerns.

Emerald Mountain is a 4,139-acre parcel of public land in Routt County, Colorado. The parcel is surrounded by private land, a Colorado Division of Wildlife State Wildlife Area and property owned by the Colorado State Land Board. Cow Creek Road (Routt County Road 45) provides legal public access to Emerald Mountain.

These final supplementary rules would apply to Emerald Mountain SRMA, identified as follows:

Routt County, Colorado

Sixth Principal Meridian

T. 6 N., R. 85 W.,
Secs. 13, 15, 22, 23, 24, 25, 26, 27, 34, 35, and portions thereof.

A map of the area is available at the Little Snake Field Office.

Emerald Mountain is managed as an SRMA with two adjoining Recreation Management Zones. Zone 1 is managed under a destination recreation-tourism market strategy. The strategy targets Steamboat Springs-area visitors, including local residents, wanting to participate in strenuous and challenging mountain biking and Nordic skiing on primitive trails that are close to the town. Zone 2 is managed under a community recreation market strategy, primarily for Steamboat Springs area

residents to engage in wildlife viewing, hiking and horseback riding in a backcountry setting. Both zones are open to hunting. Other recreation activities are allowable to the extent they are compatible with the primary targeted activities. Both areas are closed to recreational motorized use.

These final supplementary rules implement management decisions made in the Emerald Mountain Land Exchange Environmental Assessment (EA)/Plan Amendment approved in October 2006; the Recreation Activity Management Plan and Transportation Management Plan (RAMP/TMP Phase 1) approved in June 2007; and the Emerald Mountain SRMA Implementation Plan Amendment approved in December 2008, which further defined the final supplementary rules. These documents are available for review at the BLM Little Snake Field Office. The Emerald Mountain SRMA Implementation Plan Amendment included considerable public involvement and review, including six public meetings held at three separate locations.

II. Discussion of Public Comments and Final Supplementary Rules

The BLM published proposed supplementary rules in the **Federal Register** on August 18, 2010 (75 FR 51107). The public comment period ended September 17, 2010. The BLM received seven public comments, three of which were in support of the proposed supplementary rules.

Of the four opposing comments, three opposed proposed supplementary rule number 5, requiring non-working dogs to be on a leash, but allowing working dogs to be off-leash during legal hunting periods when controlled by someone legally hunting or when working as cattle dogs. Two of the opposing comments suggested that dogs should be allowed off-leash while under voice control. The BLM has not revised the proposed supplementary rules in response to these comments because changes would result in conflicts with the SRMA's goal of protecting wildlife resources. The leash requirements in the final supplementary rules allow recreationists and other members of the public to have dogs within the Emerald Mountain SRMA but provide for the protection of wildlife resources.

The third opposing comment to rule number 5 suggested that restraining a dog on a leash would not work when grouse hunting. In response to this comment, the BLM has revised the proposed supplementary rules by adding a definition of ''working dog'' to mean a dog suitable by size, breeding or training for useful work such as hunting or livestock herding. The definition of ''working dog'' was inadvertently left out of the proposed supplementary rules and was added to the final supplementary rule for clarity. The BLM revised final supplementary rule number 5 to be consistent with the new definition of ''working dog.''

The final opposing comment concerned game carts not being allowed in Zone 2 of the Emerald Mountain SRMA. This individual felt that game carts should be allowed in all zones for the purpose of retrieving big game. The BLM has not revisited the rules in response to this comment because the suggested change would be in conflict with land use planning decisions that restrict mechanized use in Zone 2. Comprehensive travel management planning addresses all resource use aspects, accompanying modes and conditions of travel on the public lands. Land use plan decisions must delineate Travel Management Areas (TMAs). Zone 2 of the Emerald Mountain SRMA was delineated for non-mechanized use only.

The BLM revised the proposed supplementary rules by listing the definitions in alphabetical order, deleting the definition of ''official use'' and adding the definition of ''official duty'' in the final supplementary rules. ''Official duty'' means use by an employee, agent or designated representative of the Federal government or one of its contractors, in the course of his or her employment, agency or representation. The term ''official use'' was defined in the proposed supplementary rules, but was not referenced in the proposed or final supplementary rules. The term ''official duty'' is listed in the exemptions in both the proposed and final supplementary rules.

The BLM also revised the proposed supplementary rules by adding penalties under the Taylor Grazing Act, which were inadvertently omitted in the proposed supplementary rules.

III. Procedural Matters

Executive Order 12866, Regulatory Planning and Review

The final supplementary rules do not comprise a significant regulatory action and are not subject to review by the Office of Management and Budget under Executive Order 12866. They do not have an annual effect of $100 million or more on the economy. They do not adversely affect, in a material way, the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities. They do not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency. They do not materially alter the budgetary effects of entitlements, grants, user fees, loan programs, or the rights or obligations of their recipients, nor do they raise novel legal or policy issues. The final supplementary rules merely establish rules of conduct for public use of a limited area of public lands.

Clarity of the Supplementary Rules

Executive Order 12866 requires each agency to write regulations that are simple and easy to understand. The BLM invites your comments on how to make these supplementary rules easier to understand, including answers to questions such as the following:

(1) Are the requirements in the supplementary rules clearly stated?

(2) Do the supplementary rules contain technical language or jargon that interferes with their clarity?

(3) Does the format of the supplementary rules (grouping and order or sections, use of headings, paragraphing, *etc.*) aid or reduce their clarity?

(4) Would the supplementary rules be easier to understand if they were divided into more (but shorter) sections?

(5) Is the description of the supplementary rules in the **SUPPLEMENTARY INFORMATION** section of this preamble helpful to your understanding of the supplementary rules? How could this description be more helpful in making the supplementary rules easier to understand?

Please send any comments you have on the clarity of the supplementary rules to the address specified in the **ADDRESSES** section.

National Environmental Policy Act of 1969

The BLM prepared two EAs: the Emerald Mountain Land Exchange EA/Plan Amendment (EA CO–100–2006–089) and the Recreation Activity Management Plan and Transportation Management Plan (EA CO–100–2007–057). The impacts of the proposed supplemental rules were analyzed in both documents. The proposed supplementary rules were published in the **Federal Register** on August 18, 2010 (75 FR 51107). There has been no change from the proposed supplementary rules to the final supplementary rules that would necessitate further NEPA analysis. The final supplementary rules would merely establish rules of conduct for public use of a limited area of public lands. Therefore, based on the foregoing, the

BLM has determined that these final supplementary rules would not constitute a major Federal action significantly affecting the quality of the human environment under section 102(2)(C) of the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4332(2)(C). The BLM has placed both EA's and Findings of No Significant Impact on file in the BLM Administrative Record at the address specified in the **ADDRESSES** section.

Regulatory Flexibility Act

Congress enacted the Regulatory Flexibility Act of 1980 (RFA), as amended, 5 U.S.C. 601–612, to ensure that government regulations do not unnecessarily or proportionately burden small entities. The RFA requires a regulatory flexibility analysis if a rule would have a significant economic impact, either detrimental or beneficial, on a substantial number of small entities. These final supplementary rules merely establish rules of conduct for public use of a limited area of public lands. Therefore, the BLM has determined under the RFA that these rules would not have a significant economic impact on a substantial number of small entities.

Small Business Regulatory Enforcement Fairness Act

These final supplementary rules are not considered a 'major rule' as defined under 5 U.S.C. 804(2). The supplementary rules merely establish rules of conduct for public use of a limited area of public lands and do not affect commercial or business activities of any kind.

Unfunded Mandates Reform Act

These final supplementary rules will not impose an unfunded mandate on state, local, or tribal governments in the aggregate, or the private sector of more than $100 million per year; nor will they have a significant or unique effect on small governments. The final supplementary rules will have no effect on governmental or tribal entities and will impose no requirements on any of these entities. The final supplementary rules merely establish rules of conduct for public use of a limited area of public lands and do not affect tribal, commercial or business activities of any kind. Therefore, the BLM is not required to prepare a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*).

Executive Order 12630, Governmental Actions and Interference With Constitutionally Protected Property Rights (Takings)

The final supplementary rules do not represent a government action capable of interfering with constitutionally protected property rights. Therefore, the BLM has determined that the final supplementary rules will not cause a taking of private property or require further discussion of takings implications under this Executive Order.

Executive Order 13132, Federalism

The final supplementary rules 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. Therefore, in accordance with Executive Order 13132, the BLM has determined that the supplementary rules will not have sufficient Federalism implications to warrant preparation of a Federalism Assessment.

Executive Order 12988, Civil Justice Reform

Under Executive Order 12988, the BLM determined that these final supplementary rules would not unduly burden the judicial system and that they meet the requirements of sections 3(a) and 3(b)(2) of Executive Order 12988.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

In accordance with Executive Order 13175, the BLM initiated consultation with the following Native American tribes regarding the proposed Emerald Mountain Land Exchange project in September 2004: Southern Ute Tribe, Ute Mountain Ute Tribal Council, Colorado Commission of Indian Affairs, and the Uintah and Ouray Tribal Council. The tribes did not identify any concerns regarding traditional or religious cultural properties in the Emerald Mountain SRMA. These supplementary rules would not affect Indian land, resources, or religious rights.

Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

Under Executive Order 13211, the BLM determined that the final supplementary rules will not comprise a significant energy action, and that they will not have an adverse effect on energy supplies, production or consumption.

Paperwork Reduction Act

The final supplementary rules do not directly provide for any information collection that the Office of Management and Budget must approve under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.* Moreover, any information collection that may result from Federal criminal investigations or prosecutions conducted under these rules are exempt from the provisions of 44 U.S.C. 3518(c)(1).

Author

The principal author of these final supplementary rules is Gina Robison, Outdoor Recreation Planner, BLM Little Snake Field Office.

IV. Final Supplementary Rules

For the reasons stated in the Preamble, and under the authority of the Federal Land Policy and Management Act (FLPMA), 43 U.S.C. 1733 and 1740, 43 U.S.C. 315a, 43 CFR 8364.1, and 43 CFR 8365.1–6, the BLM Colorado State Director establishes the following final supplementary rules for public lands within the Emerald Mountain SRMA.

Final Supplementary Rules for the Emerald Mountain Special Recreation Management Area

Definitions

Camping means the erecting of a tent or shelter of natural or synthetic material; preparing a sleeping bag or other bedding material for use; parking a motor vehicle, motor home or trailer; or mooring a vessel for the apparent purpose of overnight occupancy.

Designated Trail means a trail developed, maintained, and explicitly identified for public use by the BLM. All designated trails will be identified by a combination of trailhead maps and on-site signage listing allowable uses.

Firearm or Other Projectile Shooting Device means all firearms, air rifles, pellet and BB guns, spring guns, bows and arrows, slings, paint ball markers, other instruments that can propel a projectile (such as a bullet, dart or pellet by combustion, air pressure, gas pressure or other means) or any instrument that can be loaded with and fire blank cartridges.

Mechanized Transport means any vehicle, device or contrivance for moving people or material in or over land, water, snow or air that has moving parts, including, but not limited to, bicycles, game carriers, carts and wagons. The term does not include

wheelchairs, horses or other pack stock, skis or snowshoes.

Motorized Vehicle means any self-propelled device in, upon or by which any person or property is or may be propelled, moved or drawn, including, but not limited to, cars, trucks, vans, motorcycles, all-terrain vehicles, motor-driven cycles, motorized scooters, motorized skateboards and snowmobiles. ''Motorized vehicle'' does not include a self-propelled wheelchair, invalid tricycle or motorized quadricycle when operated by a person who, by reason of physical disability, is otherwise unable to move about as a pedestrian.

Official Duty means use by an employee, agent or designated representative of the Federal government or one of its contractors, in the course of his employment, agency or representation.

Working Dog means a dog suitable by size, breeding or training for useful work such as hunting or livestock herding.

Prohibited Acts

Unless otherwise authorized by the Little Snake Field Manager, the following rules apply within the Emerald Mountain SRMA boundary:

1. Camping and overnight use is prohibited. The area is closed between sunset and sunrise, except for lawful hunting licensed periods and for retrieval of legally-taken game. Hunters are not allowed to camp overnight.

2. No mechanized transport activities are allowed within Zone 2, including game carts.

3. No person or persons shall discharge a firearm or other projectile shooting device of any kind, including those used for target shooting or paintball, except licensed hunters in pursuit of game during the proper season with appropriate firearms, as defined by the Colorado Division of Wildlife (CDOW), Section 33–1–102, Colorado Revised Statutes, Article IV, Number 004: Manner of Taking Wildlife.

4. Zone 2 and trails south of Ridge Trail in Zone 1 are closed to the public from December 1 to June 30 to protect wintering and calving elk.

5. Non-working dogs must be on a six-foot or less hand-held leash at all times. Working dogs are allowed off-leash only during legal hunting periods when controlled by someone legally hunting, or when working to herd livestock.

6. Fires are not allowed except at the trailheads in a mechanical stove or other appliance fueled by gas and equipped with a valve that allows the operator to turn the flame on and off.

7. Possession of glass containers is prohibited.

8. The entire area is designated closed to motorized vehicle travel, with the exception of Cow Creek Road (Routt County Road 45). The closure excludes:

(a) Any military, fire, emergency or law enforcement vehicle being used for emergency purposes;

(b) Any vehicle expressly authorized by the authorized officer, or otherwise officially approved (*e.g.,* grazing permittee, CDOW, Routt County personnel).

Exemptions

The following persons are exempt from these supplementary rules: any Federal, state, local and/or military employee acting within the scope of their official duties; members of any organized rescue or fire-fighting force performing an official duty; and persons, agencies, municipalities or companies holding an existing special-use permit inside the SRMA and operating within the scope of their permit.

Penalties

Under the *Taylor Grazing Act of 1934, 43 U.S.C. 315a,* any willful violation of these supplementary rules on public lands within a grazing district, and within the boundaries established in the rules shall be punishable by a fine of not more than $500 or,

Under Section 303(a) of FLPMA, 43 U.S.C. 1733(a), if you violate any of these supplementary rules on public lands within the boundaries established in the rules, you may be tried before a United States Magistrate and fined no more than $1,000 or imprisoned for no more than 12 months, or both. Such violations may also be subject to the enhanced fines provided for by 18 U.S.C. 3571.

Helen M. Hankins,

State Director.

[FR Doc. 2011–26184 Filed 10–7–11; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY–923–1310–FI; WYW174755]

Notice of Proposed Reinstatement of Terminated Oil and Gas Lease WYW174755, Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Under the provisions of the Mineral Leasing Act of 1920, as amended, the Bureau of Land Management (BLM) received a petition for reinstatement from Hot Springs Resources LTD for renewal of oil and gas lease WYW174755 for land in Natrona County, Wyoming. The petition was filed on time and was accompanied by all the rentals due since the date the lease terminated under the law.

FOR FURTHER INFORMATION CONTACT: BLM, Julie L. Weaver, Chief, Fluid Minerals Adjudication, at (307) 775–6176.

SUPPLEMENTARY INFORMATION: The lessee has agreed to the amended lease terms for rentals and royalties at rates of $10 per acre or fraction thereof, per year and 16–2/3 percent, respectively. The lessee has paid the required $500 administrative fee and $163 to reimburse the Department for the cost of this **Federal Register** notice. The lessee has met all the requirements for reinstatement of the lease as set out in Sections 31(d) and (e) of the Mineral Lands Leasing Act of 1920 (30 U.S.C. 188), and the BLM is proposing to reinstate lease WYW174755 effective April 1, 2011, under the original terms and conditions of the lease and the increased rental and royalty rates cited above. The BLM has not issued a valid lease to any other interest affecting the lands.

Julie L. Weaver,

Chief, Fluid Minerals Adjudication.

[FR Doc. 2011–26006 Filed 10–7–11; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ES–930–1310–FI; MSES 56250]

Notice of Proposed Reinstatement of Terminated Oil and Gas Lease, Mississippi

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Under the provisions of the Mineral Leasing Act of 1920, as amended, the Bureau of Land Management-Eastern States (BLM–ES) received a petition for reinstatement of oil and gas lease MSES 56250 from Antares Exploration Fund, L.P. for lands in Perry County, Mississippi. The petition was filed on time and was accompanied by all the rentals due since the date the lease terminated under the law.

FOR FURTHER INFORMATION CONTACT: Kemba Anderson-Artis, Supervisory Land Law Examiner, BLM–ES, 7450

Boston Boulevard, Springfield, Virginia, at (703) 440–1659. 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: No valid lease has been issued affecting these lands. The lessee has agreed to the new lease terms for rental and royalties at rates of $10 per acre or fraction thereof, per year, and 16 ⅔ percent, respectively. The lessee has paid the required $500 administrative fee and $163 to reimburse the BLM for the cost of publishing this Notice in the **Federal Register**. The lessee has met all the requirements for reinstatement as set out in Sections 31(d) and (e) of the Mineral Leasing Act of 1920 (30 U.S.C. 188), and the BLM is proposing to reinstate the lease effective June 1, 2011, under the original terms and conditions of the lease and the increased rental and royalty rates cited above.

Kemba Anderson-Artis,

Supervisory, Land Law Examiner, Division of Natural Resources.

[FR Doc. 2011–26193 Filed 10–7–11; 8:45 am]

BILLING CODE 4310–GJ–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WYW 115104]

Public Land Order No. 7784; Extension of Public Land Order No. 6886; Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order extends the duration of the withdrawal created by Public Land Order No. 6886 for an additional 20-year period. This extension is necessary to continue the protection of the unique topographic characteristics and recreational values of the Snowy Range Recreation Area, which would otherwise expire on October 7, 2011.

DATES: *Effective Date:* October 8, 2011.

FOR FURTHER INFORMATION CONTACT: Nathan Haynes, U.S. Forest Service, Region 2, Supervisors Office, 2468 Jackson Street, Laramie, Wyoming 82070–6535, (307) 745–2317, or Janelle Wrigley, BLM Wyoming State Office, 5353 N. Yellowstone Road, P.O. Box 1828, Cheyenne, Wyoming 82003, (307) 775–6257. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to reach the Forest Service or Bureau of Land Management contact 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: The purpose for which the withdrawal was first made requires this extension in order to continue the protection of the unique topographic characteristics and recreational values of the Snowy Range Recreation Area. The withdrawal extended by this order will expire on October 7, 2031, unless as a result of a review conducted prior to the expiration date pursuant to Section 204(f) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714(f), the Secretary determines that the withdrawal shall be further extended.

Order

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714, it is ordered as follows:

Public Land Order No. 6886 (56 FR 50661 (1991)), which withdrew 21,636.29 acres of National Forest System lands from location and entry under the United States mining laws (30 U.S.C. Ch. 2), but not from leasing under the mineral leasing laws, to protect the unique topographic characteristics and recreational values of the Snowy Range Area, is hereby extended for an additional 20-year period.

Authority: 43 CFR 2310.4.

Dated: September 27, 2011.

Rhea S. Suh,

Assistant Secretary—Policy, Management and Budget.

[FR Doc. 2011–26214 Filed 10–7–11; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCA930000.L58790000.EU0000; CACA 48506]

Notice of Realty Action: Direct Sale of Public Land in Shasta County, CA

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Realty Action.

SUMMARY: The Bureau of Land Management (BLM), Redding Field Office, proposes to sell a parcel of public land consisting of 160.03 acres, more or less, in Shasta County, California. The public land would be sold to the County of Shasta for the appraised fair market value of $176,000.

DATES: Written comments regarding the proposed sale must be received by the BLM on or before November 25, 2011.

ADDRESSES: Written comments concerning the proposed sale should be sent to the Field Manager, BLM Redding Field Office, 355 Hemsted Drive, Redding, California 96002.

FOR FURTHER INFORMATION CONTACT: Ilene Emry, Realty Specialist, BLM Redding Field Office, 355 Hemsted Drive, Redding, California 96002, phone (530) 224–2122 or visit the Web site at *http://www.blm.gov/ca/st/en/prog/lands.html.* 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: The following parcel of public land is being proposed for direct sale to the County of Shasta in accordance with Sections 203 and 209 of the Federal Land Policy and Management Act of 1976 (FLPMA), as amended (43 U.S.C. 1713 and 1719).

Mount Diablo Meridian

T. 30 N., R. 6 W.,
Sec. 4, lots 1 and 2 in the NE¼.

The area described contains 160.03 acres, more or less, in Shasta County.

The public land was first identified as suitable for disposal by exchange in the 1993 BLM Redding Resource Management Plan (RMP). The Redding RMP was amended in 2005 to identify the land as available for sale. The land is not needed for any other Federal purpose, and its disposal would be in the public interest. The purpose of the sale is to dispose of public land which is difficult and uneconomic to manage as part of the public lands because it is isolated from other public lands in the area. The BLM is proposing a direct sale to the County of Shasta that wants to acquire the land as a buffer area to preclude incompatible development near its existing landfill on adjacent non-Federal land. The sale of this land to the County of Shasta would serve an important public objective, therefore a competitive sale is not considered appropriate. The BLM has completed a mineral potential report which concluded the land proposed for sale

has known mineral value for gold and aggregate materials. The BLM proposes to reserve all minerals to the U.S.

On October 11, 2011, the above described land will be segregated from all forms of appropriation under the public land laws, including the mining laws, except for the sale provisions of the FLPMA. Until completion of the sale, the BLM will no longer accept land use applications affecting the identified public lands, except applications for the amendment of previously filed right-of-way applications or existing authorizations to increase the term of the grants in accordance with 43 CFR 2802.15 and 2886.15. The segregation terminates upon issuance of a patent, publication in the **Federal Register** of a termination of the segregation, or on October 11, 2013, unless extended by the BLM State Director in accordance with 43 CFR 2711.1–2(d) prior to the termination date. The land would not be sold until at least December 12, 2011. Any conveyance document issued would contain the following terms, conditions, and reservations:

1. A reservation of a right-of-way (ROW) to the United States for ditches and canals constructed by authority of the United States under the Act of August 30, 1890 (43 U.S.C 945);
2. A reservation of all minerals to the United States, together with the right by itself, its permittees, licensees and lessees to prospect for, mine, and remove the minerals under applicable law and such regulations as the Secretary of the Interior may prescribe.
3. Subject to the following existing ROWs: a ROW for a power-line issued under serial number CACA 24929 and a ROW for a telephone line issued under serial number CACA 26611.
4. A condition that the conveyance be subject to valid existing rights;
5. An appropriate indemnification clause protecting the United States from claims arising out of the patentee's use, occupancy, or operations on the patented lands; and
6. Additional terms and conditions that the authorized officer deems appropriate.

The ROW's listed in 3 above may be replaced by permanent easements prior to conveyance. The parcel may be subject to applications for ROWs received prior to publication of this Notice if processing the application would not adversely affect the marketability or appraised value of the land. Case files containing details on the existing ROWs are available for review at the Redding Field Office.

Detailed information concerning the proposed land sale including the appraisal, planning and environmental documents, and a mineral report are available for review at the BLM Redding Field Office at the address above, or by calling (530) 224–2122.

Public comments regarding the proposed sale may be submitted in writing to the attention of the BLM Redding Field Manager (see **ADDRESSES** above) on or before November 25, 2011. Comments received in electronic form, such as e-mail or facsimile, will not be considered. Any adverse comments regarding the proposed sale will be reviewed by the BLM State Director or other authorized official of the Department of the Interior, who may sustain, vacate, or modify this realty action in whole or in part. In the absence of timely filed objections, this realty action will become the final determination of the Department of the Interior.

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, be advised 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 from public review your personal identifying information, we cannot guarantee that we will be able to do so.

Authority: 43 CFR 2711.1–2(a) and (c).

Tom Pogacnik,

Deputy State Director, Natural Resources.

[FR Doc. 2011–26191 Filed 10–7–11; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

National Park Service

[2031–A048–409]

Draft Environmental Impact Statement for General Management Plan, Blue Ridge Parkway, VA and NC

AGENCY: National Park Service, Interior.

ACTION: Notice of Availability of the Draft General Management Plan and Environmental Impact Statement.

SUMMARY: Pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4332(2)(C), the National Park Service (NPS) announces the availability of a Draft Environmental Impact Statement (DEIS) for the General Management Plan (GMP) for Blue Ridge Parkway (parkway).

Consistent with NPS laws, regulations, and policies and the purpose of the parkway, the DEIS/GMP describes the NPS preferred alternative—Alternative B—to guide the management of the parkway over the next 20 years. The preferred alternative incorporates various management strategies to ensure protection, access, and enjoyment of the parkway's resources. The document analyzes the environmental impacts of the preferred alternative, along with two other alternatives, including the no-action alternative.

DATES: The NPS will accept comments from the public on the DEIS/GMP for at least 60 days, starting from the date the Environmental Protection Agency publishes the Notice of Availability. The date, time, and location of public meetings will be announced through the NPS Planning, Environment, and Public Comment (PEPC) Web site: *http://parkplanning.nps.gov/BLRI* and other media outlets.

ADDRESSES: Electronic copies of the draft DEIS/GMP will be available online at *http://parkplanning.nps.gov/BLRI.* To request a copy, contact Superintendent Phil Francis, Blue Ridge Parkway, 199 Hemphill Knob Road, Asheville, NC 28803.

Comments may be submitted by several methods. The preferred method is commenting via the internet on the PEPC website above. An electronic public comment form is provided on this website. You may also mail comments to Superintendent Phil Francis, Blue Ridge Parkway, 199 Hemphill Knob Road, Asheville, NC 28803. Finally, you may hand-deliver comments to the parkway. Before including your address, phone number, email address, or other personal identifying information in your comment, please 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. We will always make submissions from organizations or businesses, and from individuals identifying themselves as representatives of or officials of organizations or businesses, available for public inspection in their entirety. A limited number of compact disks and printed copies of the DEIS/GMP will be made available at Blue Ridge Parkway Headquarter, 199 Hemphill Knob Road, Asheville, NC 28803.

SUPPLEMENTARY INFORMATION: Public meetings, newsletters, and internet updates have kept the public informed and involved throughout the planning process. The DEIS/GMP provides a framework for management, use, and

development of the parkway for the next 20 years. It presents and analyzes three alternatives: Alternative A (no action) provides a baseline for evaluating changes and impacts of the two action alternatives. Alternative B is the NPS preferred alternative. The concept for management under alternative B emphasizes the original parkway design and traditional driving experience, while enhancing outdoor recreational opportunities and regional natural resource connectivity, and providing modest improvements to visitor services. In essence, the preferred alternative seeks to reinvest in the parkway's aging infrastructure, update inadequate visitor services and facilities, and protect a biologically diverse natural environment that is only surpassed by two other units in the national park system. Under Alternative C, the parkway would seek to significantly expand regional recreation opportunities, re-design campgrounds and other facilities to provide more modern visitor services, and focuses on partnerships to enhance regional natural resource connectivity. The three alternatives are described in detail in chapter 2 of the draft plan. The key impacts of implementing the three alternatives are detailed in chapter 4 and summarized in chapter 2.

Authority: The authority for publishing this notice is contained in 40 CFR 1506.6.

FOR FURTHER INFORMATION CONTACT: Superintendent Phil Francis, Blue Ridge Parkway, 199 Hemphill Knob Road, Asheville, NC 28803 or telephone at (828) 271–4779.

The responsible official for this Draft EIS is the Regional Director, NPS Southeast Region, 100 Alabama Street, SW., 1924 Building, Atlanta, Georgia 30303.

Dated: October 3, 2011.

Ben West,

Acting Regional Director, Southeast Region.

[FR Doc. 2011–26163 Filed 10–7–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

National Park Service

[2253–665]

Notice of Intent To Repatriate a Cultural Item: Peabody Museum of Natural History, Yale University, New Haven, CT

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Peabody Museum of Natural History, Yale University, in consultation with the appropriate Indian tribe, has determined that the cultural item meets the definition of unassociated funerary object and repatriation to the Indian tribe stated below may occur if no additional claimants come forward. Representatives of any Indian tribe that believes itself to be culturally affiliated with the cultural item may contact the Peabody Museum of Natural History, Yale University.

DATES: Representatives of any Indian tribe that believes it has a cultural affiliation with the cultural item should contact the Peabody Museum of Natural History, Yale University at the address below by November 10, 2011.

ADDRESSES: Professor Derek E.G. Briggs, Director, Peabody Museum of Natural History, P.O. Box 208118, New Haven, CT 06520–8118, telephone (203) 432–3752.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate a cultural item in the possession of the Peabody Museum of Natural History, Yale University, New Haven, CT, that meets the definition of unassociated funerary object under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the cultural item. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Item

In 1886, Mrs. Kate Foot Coe collected one chilkat blanket on Kiloosnoo Island, AK. On November 19, 1902, Mrs. Foot Coe donated it to the Peabody Museum of Natural History. The museum's catalog describes the blanket as being found in a ''receptacle on the top of a totem pole containing the bones and ashes of a cremated body.'' No human remains associated with this blanket are in the museum's collection.

The catalog description of the blanket indicates that it was collected from a funerary context and was in association with bones at the time that it was collected. Based on the collection location on Kiloosnoo Island in the Northwest Coast culture area, the recovery of the blanket from a grave pole, and the type of object (chilkat blanket), this item is believed to be culturally affiliated with the Central Council of the Tlingit & Haida Indian Tribes.

Determinations Made by the Peabody Museum of Natural History, Yale University

Officials of the Peabody Museum of Natural History, Yale University have determined that:

- Pursuant to 25 U.S.C. 3001(3)(B), the single cultural item described above is reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and is believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the unassociated funerary object and the Central Council of the Tlingit & Haida Indian Tribes.

Additional Requestors and Disposition

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the unassociated funerary object should contact Professor Derek E.G. Briggs, Director, Peabody Museum of Natural History, P.O. Box 208118, New Haven, CT 06520–8118, telephone (203) 432–3752, before November 10, 2011. Repatriation of the unassociated funerary object to the Central Council of the Tlingit & Haida Indian Tribes may proceed after that date if no additional claimants come forward.

The Peabody Museum of Natural History, Yale University is responsible for notifying the Central Council of the Tlingit & Haida Indian Tribes that this notice has been published.

Dated: October 3, 2011.

Sherry Hutt,

Acting Manager, National NAGPRA Program.

[FR Doc. 2011–26179 Filed 10–7–11; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[2253–665]

Notice of Inventory Completion: University of Colorado Museum, Boulder, CO

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The University of Colorado Museum has completed an inventory of human remains and an associated funerary object in consultation with the appropriate Indian tribes, and has

determined that there is no cultural affiliation between the human remains and associated funerary object and any present-day Indian tribe. Representatives of any Indian tribe that believes itself to be culturally affiliated with the human remains and associated funerary object may contact the University of Colorado Museum. Disposition of the human remains and associated funerary object to the Indian tribes stated below may occur if no additional requestors come forward.

DATES: Representatives of any Indian tribe that believes it has a cultural affiliation with the human remains and associated funerary object should contact the University of Colorado Museum at the address below by November 10, 2011.

ADDRESSES: Steve Lekson, Curator of Anthropology, University of Colorado Museum, Campus Box 218, Boulder, CO 80309, telephone (303) 492–6671.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and an associated funerary object in the possession of the University of Colorado Museum, Boulder, CO. The human remains and associated funerary object were removed from Culberson, El Paso, and Hudspeth Counties, TX.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary object. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains and associated funerary object was made by the University of Colorado Museum professional staff in consultation with representatives of the Apache Tribe of Oklahoma; Fort Sill Apache Tribe of Oklahoma; Hopi Tribe of Arizona; Jicarilla Apache Nation, New Mexico; Mescalero Apache Tribe of the Mescalero Reservation, New Mexico; Pueblo of Acoma, New Mexico; Pueblo of Zia, New Mexico; San Carlos Apache of the San Carlos Reservation, Arizona; Tonto Apache Tribe of Arizona; White Mountain Apache Tribe of the Fort Apache Reservation, Arizona; Ysleta del Sur Pueblo of Texas; and Zuni Tribe of the Zuni Reservation, New Mexico (hereinafter referred to as ''The Tribes'').

History and Description of the Remains

On an unknown date, human remains (a cremation) representing a minimum of one individual were removed from south of Van Horn, Culberson County, TX by Joe Ben Wheat, the University of Colorado Museum's curator of anthropology from 1953 to 1988. In November 2009, the human remains (TIN 0290) were found in the museum collection. The human remains have been identified as Jornada Mogollon based on other material culture collected from the same location. No known individual was identified. No associated funerary objects are present.

On an unknown date, human remains representing a minimum of one individual were removed from either Culberson, El Paso, or Hudspeth County, TX by Dr. Wheat, or near Fort Bayard, Grant County, NM by Hugo G. Rodeck, the University of Colorado Museum's director from 1939 to 1971. In November 2009, the human remains (a tooth) (TIN 0091) were found in the collection. The human remains have been identified as Mogollon- most likely Jornada Mogollon- based on the material culture collected from the same location. No known individual was identified. No associated funerary objects are present.

On an unknown date, human remains representing a minimum of one individual were removed from ''Hueco Mountain area camps 1, 2, 3; Hot Wells Section; below Basketmaker caves,'' in El Paso or Hudspeth Counties, TX by Dr. Wheat. In November 2009, the human remains (a tooth) (TIN 0162) were found in the collection. The human remains have been identified as Jornada Mogollon based on the provenience. No known individual was identified. No associated funerary objects are present.

On an unknown date, human remains representing a minimum of three individuals were removed from the Hueco Mountains, El Paso and Hudspeth Counties, TX by Dr. Wheat. In November 2009, the human remains (a tooth (TIN 0195) and two vertebrae (TIN 0257) and (TIN 0458)) were found in the collection. The human remains have been identified as Jornada Mogollon based on other material culture collected from the same location. No known individuals were identified. One funerary object, a projectile point, is associated with one of the vertebrae (TIN 0458).

On an unknown date, human remains representing a minimum of one individual were removed from Hudspeth County, TX by Dr. Wheat. In November 2009, the human remains (a tooth) (TIN 0186) were found in the collection. The human remains have been identified as Jornada Mogollon based on other material culture collected from the same location. No known individual was identified. No associated funerary objects are present.

Determinations Made by the University of Colorado Museum

Officials of the University of Colorado Museum have determined that:

- Based on locational information and the material culture believed to have come from those same locations, the human remains are Native American.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and associated funerary object and any present-day Indian tribe.
- According to final judgments of the Indian Claims Commission, the land from which the Native American human remains and associated funerary object were removed is the aboriginal land of the Fort Sill Apache Tribe of Oklahoma; Mescalero Apache Tribe of the Mescalero Reservation, New Mexico; White Mountain Apache Tribe of the Fort Apache Reservation, Arizona; and Ysleta del Sur Pueblo of Texas.
- Multiple lines of evidence, including treaties, Acts of Congress, and Executive Orders, indicate that the land from which the Native American human remains and associated funerary object were removed is the aboriginal land of the Apache Tribe of Oklahoma; Fort Sill Apache Tribe of Oklahoma; Jicarilla Apache Nation, New Mexico; Mescalero Apache Tribe of the Mescalero Reservation, New Mexico; San Carlos Apache of the San Carlos Reservation, Arizona; Tonto Apache Tribe of Arizona; and White Mountain Apache Tribe of the Fort Apache Reservation, Arizona.
- Other credible lines of evidence indicate that the land from which the Native American human remains and associated funerary object were removed is the aboriginal land of the Hopi Tribe of Arizona; Pueblo of Acoma, New Mexico; Pueblo of Zia, New Mexico; and Zuni Tribe of the Zuni Reservation, New Mexico.
- Pursuant to 25 U.S.C. 3001(9), the human remains described above represent the physical remains of seven individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the one object described above is reasonably believed to have been placed with or near individual human remains

at the time of death or later as part of the death rite or ceremony.

• Pursuant to 43 CFR 10.11(c)(1), the disposition of the human remains and associated funerary object is to the Pueblo of Acoma, New Mexico.

Additional Requestors and Disposition

Representatives of any Indian tribe that believes itself to be culturally affiliated with the human remains and associated funerary object, or any other Indian tribe that believes it satisfies the criteria in 43 CFR 10.11(c)(1) should contact Steve Lekson, Curator of Anthropology, University of Colorado Museum, Campus Box 218, Boulder, CO 80309, telephone (303) 492–6671, before November 10, 2011. Disposition of the human remains and associated funerary object to the Pueblo of Acoma, New Mexico, may proceed after that date if no additional claimants come forward.

The University of Colorado Museum is responsible for notifying The Tribes that this notice has been published.

Dated: October 3, 2011.

Sherry Hutt,

Manager, National NAGPRA Program.

[FR Doc. 2011–26153 Filed 10–7–11; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[2253–665]

Notice of Inventory Completion: Fort Lewis College, Durango, CO

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Fort Lewis College has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian tribes, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian tribes. Representatives of any Indian tribe that believes itself to be culturally affiliated with the human remains and associated funerary objects may contact Fort Lewis College. Repatriation of the human remains and associated funerary objects to the Indian tribes stated below may occur if no additional claimants come forward.

DATES: Representatives of any Indian tribe that believes it has a cultural affiliation with the human remains and associated funerary objects should contact the Fort Lewis College at the address below by November 10, 2011.

ADDRESSES: Dawn Mulhern, Department of Anthropology, Fort Lewis College, 1000 Rim Dr., Durango, CO 81301, telephone (970) 247–7500.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects in the possession of Fort Lewis College, Durango, CO. The human remains and associated funerary objects were removed from Archuleta, La Plata, and Montezuma Counties, CO.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by Fort Lewis College professional staff in consultation with representatives of the Hopi Tribe of Arizona; Jicarilla Apache Nation, New Mexico; Navajo Nation, Arizona, New Mexico & Utah; Pueblo of Acoma, New Mexico; Pueblo of Jemez, New Mexico; Pueblo of Nambe, New Mexico; Pueblo of Pojoaque, New Mexico; Pueblo of Santa Clara, New Mexico; Pueblo of Taos, New Mexico; Pueblo of Tesuque, New Mexico; Pueblo of Zia, New Mexico; Southern Ute Indian Tribe of the Southern Ute Reservation, Utah; Ute Indian Tribe of the Uintah & Ouray Reservation, Colorado, New Mexico & Utah; Ute Mountain Tribe of the Ute Mountain Reservation, Colorado; and the Zuni Tribe of the Zuni Reservation, New Mexico.

History and Description of the Remains

In the 1970s, human remains representing a minimum of one individual were removed from the Arboles area, Archuleta County, CO. Dr. Susan Riches, archeologist, reported that Dr. Katherine Hulbert, a physical anthropologist at Fort Lewis College in the 1970s, noted that the remains are ''10th Century Arboles Area.'' No known individual was identified. No associated funerary objects are present.

In the early 1980s, human remains representing a minimum of one individual were removed from private land at 6775 County Road 203, West Animas Valley, near Durango, La Plata County, CO. This burial was recovered as a result of construction in the area. No known individual was identified. The 11 associated funerary objects are 1 gray Chapin pitcher and 10 sherds of grayware pottery.

In 1978, human remains representing a minimum of one individual were removed from a construction site on Forest Avenue, in Durango, La Plata County, CO. The human remains were uncovered by workers from a local contracting company and brought to the college in a box. The immediate location is destroyed. According to Dr. Riches, the remains seem to be an isolated burial and are associated with a grayware jar. No known individual was identified. The one associated funerary object is a partial ceramic jar.

In 1958, human remains representing a minimum of three individuals were removed from the Crestview area of Durango, La Plata County, CO. The remains were found by Pat Murphy and were donated to Fort Lewis College by Murphy in October 1995. No known individuals were identified. The two associated funerary objects are a pottery bowl and pot.

In 1989, human remains representing a minimum of one individual were removed from 5LP 4883, in La Plata County, CO. These remains were found along Rim Drive (County Road 239), near the Fort Lewis College Campus on City of Durango land. These remains were exposed as the result of road construction and subsequent erosion. The control of these remains were officially transferred to Fort Lewis College in 2011. No known individual was identified. The one associated funerary object is a reconstructed Chapin grayware pot.

The associated funerary objects for the above four sites are consistent with the Basketmaker III/Pueblo I period (A.D. 650–840).

In 1984, human remains representing a minimum of one individual were removed from 5LP 1421, in La Plata County, CO. The remains were found on Rim Road on the Fort Lewis College campus and the site was disturbed due to road construction. No known individual was identified. The eight associated funerary objects are pottery sherds (one grayware jar sherd and seven Rosa black-on-white bowl sherds).

According to the site form, this site dates to the Basketmaker III/Pueblo I period (7th or 8th century A.D.) based on ceramic evidence.

In 1997, human remains representing a minimum of one individual were removed from site 5LP 4847, in La Plata County, CO. The remains were excavated by archeologists from Fort Lewis College from a burial context

directly behind the Iron Horse Inn, on the west side of the Animas River Valley, north of Durango. No known individual was identified. The one associated funerary object is a black-on-white Rosa bowl.

The bowl is consistent with the Pueblo I period (A.D. 700–840).

In 1977, human remains representing a minimum of three individuals were removed from 5LP 135 (the Hurlbutt Site), in La Plata County, CO. The burial was recovered from the floor of an abandoned pit structure under the direction of Dr. Riches. No known individuals were identified. The 10 associated funerary objects are 1 complete bowl, 1 reconstructed piece of pottery, 2 smaller reconstructed pieces of pottery, and 6 sherds.

This is a transitional Basketmaker III/Pueblo I site based on ceramics. The pit structure has been dated to the Pueblo I period (A.D. 700s) (Charles MC, Schriever B, 1999. ''The reexcavation of 5LP135, The Hurlbutt Site: A Basketmaker III transitional Pueblo I site in La Plata County, Colorado'').

In 1967–1968, human remains representing a minimum of six individuals were removed from a site called West Animas 4 (WA4), in La Plata County, CO. The remains were excavated by John Ives as part of the Fort Lewis College summer field program. The site was on private land. No known individuals were identified. No associated funerary objects are present.

Site WA4 is from the Pueblo I period (A.D. 700–840) based on the artifactual evidence from this site.

In 1966, human remains representing a minimum of two individuals were removed from site 5LP 245, 456, and 604 (treated as one site), 3 miles southwest of Durango on private land, in La Plata County, CO. This burial was excavated by Homer Root, an amateur archeologist, during field school excavations for Fort Lewis College. The land was subsequently bought by the Colorado Division of Wildlife and deeded to the U.S. Department of the Interior, Bureau of Reclamation. No known individuals were identified. The three associated funerary objects are two pottery bowls (one black-on-white interior decorated and one grayware storage vessel) and one mortuary slab.

The burial context is a Basketmaker III (7th century A.D.) pithouse, based on architecture, artifacts, and non-cutting dates (Duke, p. 52).

In 1967, human remains representing a minimum of 23 individuals were removed from site 5LP 238, also called WA3, in La Plata County, CO. These burials were recovered from a site on private land by John Ives. No known individuals were identified. No associated funerary objects are present.

Site 5LP 238 is determined to be from the Basketmaker III/Pueblo I period (A.D. 650–840) based on the archeological context, including architecture and ceramics (Philip G. Duke, 1985, ''Fort Lewis College Archaeological Investigations in Ridges Basin, Southwest Colorado: 1965–1982.'' Robert W. Delaney, editor. Paper No. 4. Occasional Papers of the Center of Southwest Studies, Fort Lewis College, p. 143).

In 1967–1968, human remains representing a minimum of three individuals were removed from site WA5, in La Plata County, CO. These remains were excavated by Dr. John Ives from a site designated by him as WA5 (West Animas 5). The site was on private land and was excavated as part of the Fort Lewis College summer field program. No known individuals were identified. No associated funerary objects are present.

The temporal context of the site is the Pueblo I period (A.D. 700–840) based on other artifacts from the site.

In 1981, human remains representing a minimum of two individuals were removed from 5LP630, in La Plata County, CO. These remains were recovered during the excavation of a pithouse located in Ridges Basin, approximately 3 miles southwest of Durango. The excavation was part of the 1981 archeological field program run by Fort Lewis College and directed by Philip Duke. At the time of excavation, the land was owned by the Colorado Division of Wildlife, but which has subsequently been deeded to the U.S. Department of the Interior, Bureau of Reclamation. In 2011, the Colorado Division of Wildlife officially transferred the remains to Fort Lewis College. No known individuals were identified. The three associated funerary objects are two ceramic black-on-gray interior decorated bowls and the tip of a bone awl.

These burials are from a Pueblo I (late 8th century A.D.) pithouse based on archaeomagnetic dating (Duke, pp. 147–148).

In 1985, human remains representing a minimum of four individuals were removed from site 5LP 483, in La Plata County, CO. These burials were recovered during excavations of sites in Bodo Canyon, approximately 3 miles southwest of Durango. This project was funded by the government as part of the Uranium Mill Tailings Remedial Action Project. No known individuals were identified. The two associated funerary objects are the tip of a bone awl and a Chapin gray jar.

These burials are from a late Basketmaker III-Pueblo I pithouse based on ceramics and tree-ring dates, giving a range of dates from A.D. 650 through the early A.D. 800s (Steven L. Fuller, 1988, ''Archaeological Investigations in the Bodo Canyon Area, La Plata County, CO. UMTRA Archaeological Report 25,'' p. 198). The date and geographic location of this site are consistent with Ancestral Puebloan burials.

In 1985, human remains representing a minimum of eight individuals were removed from site 5LP 481, in La Plata County, CO. These burials were recovered during excavations of sites in Bodo Canyon, approximately 3 miles southwest of Durango. This project was funded by the government as part of the Uranium Mill Tailings Remedial Action Project. No known individuals were identified. The 66 associated funerary objects are 1 Chapin gray jar, 1 Chapin black-on-white bowl, 55 grayware sherds, 1 quartzite flake, and 8 artifacts (which possibly represents a medicine pouch).

These burials are from a late Basketmaker III-Pueblo I (8th century A.D.) pithouse based on ceramics and architecture (Fuller, 1988; p. 117, 158–159).

In 1978, human remains representing a minimum of 11 individuals were removed from site 5LP 117, in La Plata County, CO. These burials were recovered by Dr. Riches in the Bodo Industrial Park just south of Durango along the Animas River. Salvage excavations were carried out as part of the Fort Lewis College summer field school. The site was on private land. No known individuals were identified. The 36 associated funerary objects are 32 grayware sherds, 2 Olivella shells, 1 chert biface, and 1 lithic point.

These burials are from the Pueblo I period (A.D. 700–840) based on the artifactual evidence from the site (Charles, MC, 1996. ''The Emergency Excavations of Three Human Burials in Bodo Industrial Ranches, La Plata County, CO'').

In 1978, human remains representing a minimum of one individual were removed from site 5LP 119, in La Plata County, CO. This burial was recovered from the surface of site 5LP 119 on the Bodo Industrial Park south of Durango on the Animas River. The site was on private land. No known individual was identified. No associated funerary objects are present.

The archeological context of this site was determined to be Basketmaker III/Pueblo I (A.D. 650–840) (Charles, MC, 1994. ''A Cultural Resource Inventory of

Lot 7B, Bodo Ranches, La Plata County, CO (Volume 1)'' and ''Archaeological Test Evaluations, Lot 7B, Bodo Industrial Ranches, La Plata County, CO (Volume 2),'' on file at the Colorado Historical Society, Denver, CO).

In 1978, human remains representing a minimum of two individuals were removed from site 5LP 138, in La Plata County, CO. This burial was recovered from the surface of the site, on private land, in Bodo Industrial Park, south of Durango, CO, by students undertaking survey and salvage excavations under the direction of Dr. Riches. No known individuals were identified. The three associated funerary objects are one partial bear mandible, one dog vertebra, and one bone awl.

These burials were determined to be from the Basketmaker III/Pueblo I period based on artifactual evidence from the site.

In 1975, human remains representing a minimum of five individuals were removed from site 5LP 115, in La Plata County, CO. These remains were recovered by Jeff Wharton and Barry Hibbets on private land in the Bodo Industrial Park under the direction of John Ives and Dr. Riches. The site, a pit structure, had been partially removed by road construction. No known individuals were identified. No associated funerary objects are present.

The site dates to the Pueblo I–III period (A.D. 700–1300) according to the Colorado Historical Society Office of Archaeology and Historic Preservation Compass Database, an online cultural resource database.

In 1980, human remains representing a minimum of one individual were removed from site 5LP 425, in La Plata County, CO. The burial was recovered as part of salvage excavations under the direction of Jamie Carlson during a summer field program at Fort Lewis College. No known individual was identified. No associated funerary objects are present.

The archeological context of this site was determined to be Pueblo I (A.D. 700–840) based on ceramics (Charles MC, 2005. ''A report on the archaeological excavations at site 5LP425, the Seven Dog Site: A Pueblo I habitation site, La Plata County, CO'').

In the 1970s, human remains representing a minimum of five individuals were removed from the Mancos River Area, Montezuma County, CO. No known individuals were identified. No associated funerary objects are present.

Dr. Riches reported that a note by Katherine Hulbert, physical anthropologist at Fort Lewis College in the 1970s, indicates that the remains were recovered from the Mancos River Area. Further documentation by Katherine Hulbert indicates that the remains date to approximately A.D. 1070 (Pueblo II period). One cranium exhibits posterior cranial flattening due to cradleboarding, a cultural practice consistent with this time period.

In 1978, human remains representing a minimum of one individual were removed from a site on private land identified by John Ives as ''Treptow'' near Mancos, in Montezuma County, CO. No known individual was identified. No associated funerary objects are present.

Without associated funerary objects present the exact date of the remains is uncertain. However, the presence of posterior cranial flattening due to cradleboarding and location of this site are consistent with an Ancestral Puebloan burial, no earlier than the Pueblo I period (beginning A.D. 700).

In 1977–78, human remains representing a minimum of one individual were removed from site MT 4037, in Montezuma County, CO. The site was excavated by Metropolitan State College of Denver. No known individual was identified. No associated funerary objects are present.

The archeological context of this site was determined to be Pueblo I–III (A.D. 650–1250) based on the Colorado Historical Society Office of Archaeology and Historic Preservation Compass Database.

In the 1990s, human remains representing a minimum of four individuals were removed from site 5MT 4802 (the Pigg site), in Montezuma County, CO, excavated by Jim Judge. No known individuals were identified. No associated funerary objects are present.

Based on architectural and artifactual evidence, the archeological context of this site was determined to be Pueblo II/III (A.D. 1150–1250).

In summary, the human remains and associated funerary objects all are from Ancestral Puebloan sites (Basketmaker and/or Pueblo periods). The preponderance of geographical, kinship, biological, archeological, linguistic, folklore, oral tradition and historic evidence, as well as expert opinion, suggests that Ancestral Puebloan sites are culturally affiliated with the 21 modern Puebloan tribes: The Hopi Tribe of Arizona; Kewa Pueblo, New Mexico; Ohkay Owingeh, New Mexico; Pueblo of Acoma, New Mexico; Pueblo of Cochiti, New Mexico; Pueblo of Jemez, New Mexico; Pueblo of Isleta, New Mexico; Pueblo of Laguna, New Mexico; Pueblo of Nambe, New Mexico; Pueblo of Picuris, New Mexico; Pueblo of Pojoaque, New Mexico; Pueblo of San Felipe, New Mexico; Pueblo of San Ildefonso, New Mexico; Pueblo of Sandia, New Mexico; Pueblo of Santa Ana, New Mexico; Pueblo of Santa Clara, New Mexico; Pueblo of Taos, New Mexico; Pueblo of Tesuque, New Mexico; Pueblo of Zia, New Mexico; Ysleta Del Sur Pueblo of Texas; and the Zuni Tribe of the Zuni Reservation, New Mexico (hereinafter referred to as ''The Tribes'').

Aspects of a shared group identity between the Athapaskan speaking tribes of the Southwest-Navajo and Jicarilla Apache and Ancestral Puebloans, as well as the Ute tribes and Ancestral Puebloans were also considered, but cultural affiliation was not supported by a preponderance of evidence. The Athapaskan speaking tribes of the Southwest have geographic, folklore, oral traditional, ethnohistorical, and/or historical ties to the Durango area. Cross-cultural influences and intermarriage with Puebloans also support a relationship of shared group identity between Athapaskan and Puebloan groups. However, current archeological evidence does not support a common Athapaskan and Puebloan origin prior to about A.D. 1500. Thus, from an archeological perspective, the evidence does not support cultural affiliation for the Navajo Nation and Jicarilla Apache with the predominantly Basketmaker and Pueblo I human remains and associated funerary objects described in this Notice of Inventory Completion.

The Ute Mountain Ute Tribe, Southern Ute Indian Tribe, and Ute Indian Tribe of the Uintah & Ouray Reservation have geographic, ethnohistorical, and/or historical ties to the Durango area and linguistic ties to the Hopi tribe. Intermarriage with Puebloan peoples is also recognized as a potential link between these groups. However, the body of evidence does not collectively support a common Ute and Puebloan origin. Therefore, a preponderance of evidence does not support cultural affiliation for the contemporary Ute tribes with the predominantly Basketmaker and Pueblo I period human remains and associated funerary objects described in this Notice of Inventory Completion.

Determinations Made by the Fort Lewis College

Officials of Fort Lewis College have determined that

- Pursuant to 25 U.S.C. 3001(9), the human remains described above represent the physical remains of 91 individuals of Native American ancestry.

• Pursuant to 25 U.S.C. 3001(3)(A), the 147 objects described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.

• Pursuant to 25 U.S.C. 3001(2), that there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and The Tribes.

Additional Requestors and Disposition

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the human remains and/or associated funerary objects should contact Dawn Mulhern, Department of Anthropology, Fort Lewis College, 1000 Rim Dr., Durango, CO 81301, telephone (970) 247–7500, before November 10, 2011. Repatriation of the human remains and/or associated funerary objects to The Tribes may proceed after that date if no additional claimants come forward.

Fort Lewis College is responsible for notifying the Hopi Tribe of Arizona; Jicarilla Apache Nation, New Mexico; Kewa Pueblo, New Mexico; Navajo Nation, Arizona, New Mexico & Utah; Ohkay Owingeh, New Mexico; Pueblo of Acoma, New Mexico; Pueblo of Cochiti, New Mexico; Pueblo of Jemez, New Mexico; Pueblo of Isleta, New Mexico; Pueblo of Laguna, New Mexico; Pueblo of Nambe, New Mexico; Pueblo of Picuris, New Mexico; Pueblo of Pojoaque, New Mexico; Pueblo of San Felipe, New Mexico; Pueblo of San Ildefonso, New Mexico; Pueblo of Sandia, New Mexico; Pueblo of Santa Ana, New Mexico; Pueblo of Santa Clara, New Mexico; Pueblo of Taos, New Mexico; Pueblo of Tesuque, New Mexico; Pueblo of Zia, New Mexico; Southern Ute Indian Tribe of the Southern Ute Reservation, Utah; Ute Indian Tribe of the Uintah & Ouray Reservation, Colorado, New Mexico & Utah; Ute Mountain Tribe of the Ute Mountain Reservation, Colorado; Ysleta Del Sur Pueblo of Texas; and the Zuni Tribe of the Zuni Reservation, New Mexico, that this notice has been published.

Dated: October 3, 2011.

Sherry Hutt,

Manager, National NAGPRA Program.

[FR Doc. 2011–26182 Filed 10–7–11; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[2253–665]

Notice of Inventory Completion: The University of Toledo, Toledo, OH

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The University of Toledo has completed an inventory of human remains, in consultation with the appropriate Indian tribes, and has determined that there is no cultural affiliation between the remains and any present-day Indian tribe. Representatives of any Indian tribe that believes itself to be culturally affiliated with the human remains may contact The University of Toledo, Office of General Counsel, 2801 W. Bancroft St., Toledo, OH 43606, telephone (419) 530–8412. Disposition of the human remains to the Indian tribes stated below may occur if no additional requestors come forward.

DATES: Representatives of any Indian tribe that believes it has a cultural affiliation with the human remains should contact The University of Toledo at the above-stated address by November 10, 2011.

ADDRESSES: Peter J. Papadimos, Vice President and General Counsel, The University of Toledo, 2801 W. Bancroft St., Toledo, OH 43606, telephone (419) 530–8412.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains in the possession of The University of Toledo, Toledo, OH. The human remains were removed from Gard Island, Lake Erie, Monroe County, MI.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by The University of Toledo professional staff in consultation with representatives of the Forest County Potawatomi Community, Wisconsin; Ottawa Tribe of Oklahoma; and the Hannahville Indian Community, Michigan.

History and Description of the Remains

In the mid 1970's and early 1980's, human remains, consisting of bone and skull fragments and teeth, representing a minimum of forty-six individuals were removed from Gard Island in Lake Erie, Monroe County, MI in a series of archeological digs sponsored by The University's Department of Sociology and Anthropology. No known individuals were identified. No associated funerary objects were present.

Determinations Made by The University of Toledo Are That:

• Based on laboratory and field analysis, the human remains are determined to be Native American. The remains are attributed to the Western Basin tradition of early farmers who inhabited the coastline of Lake Erie in and around the 8th Century A.D. and who were either annihilated and/or assimilated by subsequent tribal groups.

• Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and any present-day Indian tribe.

• According to final judgments of the Indian Claims Commission, the land from which the Native American human remains were removed is the aboriginal land of the Forest County Potawatomi Community, Wisconsin; Ottawa Tribe of Oklahoma; and the Hannahville Indian Community, Michigan.

• Multiple lines of evidence, including treaties, Acts of Congress, and Executive Orders, indicate that the land from which the Native American human remains were removed is the aboriginal land of the Forest County Potawatomi Community, Wisconsin; Ottawa Tribe of Oklahoma; and the Hannahville Indian Community, Michigan.

• Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of forty-six individuals of Native American ancestry.

• Pursuant to 43 CFR 10.11(c)(1), disposition of the human remains is to the twelve Federally recognized tribes in the Michigan Anishinaabek Cultural Preservation and Repatriation Alliance: the Bay Mills Indian Community, Michigan; Grand Traverse Band of Ottawa and Chippewa Indians, Michigan; Hannahville Indian Community, Michigan; Keweenaw Bay Indian Community, Michigan; Lac Vieux Desert Band of Lake Superior Chippewa Indians, Michigan; Little River Band of Ottawa Indians,

Michigan; Little Traverse Bay Band of Odawa Indians, Michigan; Match-E–Be-Nash-She-Wish Band of Potawatomi Indians of Michigan; Nottawaseppi Huron Band of Potawatomi, Michigan; Pokagon Band of Potawatomi Indians, Michigan and Indiana; Saginaw Chippewa Indian Tribe of Michigan; and the Sault Ste. Marie Tribe of Chippewa Indians of Michigan (hereinafter referred to as ''The Tribes'').

Additional Requestors and Disposition

Representatives of any Indian tribe that believes itself to be culturally affiliated with the human remains or any other Indian tribe that believes it satisfies the criteria in 43 CFR 10.11(c)(1) should contact Peter J. Papadimos, Vice President and General Counsel, The University of Toledo, 2801 W. Bancroft St., Toledo, OH 43605; telephone (419) 530–8412, before November 10, 2011. Disposition of the human remains to The Tribes may proceed after that date if no additional requestors come forward.

The University of Toledo, Toledo, Ohio is responsible for notifying The Tribes that this notice has been published.

Dated: October 3, 2011.

Sherry Hutt,

Manager, National NAGPRA Program.

[FR Doc. 2011–26174 Filed 10–7–11; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[2253–665]

Notice of Inventory Completion: University of Colorado Museum, Boulder, CO

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The University of Colorado Museum has completed an inventory of human remains, in consultation with the appropriate Indian tribes, and has determined that there is no cultural affiliation between the human remains and any present-day Indian tribe. Representatives of any Indian tribe that believes itself to be culturally affiliated with the human remains may contact the University of Colorado Museum. Disposition of the human remains to the Indian tribes stated below may occur if no additional requestors come forward.

DATES: Representatives of any Indian tribe that believes it has a cultural affiliation with the human remains should contact the University of Colorado Museum at the address below by November 10, 2011.

ADDRESSES: Steve Lekson, Curator of Anthropology, University of Colorado Museum, Campus Box 218, Boulder, CO 80309, telephone (303) 492–6671.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains in the possession of the University of Colorado Museum, Boulder, CO. The human remains were removed from California.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by University of Colorado Museum professional staff in consultation with representatives of the Agua Caliente Band of Cahuilla Mission Indians, California; Alturas Indian Rancheria, California; Augustine Band of Cahuilla Mission Indians, California; Barona Group of Capitan Grande Ban of Mission Indians of the Barona Reservation, California; Bear River Band of Rohnerville Rancheria, California; Berry Creek Rancheria of Maidu Indians of California; Big Lagoon Rancheria, California; Big Pine Band of Owens Valley Paiute Shoshone Indians of the Big Pine Reservation, California; Big Sandy Rancheria of Mono Indians of California; Big Valley Band of Pomo Indians of the Big Valley Rancheria, California; Blue Lake Rancheria, California; Bridgeport Paiute Indian Colony of California; Buena Vista Rancheria of Me-Wuk Indians of California; Burns Paiute Tribe of the Burns Paiute Indian Colony of Oregon; Cabazon Band of Mission Indians, California; Cachil DeHe Band of Wintun Indians of the Colusa Indian Community of the Colusa Rancheria, California; Caddo Nation of Oklahoma; Cahto Indian Tribe of the Laytonville Rancheria, California; Cahuilla Band of Mission Indians of the Cahuilla Reservation, California; California Valley Miwok Tribe, California; Campo Band of Diegueno Mission Indians of the Campo Reservation, California; Cedarville Rancheria, California; Chemehuevi Indian Tribe of the Chemehuevi Reservation, California; Cher-Ae Heights Indian Community of the Trinidad Rancheria, California; Chicken Ranch Rancheria of Me-Wuk Indians of California; Cloverdale Rancheria of Pomo Indians of California; Cold Springs Rancheria of Mono Indians of California; Colorado River Indian Tribes of the Colorado River Indian Reservation, Arizona and California; Confederated Tribes of the Grand Ronde Community of Oregon; Confederated Tribes of the Siletz Reservation, Oregon; Coyote Valley Band of Pomo Indians of California; Death Valley Timbi-Sha Shoshone Band of California; Dry Creek Rancheria of Pomo Indians of California; Elem Indian Colony of Pomo Indians of the Sulphur Bank Rancheria, California; Elk Valley Rancheria, California; Enterprise Rancheria of Maidu Indians of California; Ewiiaapaayp Band of Kumeyaay Indians, California; Federated Indians of Graton Rancheria, California; Fort Bidwell Indian Community of the Fort Bidwell Reservation of California; Fort Independence Indian Community of Paiute of the Fort Independence Reservation, California; Fort McDermitt Paiute and Shoshone Tribes of the Fort McDermitt Indian Reservation, Nevada and Oregon; Fort McDowell Yavapai Nation, Arizona; Fort Mohave Indian Tribes of Arizona, California & Nevada; Greenville Rancheria of Maidu Indians of California; Grindstone Indian Rancheria of Wintun-Wailaki Indians of California; Guidiville Rancheria of California; Habematolel Pomo of Upper Lake, California; Hoopa Valley Tribe, California; Hopland Band of Pomo Indians of the Hopland Rancheria, California; Iipay Nation of Santa Ysabel, California; Inaja Band of Diegueno Mission Indians of the Inaja and Cosmit Reservation, California; Ione Band of Miwok Indians of California; Jackson Rancheria of Me-Wuk Indians of California; Jamul Indian Village of California; Kaibab Band of Paiute Indians of the Kaibab Indian Reservation, Arizona; Karuk Tribe; Kashia Band of Pomo Indians of the Stewarts Point Rancheria, California; Klamath Tribes, Oregon; La Jolla Band of Luiseno Indians, California; La Posta Band of Diegueno Mission Indians of the La Posta Indian Reservation, California; Las Vegas Tribe of Paiute Indians of the Las Vegas Indian Colony, Nevada; Los Coyotes Band of Cahuilla & Cupeno Indians, California; Lovelock Paiute Tribe of the Lovelock Indian Colony, Nevada; Lower Lake Rancheria, California; Lytton Rancheria of California; Manchester Band of Pomo Indians of the Manchester-Point Arena

Rancheria, California; Manzanita Band of Diegueno Mission Indians of the Manzanita Reservation, California; Mechoopda Indian Tribe of the Chico Rancheria, California; Mesa Grande Band of Diegueno Mission Indians of the Mesa Grande Reservation, California; Middletown Rancheria of Pomo Indians of California; Moapa Band of Paiute Indians of the Moapa River Indian Reservation, Nevada; Modoc Tribe of Oklahoma; Mooretown Rancheria of Maidu Indians of California; Morongo Band of Cahuilla Mission Indians, California; Northfork Rancheria of Mono Indians of California; Northwest Band of Shoshoni Nation of Utah (Washakie); Paiute Indian Tribe of Utah (Cedar Band of Paiutes, Kanosh Band of Paiutes, Koosharem Band of Paiutes, Indian Peaks Band of Paiutes, and Shivwits Band of Paiutes); Paiute-Shoshone Indians of the Bishop Community of the Bishop Colony, California; Paiute-Shoshone of the Fallon Reservation and Colony, Nevada; Paiute-Shoshone Indians of the Lone Pine Community of the Lone Pine Reservation, California; Pala Band of Luiseno Mission Indians of the Pala Reservation, California; Paskenta Band of Nomlaki Indians of California; Pauma Band of Luiseno Mission Indians of the Pauma & Yuima Reservation, California; Pechanga Band of Luiseno Mission Indians of the Pechanga Reservation, California; Picayune Rancheria of Chukchansi Indians of California; Pinoleville Pomo Nation, California; Pit River Tribe, California (includes XL Ranch, Big Bend, Likely, Lookout, Montgomery Creek and Roaring Creek Rancherias); Potter Valley Tribe, California; Pyramid Lake Paiute Tribe of the Pyramid Lake Reservation, Nevada; Quartz Valley Indian Community of the Quartz Valley Reservation of California; Quechan Tribe of the Fort Yuma Indian Reservation, California & Arizona; Ramona Band of Cahuilla, California; Redding Rancheria California; Redwood Valley Rancheria of Pomo Indians of California; Reno-Sparks Indian Colony, Nevada; Resighini Rancheria, California; Rincon Band of Luiseno Mission Indians of the San Manuel Reservation, California; Robinson Rancheria of Pomo Indians of California; Round Valley Indian Tribes of the Round Valley Reservation, California; San Juan Southern Paiute Tribe of Arizona; San Manuel Band of Mission Indians, California; San Pasqual Band of Diegueno Mission Indians of California; Santa Rosa Band of Cahuilla Indians; Santa Rosa Indian Community of the Santa Rosa Rancheria, California; Santa Ynez Band of Chumash Mission Indians of the Santa Ynez Reservation, California; Scotts Valley Band of Pomo Indians of California; Sherwood Valley Rancheria of Pomo Indians of California; Shingle Springs Band of Miwok Indians, Shingle Springs Rancheria (Verona Tract), California; Shoshone-Paiute Tribes of the Duck Valley Reservation, Nevada; Smith River Rancheria, California; Soboba Band of Luiseno Indians, California; Summit Lake Paiute Tribe of Nevada; Susanville Indian Rancheria, California; Sycuan Band of the Kumeyaay Nation; Table Mountain Rancheria of California; Te-Moak Tribe of Western Shoshone Indians of Nevada (Four constituent bands: Battle Mountain Band; Elko Band; South Fork Band and Wells Band); Torres Martinez Desert Cahuilla Indians, California; Tule River Indian Tribe of the Tule River Reservation, California; Tuolumne Band of Me-Wuk Indians of the Tuolumne Rancheria of California; Twenty-Nine Palms Band of Mission Indians of California; United Auburn Indian Community of the Auburn Rancheria of California; Utu Utu Gwaitu Paiute Tribe of the Benton Paiute Reservation, California; Viejas (Baron Long) Group of Capitan Grande Band of Mission Indians of the Viejas Reservation, California; Walker River Paiute Tribe of the Walker River Reservation, Nevada; Washoe Tribe of Nevada & California (Carson Colony, Dresslerville Colony, Woodfords Community, Stewart Community, & Washoe Ranches); Wiyot Tribe, California; Yavapai-Apache Nation of the Camp Verde Indian Reservation, Arizona; Yerington Paiute Tribe of the Yerington Colony & Campbell Ranch, Nevada Yocha Dehe Wintun Nation, California; and Yurok Tribe of the Yurok Reservation, California (herein after ''The Tribes'').

History and Description of the Remains

On an unknown date, human remains representing a minimum of one individual were removed from California by Joe Ben Wheat, the curator of anthropology at the University of Colorado Museum from 1953 to 1988. In November 2009, the human remains (a tooth) (TIN 0058) were found in the collection. No known individual was identified. No associated funerary objects are present.

Determinations Made by the University of Colorado Museum

Officials of the University of Colorado Museum have determined that:

- Based on the collecting history of Joe Ben Wheat, the human remains are Native American.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and any present-day Indian tribe.
- According to final judgments of the Indian Claims Commission, the land from which the Native American human remains were removed is the aboriginal land of the Colorado River Indian Tribes of the Colorado River Indian Reservation, Arizona and California; Fort McDermitt Paiute and Shoshone Tribes of the Fort McDermitt Indian Reservation, Nevada and Oregon; Fort McDowell Yavapai Nation, Arizona; Fort Mohave Indian Tribes of Arizona, California & Nevada; Kaibab Band of Paiute Indians of the Kaibab Indian Reservation, Arizona; Klamath Tribes, Oregon; Las Vegas Tribe of Paiute Indians of the Las Vegas Indian Colony, Nevada; Moapa Band of Paiute Indians of the Moapa River Indian Reservation, Nevada; Paiute Indian Tribe of Utah (Cedar Band of Paiutes, Kanosh Band of Paiutes, Koosharem Band of Paiutes, Indian Peaks Band of Paiutes, and Shivwits Band of Paiutes); Paiute-Shoshone Tribe of the Fallon Reservation and Colony, Nevada; Pit River Tribe, California (includes XL Ranch, Big Bend, Likely, Lookout, Montgomery Creek and Roaring Creek Rancherias); Pyramid Lake Paiute Tribe of the Pyramid Lake Reservation, Nevada; Quechan Tribe of the Fort Yuma Indian Reservation, California & Arizona; Reno-Sparks Indian Colony, Nevada; Walker River Paiute Tribe of the Walker River Reservation, Nevada; Washoe Tribe of Nevada & California (Carson Colony, Dresslerville Colony, Woodfords Community, Stewart Community, & Washoe Ranches); Yavapai-Apache Nation of the Camp Verde Indian Reservation, Arizona; and Yerington Paiute Tribe of the Yerington Colony & Campbell Ranch, Nevada.
- Multiple lines of evidence, including treaties, Acts of Congress, and Executive Orders, indicate that the land from which the Native American human remains were removed is the aboriginal land of the Agua Caliente Band of Cahuilla Mission Indians, California; Augustine Band of Cahuilla Mission Indians, California; Berry Creek Rancheria of Maidu Indians of California; Big Pine Band of Owens Valley Paiute Shoshone Indians of the Big Pine Reservation, California; Big Sandy Rancheria of Mono Indians of California; Big Valley Band of Pomo Indians of the Big Valley Rancheria, California; Bridgeport Paiute Indian Colony of California; Buena Vista Rancheria of Me-Wuk Indians of California; Burns Paiute Tribe of the

Burns Paiute Indian Colony of Oregon; Caddo Nation of Oklahoma; California Valley Miwok Tribe, California; Chicken Ranch Rancheria of Me-Wuk Indians of California; Cloverdale Rancheria of Pomo Indians of California; Cold Springs Rancheria of Mono Indians of California; Colorado River Indian Tribes of the Colorado River Indian Reservation, Arizona and California; Confederated Tribes of the Grand Ronde Community of Oregon; Confederated Tribes of the Siletz Reservation, Oregon; Coyote Valley Band of Pomo Indians of California; Dry Creek Rancheria of Pomo Indians of California; Elem Indian Colony of Pomo Indians of the Sulphur Bank Rancheria, California; Enterprise Rancheria of Maidu Indians of California; Fort McDermitt Paiute and Shoshone Tribes of the Fort McDermitt Indian Reservation, Nevada and Oregon; Grindstone Indian Rancheria of Wintun-Wailaki Indians of California; Hoopa Valley Tribe, California; Hopland Band of Pomo Indians of the Hopland Rancheria, California; Ione Band of Miwok Indians of California; Jackson Rancheria of Me-Wuk Indians of California; Kaibab Band of Paiute Indians of the Kaibab Indian Reservation, Arizona; Kashia Band of Pomo Indians of the Stewarts Point Rancheria, California; Klamath Tribes, Oregon; La Jolla Band of Luiseno Indians, California; Las Vegas Tribe of Paiute Indians of the Las Vegas Indian Colony, Nevada; Los Coyotes Band of Cahuilla & Cupeno Indians, California; Lovelock Paiute Tribe of the Lovelock Indian Colony, Nevada; Manchester Band of Pomo Indians of the Manchester-Point Arena Rancheria, California; Middletown Rancheria of Pomo Indians of California; Moapa Band of Paiute Indians of the Moapa River Indian Reservation, Nevada; Modoc Tribe of Oklahoma; Mooretown Rancheria of Maidu Indians of California; Morongo Band of Cahuilla Mission Indians, California; Northfork Rancheria of Mono Indians of California; Northwest Band of Shoshoni Nation of Utah (Washakie); Paiute Indian Tribe of Utah (Cedar Band of Paiutes, Kanosh Band of Paiutes, Koosharem Band of Paiutes, Indian Peaks Band of Paiutes, and Shivwits Band of Paiutes); Paiute-Shoshone Indians of the Bishop Community of the Bishop Colony, California; Paiute-Shoshone of the Fallon Reservation and Colony, Nevada; Paiute-Shoshone Indians of the Lone Pine Community of the Lone Pine Reservation, California; Pala Band of Luiseno Mission Indians of the Pala Reservation, California; Paskenta Band of Nomlaki Indians of California; Pauma Band of Luiseno Mission Indians of the Pauma & Yuima Reservation, California; Pechanga Band of Luiseno Mission Indians of the Pechanga Reservation, California; Picayune Rancheria of Chukchansi Indians of California; Pinoleville Pomo Nation, California; Pyramid Lake Paiute Tribe of the Pyramid Lake Reservation, Nevada; Quechan Tribe of the Fort Yuma Indian Reservation, California & Arizona; Ramona Band of Cahuilla, California; Redwood Valley Rancheria of Pomo Indians of California; Rincon Band of Luiseno Mission Indians of the San Manuel Reservation, California; Robinson Rancheria of Pomo Indians of California; Round Valley Indian Tribes of the Round Valley Reservation, California; San Juan Southern Paiute Tribe of Arizona; San Pasqual Band of Diegueno Mission Indians of California; Santa Rosa Indian Community of the Santa Rosa Rancheria, California; Santa Rosa Band of Cahuilla Indians; Scotts Valley Band of Pomo Indians of California; Sherwood Valley Rancheria of Pomo Indians of California; Shingle Springs Band of Miwok Indians, Shingle Springs Rancheria (Verona Tract), California; Shoshone-Paiute Tribes of the Duck Valley Reservation, Nevada; Smith River Rancheria, California; Soboba Band of Luiseno Indians, California; Summit Lake Paiute Tribe of Nevada; Table Mountain Rancheria of California; Te-Moak Tribe of Western Shoshone Indians of Nevada (Four constituent bands: Battle Mountain Band; Elko Band; South Fork Band and Wells Band); Torres Martinez Desert Cahuilla Indians, California; Tule River Indian Tribe of the Tule River Reservation, California; Tuolumne Band of Me-Wuk Indians of the Tuolumne Rancheria of California; Utu Utu Gwaitu Paiute Tribe of the Benton Paiute Reservation, California; Walker River Paiute Tribe of the Walker River Reservation, Nevada; Washoe Tribe of Nevada & California (Carson Colony, Dresslerville Colony, Woodfords Community, Stewart Community, & Washoe Ranches); and Yerington Paiute Tribe of the Yerington Colony & Campbell Ranch, Nevada.

• Other credible lines of evidence indicate that the land from which the Native American human remains and associated funerary object were removed is the aboriginal land of the Alturas Indian Rancheria, California; Barona Group of Capitan Grande Ban of Mission Indians of the Barona Reservation, California; Bear River Band of Rohnerville Rancheria, California; Big Lagoon Rancheria, California; Blue Lake Rancheria, California; Cabazon Band of Mission Indians, California; Cachil DeHe Band of Wintun Indians of the Colusa Indian Community of the Colusa Rancheria, California; Cahto Indian Tribe of the Laytonville Rancheria, California; Cahuilla Band of Mission Indians of the Cahuilla Reservation, California; Campo Band of Diegueno Mission Indians of the Campo Reservation, California; Cedarville Rancheria, California; Chemehuevi Indian Tribe of the Chemehuevi Reservation, California; Cher-Ae Heights Indian Community of the Trinidad Rancheria, California; Death Valley Timbi-Sha Shoshone Band of California; Elk Valley Rancheria, California; Ewiiaapaayp Band of Kumeyaay Indians, California; Federated Indians of Graton Rancheria, California; Fort Bidwell Indian Community of the Fort Bidwell Reservation of California; Fort Independence Indian Community of Paiute of the Fort Independence Reservation, California; Greenville Rancheria of Maidu Indians of California; Guidiville Rancheria of California; Habematolel Pomo of Upper Lake, California; Iipay Nation of Santa Ysabel, California; Inaja Band of Diegueno Mission Indians of the Inaja and Cosmit Reservation, California; Jamul Indian Village of California; Karuk Tribe; La Posta Band of Diegueno Mission Indians of the La Posta Indian Reservation, California; Lower Lake Rancheria, California; Lytton Rancheria of California; Manzanita Band of Diegueno Mission Indians of the Manzanita Reservation, California; Mechoopda Indian Tribe of the Chico Rancheria, California; Mesa Grande Band of Diegueno Mission Indians of the Mesa Grande Reservation, California; Potter Valley Tribe, California; Quartz Valley Indian Community of the Quartz Valley Reservation of California; Redding Rancheria California; Resighini Rancheria California; San Manuel Band of Mission Indians, California; Santa Ynez Band of Chumash Mission Indians of the Santa Ynez Reservation, California; Susanville Indian Rancheria, California; Sycuan Band of the Kumeyaay Nation; Twenty-Nine Palms Band of Mission Indians of California; United Auburn Indian Community of the Auburn Rancheria or California; Viejas (Baron Long) Group of Capitan Grande Band of Mission Indians of the Viejas Reservation, California; Wiyot Tribe, California; Yocha Dehe Wintun Nation, California; and Yurok Tribe of the Yurok Reservation, California.

• Pursuant to 25 U.S.C. 3001(9), the human remains described above

represent the physical remains of one individual of Native American ancestry.

• Pursuant to 43 CFR 10.11(c)(1), the disposition of the human remains is to the Santa Rosa Indian Community of the Santa Rosa Rancheria, California.

Additional Requestors and Disposition

Representatives of any Indian tribe that believes itself to be culturally affiliated with the human remains or any other Indian tribe that believes it satisfies the criteria in 43 CFR 10.11(c)(1) should contact Steve Lekson, Curator of Anthropology, University of Colorado Museum, Campus Box 218, Boulder, CO 80309, telephone (303) 492–6671, before November 10, 2011. Disposition of the human remains to the Santa Rosa Indian Community of the Santa Rosa Rancheria, California may proceed after that date if no additional claimants come forward.

The University of Colorado Museum is responsible for notifying The Tribes that this notice has been published.

Dated: October 3, 2011.

Sherry Hutt,

Manager, National NAGPRA Program.

[FR Doc. 2011–26164 Filed 10–7–11; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[2253–665]

Notice of Inventory Completion: Peabody Museum of Archaeology and Ethnology, Harvard University, Cambridge, MA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Peabody Museum of Archaeology and Ethnology, Harvard University has completed an inventory of human remains, in consultation with the appropriate Indian tribes, and has determined that there is a cultural affiliation between the human remains and present-day Indian tribes. Representatives of any Indian tribe that believes itself to be culturally affiliated with the human remains may contact the Peabody Museum of Archaeology and Ethnology, Harvard University. Repatriation of the human remains to the Indian tribes stated below may occur if no additional claimants come forward.

DATES: Representatives of any Indian tribe that believes it has a cultural affiliation with the human remains should contact the Peabody Museum of Archaeology and Ethnology, Harvard University at the address below by November 10, 2011.

ADDRESSES: Patricia Capone, Repatriation Coordinator, Peabody Museum of Archaeology and Ethnology, Harvard University, 11 Divinity Ave., Cambridge, MA 02138, telephone (617) 496–3702.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains in the possession of the Peabody Museum of Archaeology and Ethnology, Harvard University (Peabody Museum), Cambridge, MA. The human remains were removed from Cayuga County, NY.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Peabody Museum professional staff in consultation with representatives of the Cayuga Nation of New York; Oneida Nation of New York; Oneida Tribe of Indians of Wisconsin; Onondaga Nation of New York; Saint Regis Mohawk Tribe, New York; Seneca Nation of New York; Seneca-Cayuga Tribe of Oklahoma; Tonawanda Band of Seneca Indians of New York; and the Tuscarora Nation of New York (hereinafter ''The Tribes'').

History and Description of the Remains

At an unknown date, human remains representing a minimum of two individuals were removed from Cayuga County, NY, by an unknown collector. In 1950 the remains were donated to the Peabody Museum by the Peabody Museum in Salem, MA (now the Peabody Essex Museum). No known individuals were identified. No associated funerary objects are present.

Museum documentation describes these individuals as ''Iroquois''. The designation ''Iroquois'' post-dates contact between Native American groups and Euro-American people in this area and suggests that the human remains date to the Historic period (post-A.D. 1540). The western portion of central New York, including Cayuga County, is the traditional heartland of the Cayuga Nation. Consultation with representatives of The Tribes indicates that Cayuga County, NY, was inhabited by members of the historic Cayuga Nation. However, The Tribes have requested that, due to a shared cultural identity among all Iroquois Nations, the remains be affiliated and repatriated collectively to The Tribes.

Determinations Made by the Peabody Museum

Officials of the Peabody Museum have determined that:

• Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of two individuals of Native American ancestry.

• Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and The Tribes.

Additional Requestors and Disposition

Representatives of any Indian tribe that believes itself to be culturally affiliated with the human remains should contact Patricia Capone, Repatriation Coordinator, Peabody Museum of Archaeology and Ethnology, Harvard University, 11 Divinity Ave., Cambridge, MA 02138, telephone (617) 496–3702, before November 10, 2011. Repatriation of the human remains to The Tribes may proceed after that date if no additional claimants come forward.

The Peabody Museum is responsible for notifying The Tribes that this notice has been published.

Dated: October 3, 2011.

Sherry Hutt,

Manager, National NAGPRA Program.

[FR Doc. 2011–26158 Filed 10–7–11; 8:45 am]

BILLING CODE 4312–50–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *In Re Certain Integrated Solar Systems and Components Thereof,* DN 2847; the Commission is soliciting comments on any public interest issues raised by the complaint.

FOR FURTHER INFORMATION CONTACT: James R. Holbein, Secretary to the

Commission, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov,* and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint filed on behalf of Westinghouse Solar, Inc. on October 4, 2011. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain integrated solar systems and components thereof. The complaint names as respondents Zep Solar, Inc. of CA; Canadian Solar Inc. of Canada; and Canadian Solar (USA) Inc. of CA.

The complainant, proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five pages in length, on any public interest issues raised by the complaint. Comments should address whether issuance of an exclusion order and/or a cease and desist order in this investigation would negatively affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the orders are used in the United States;

(ii) Identify any public health, safety, or welfare concerns in the United States relating to the potential orders;

(iii) Indicate the extent to which like or directly competitive articles are produced in the United States or are otherwise available in the United States, with respect to the articles potentially subject to the orders; and

(iv) Indicate whether Complainant, Complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to an exclusion order and a cease and desist order within a commercially reasonable time.

Written submissions must be filed no later than by close of business, five business days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

Persons filing written submissions must file the original document and 12 true copies thereof on or before the deadlines stated above with the Office of the Secretary. Submissions should refer to the docket number (''Docket No. 2847'') in a prominent place on the cover page and/or the first page. The Commission's rules authorize filing submissions with the Secretary by facsimile or electronic means only to the extent permitted by section 201.8 of the rules (see Handbook for Electronic Filing Procedures, *http://www.usitc.gov/secretary/fed_reg_notices/rules/documents/handbook_on_electronic_filing.pdf*). Persons with questions regarding electronic filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of sections 201.10 and 210.50(a)(4) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.50(a)(4)).

By order of the Commission.

Issued: October 4, 2011.

James R. Holbein,

Secretary to the Commission.

[FR Doc. 2011–26097 Filed 10–7–11; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–318 and 731–TA–538 and 561 (Third Review)]

Sulfanilic Acid From China and India

Determination

On the basis of the record [1] developed in the subject five-year reviews, the United States International Trade Commission (Commission) determines, pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. § 1675(c)), that revocation of the countervailing duty order on sulfanilic acid from India and antidumping duty orders on sulfanilic acid from China and India would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission instituted these reviews on April 1, 2011 (76 FR 18248) and determined on July 5, 2011 that it would conduct expedited reviews (76 FR 50756, August 16, 2011).

The Commission transmitted its determination in these reviews to the Secretary of Commerce on October 4, 2011. The views of the Commission are contained in USITC Publication 4270 (October 2011), entitled *Sulfanilic Acid From China and India: Investigation Nos. 701–TA–318 and 731–TA–538 and 561 (Third Review).*

By order of the Commission.

Issued: October 4, 2011.

James R. Holbein,

Secretary to the Commission.

[FR Doc. 2011–26114 Filed 10–7–11; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Antitrust Division

United States v. Morgan Stanley; Proposed Final Judgment and Competitive Impact Statement

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), that a proposed Final Judgment, Stipulation and Competitive Impact Statement have been filed with the United States District Court for the Southern District of New York in *United States of America v. Morgan Stanley,* Civil Action No. 11–Civ–6875. On September 30, 2011, the United States filed a

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

Complaint alleging that a subsidiary of Morgan Stanley entered into an agreement with KeySpan Corporation, the likely effect of which was to increase prices in the New York City (NYISO Zone J) Capacity Market, in violation of Section 1 of the Sherman Act, 15 U.S.C. 1. The proposed Final Judgment, submitted at the same time as the Complaint, requires Morgan Stanley to pay the government $4.8 million dollars.

Copies of the Complaint, proposed Final Judgment and Competitive Impact Statement are available for inspection at the Department of Justice, Antitrust Division, Antitrust Documents Group, 450 Fifth Street NW., DC 20530 Suite 1010 (*telephone:* 202–514–2481), on the Department of Justice's Web site at *http://www.justice.gov/atr,* and at the Office of the Clerk of the United States District Court for the Southern District of New York. Copies of these materials may be obtained from the Antitrust Division upon request and payment of the copying fee set by Department of Justice regulations.

Public comment is invited within 60 days of the date of this notice. Such comments, and responses thereto, will be published in the **Federal Register** and filed with the Court. Comments should be directed to William H. Stallings, Chief, Transportation Energy and Agriculture Section, Antitrust Division, Department of Justice, Washington, DC 20530, (*telephone:* 202–514–9323).

Patricia A. Brink,

Director of Civil Enforcement.

United States District Court for the Southern District of New York

United States of America, U.S. Department of Justice, Antitrust Division, 450 5th Street, NW., Suite 8000, Washington, DC 20530, *Plaintiff,*

v.

Morgan Stanley, 1585 Broadway, New York, N.Y. 10036, *Defendant.*

Civil Action No.: 11-civ-6875.

Complaint

The United States of America, acting under the direction of the Attorney General of the United States, brings this civil antitrust action under Section 4 of the Sherman Act, as amended, 15 U.S.C. 4, to obtain equitable and other relief from Defendant's violation of Section 1 of the Sherman Act, as amended, 15 U.S.C. 1.

On January 18, 2006, KeySpan Corporation (''KeySpan'') and Morgan Stanley Capital Group Inc. (''MSGC''), a subsidiary of defendant Morgan Stanley,[1] executed an agreement (the ''Morgan/KeySpan Swap'') that ensured that KeySpan would withhold substantial output from the New York City electricity generating capacity market, a market that was created to ensure the supply of sufficient generation capacity for New York City consumers of electricity. The likely effect of the Morgan/KeySpan Swap was to increase capacity prices for the retail electricity suppliers who must purchase capacity, and, in turn, to increase the prices consumers pay for electricity. For its part, Morgan enjoyed profits arising from revenues earned in connection with the Morgan/KeySpan Swap.

I. Introduction

1. Between 2003 and 2006, KeySpan, the largest seller of electricity generating capacity (''installed capacity'') in the New York City market, earned substantial revenues due to tight supply conditions. Because purchasers of capacity required almost all of KeySpan's output to meet expected demand, KeySpan's ability to set price levels was limited only by a regulatory ceiling (called a ''bid cap''). Indeed, the market price for capacity was consistently at or near KeySpan's bid cap, with KeySpan sacrificing sales on only a small fraction of its capacity.

2. But market conditions were about to change. Two large, new electricity generation plants were slated to come on line in 2006 (with no exit expected until at least 2009), breaking the capacity shortage that had kept prices at the capped levels.

3. KeySpan could prevent the new capacity from lowering prices by withholding a substantial amount of its own capacity from the market. This ''bid the cap'' strategy would keep market prices high, but at a significant cost—the sacrificed sales would reduce KeySpan's revenues by as much as $90 million per year. Alternatively, KeySpan could compete with its rivals for sales by bidding more capacity at lower prices. This ''competitive strategy'' could earn KeySpan more than bidding its cap, but it carried a risk—KeySpan's competitors could undercut its price and take sales away, making the strategy less profitable than ''bidding the cap.''

4. KeySpan searched for a way to avoid both the revenue decline from bidding its cap and the revenue risks of competitive bidding. It decided to enter into an agreement that gave it a financial interest in the capacity of Astoria—KeySpan's largest competitor. By providing KeySpan revenues on a larger base of sales, such an agreement would make KeySpan's ''bid the cap'' strategy more profitable than a successful competitive bid strategy. Rather than directly approach its competitor, KeySpan turned to Morgan to act as the counterparty to the agreement—the Morgan/KeySpan Swap—recognizing that Morgan would, and in fact did, enter into an offsetting agreement with Astoria (the ''Morgan/Astoria Hedge'').

5. Morgan recognized that it could profit from combining the economic interests of KeySpan and Astoria. Morgan extracted revenues by entering into the financial instruments and thereby stepping into the middle of the two companies. With KeySpan deriving revenues from both its own and Astoria's capacity, the Morgan/KeySpan Swap removed any incentive for KeySpan to bid competitively, locking it into bidding its cap. Capacity prices remained as high as if no entry had occurred.

II. Defendant

6. Morgan Stanley is a Delaware corporation with its principal place of business in New York City. Morgan Stanley provides diversified financial services, operating a global asset management business, investment banking services, and a global securities business, including a commodities trading division. Morgan Stanley Capital Group, Inc., a wholly owned subsidiary of Morgan Stanley, functions as and is publicly referred to as the commodities trading division for the parent company Morgan Stanley. In 2010, Morgan Stanley had revenues of $31.6 billion.

III. Jurisdiction and Venue

7. The United States files this complaint under Section 4 of the Sherman Act, 15 U.S.C. 4, seeking equitable relief from Defendant's violation of Section 1 of the Sherman Act, 15 U.S.C. 1.

8. This court has jurisdiction over this matter pursuant to 15 U.S.C. 4 and 28 U.S.C. 1331 and 1337.

9. Defendant waives any objection to venue and personal jurisdiction in this judicial district for the purpose of this Complaint.

10. Defendant engaged in interstate commerce during the relevant period of the allegations in this Complaint; Morgan is a worldwide company that regularly engages in financial transactions across the country and throughout the world.

IV. The New York City Installed Capacity Market

11. Sellers of retail electricity must purchase a product from generators

[1] MSCG and Morgan Stanley are collectively referred to hereinafter as ''Morgan.''

known as ''installed capacity.'' Installed capacity is a product created by the New York Independent System Operator (''NYISO'') to ensure that sufficient generation capacity exists to meet expected electricity needs. Companies selling electricity to consumers in New York City are required to make installed capacity payments that relate to their expected peak demand plus a share of reserve capacity (to cover extra facilities needed in case a generating facility breaks down). These payments assure that retail electric companies do not sell more electricity than the system can deliver and also encourage electric generating companies to build new facilities as needed.

12. The price for installed capacity has been set through auctions administered by the NYISO. The rules under which these auctions are conducted have changed from time to time. Unless otherwise noted, the description of the installed capacity market in the following paragraphs relates to the period May 2003 through March 2008.

13. Because transmission constraints limit the amount of energy that can be imported into the New York City area from the power grid, the NYISO requires retail providers of electricity to customers in New York City to purchase 80% of their capacity from generators in that region. The NYISO operates separate capacity auctions for the New York City region (also known as ''In-City'' and ''Zone J''). The NYISO organizes the auctions to serve two distinct seasonal periods, summer (May through October) and winter (November through April). For each season, the NYISO conducts seasonal, monthly and spot auctions in which capacity can be acquired for all or some of the seasonal period.

14. In each of the types of auctions, capacity suppliers offer price and quantity bids. Supplier bids are ''stacked'' from lowest-priced to highest, and compared to the total amount of demand being satisfied in the auction. The offering price of the last bid in the ''stack'' needed to meet requisite demand establishes the market price for all capacity bid into that auction. Capacity bid at higher than this price is unsold, as is any excess capacity bid at what becomes the market price.

15. The New York City Installed Capacity (''NYC Capacity'') Market constitutes a relevant geographic and product market.

16. The NYC Capacity Market is highly concentrated, with three firms—KeySpan, NRG Energy, Inc. (''NRG'') and Astoria Generating Company Acquisitions, L.L.C. (a joint venture of Madison Dearborn Partners, LLC and US Power Generating Company, which purchased the Astoria generating assets from Reliant Energy, Inc. in February 2006)—controlling a substantial portion of generating capacity in the market. Because purchasers of capacity require at least some of each of these three suppliers' output to meet expected demand, the firms are subject to a bid and price cap for nearly all of their generating capacity in New York City and are not allowed to sell that capacity outside of the NYISO auction process. The NYISO-set bid cap for KeySpan is the highest of the three firms, followed by NRG and Astoria.

17. KeySpan possessed market power in the NYC Capacity Market.

18. It is difficult and time-consuming to build or expand generating facilities within the NYC Capacity Market given limited undeveloped space for building or expanding generating facilities and extensive regulatory obligations.

V. Keyspan's Plan To Avoid Competition

19. From June 2003 through December 2005, KeySpan set the market price in the New York City spot auction by bidding its capacity at its cap. Given extremely tight supply and demand conditions, KeySpan needed to withhold only a small amount of capacity to ensure that the market cleared at its cap.

20. KeySpan anticipated that the tight supply and demand conditions in the NYC Capacity Market would change in 2006, due to the entry of approximately 1000 MW of new generation. Because of the addition of this new capacity, KeySpan would have to withhold significantly more capacity from the market and would earn substantially lower revenues if it continued to bid all of its capacity at its bid cap. KeySpan anticipated that demand growth and retirement of old generation units would restore tight supply and demand conditions in 2009.

21. KeySpan could no longer be confident that ''bidding the cap'' would remain its best strategy during the 2006–2009 period. It considered various competitive bidding strategies under which KeySpan would compete with its rivals for sales by bidding more capacity at lower prices. These strategies could potentially produce much higher returns for KeySpan but carried the risk that competitors would undercut its price and take sales away, making the strategy less profitable than ''bidding the cap.''

22. KeySpan also considered acquiring Astoria's generating assets, which were for sale. This would have solved the problem that new entry posed for KeySpan's revenue stream, as Astoria's capacity would have provided KeySpan with sufficient additional revenues to make continuing to ''bid the cap'' its best strategy. KeySpan consulted with Morgan about acquiring the assets. But KeySpan soon concluded that its acquisition of its largest competitor would raise serious market power issues and communicated that conclusion to Morgan.

23. Instead of purchasing the Astoria assets, KeySpan decided to acquire a financial interest in substantially all of Astoria's capacity. KeySpan would pay Astoria's owner a fixed revenue stream in return for the revenues generated from Astoria's capacity sales in the auctions.

24. KeySpan did not approach Astoria directly, instead approaching Morgan to arrange a financial agreement providing KeySpan with payments derived from the market clearing price for an amount of capacity essentially equivalent to what Astoria owned. KeySpan recognized that Morgan would need simultaneously to enter into an off-setting financial agreement with another capacity supplier. Morgan agreed to such a Swap but, as expected, informed KeySpan that the agreement was contingent on Morgan entering into an offsetting agreement with the owner of the Astoria assets.

VI. Morgan's Agreements With Keyspan and Astoria

25. Over the course of late 2005, Morgan negotiated the terms of the derivative agreements with Astoria and KeySpan. Those negotiations illustrate that Morgan recognized its role as a principal in effectively combining the capacity of the two companies. Under the terms initially discussed with Astoria, Morgan would have controlled the bidding of Astoria's capacity. Morgan also proposed that the financial derivative with Astoria be converted into a physical contract, transferring the rights to Astoria's capacity to Morgan in exchange for fixed payments, in the event that the structure of the auction market was disrupted; and, at the same time, Morgan proposed in its negotiations with KeySpan to transfer this physical capacity to KeySpan should a market disruption occur.

26. On or about January 9, 2006, KeySpan and Morgan finalized the terms of the Morgan/KeySpan Swap. Under the agreement, if the market price for capacity was above $7.57 per kW-month, Morgan would pay KeySpan the difference between the market price and $7.57 times 1800 MW; if the market price was below $7.57, KeySpan would

pay Morgan the difference times 1800 MW.

27. The Morgan/KeySpan Swap was executed on January 18, 2006. The term of the Morgan/KeySpan Swap ran from May 2006 through April 2009.

28. On or about January 9, 2006, Morgan and Astoria finalized the terms of the Morgan/Astoria Hedge. Under that agreement, if the market price for capacity was above $7.07 per kW-month, Astoria would pay Morgan the difference times 1800 MW; if the market price was below $7.07, Astoria would be paid the difference times 1800 MW.

29. The Morgan/Astoria Hedge was executed on January 11, 2006. The term of the Morgan/Astoria Hedge ran from May 2006 through April 2009, matching the duration of the Morgan/KeySpan Swap.

VII. The Competitive Effect of the Morgan/Keyspan Swap

30. The clear tendency of the Morgan/KeySpan Swap was to alter KeySpan's bidding in the NYC Capacity Market auctions.

31. Without the Morgan/KeySpan Swap, KeySpan likely would have chosen from a range of potentially profitable competitive strategies in response to the entry of new capacity. Had it done so, the price of capacity would have declined. By transferring a financial interest in Astoria's capacity to KeySpan, however, the Morgan/KeySpan Swap effectively eliminated KeySpan's incentive to compete for sales in the same way a purchase of Astoria or a direct agreement between KeySpan and Astoria would have done. By providing KeySpan revenues from Astoria's capacity, in addition to KeySpan's own revenues, the Morgan/KeySpan Swap made bidding the cap KeySpan's most profitable strategy regardless of its rivals' bids.

32. After the Morgan/KeySpan Swap went into effect in May 2006, KeySpan paid and received revenues under the agreement with Morgan and consistently bid its capacity at its cap even though a significant portion of its capacity went unsold. Despite the addition of significant new generating capacity in New York City, the market price of capacity did not decline.

33. In August 2007, the State of New York conditioned the sale of KeySpan to a new owner on the divestiture of KeySpan's Ravenswood generating assets and required KeySpan to bid its New York City capacity at zero from March 2008 until the divestiture was completed. Since March 2008, the market price for capacity has declined.

34. But for the Morgan/KeySpan Swap, installed capacity likely would have been procured at a lower price in New York City from May 2006 through February 2008.

35. From May 2006 to April 2008, Morgan earned approximately $21.6 million in net revenues from the Morgan/KeySpan Swap and the Morgan/Astoria Hedge.

36. The Morgan/KeySpan Swap produced no countervailing efficiencies.

VIII. Violation Alleged

37. Plaintiff incorporates the allegations of paragraphs 1 through 36 above.

38. Morgan entered into an agreement the likely effect of which has been to increase prices in the NYC Capacity Market, in violation of Section 1 of the Sherman Act, 15 U.S.C. 1.

IX. Prayer for Relief

Wherefore, Plaintiff prays:

39. That the Court adjudge and decree that the Morgan/KeySpan Swap constitutes an illegal restraint in the sale of installed capacity in the New York City market in violation of Section 1 of the Sherman Act;

40. That Plaintiff shall have such other relief, including equitable monetary relief, as the nature of this case may require and as is just and proper to prevent the recurrence of the alleged violation and to dissipate the anticompetitive effects of the violation; and

41. That Plaintiff recover the costs of this action.

Dated: September 30, 2011.

Respectfully submitted,

For Plaintiff United States.

Sharis A. Pozen,
Acting Assistant Attorney General for Antitrust.

Joseph F. Wayland,
Deputy Assistant Attorney General.

Patricia A. Brink,
Director of Civil Enforcement.

Wlliam H. Stallings,
Chief, Transportation, Energy & Agriculture Section.

Jade Eaton,
Attorney, Transportation, Energy & Agriculture Section, Antitrust Division, U.S. Department of Justice, 450 Fifth Street, NW., Suite 8000, Washington, DC 20530, Telephone: (202) 353–1560, Facsimile: (202) 616–2441, e-mail: jade.eaton@usdoj.gov.

J. Richard Doidge,
John W. Elias, Attorneys for the United States.

United States of America, *Plaintiff,*

v.

Morgan Stanley, *Defendant.*

Civil Action No.: 11–civ–6875.

Competitive Impact Statement

Plaintiff United States of America (''United States''), pursuant to Section 2(b) of the Antitrust Procedures and Penalties Act (''APPA'' or ''Tunney Act''), 15 U.S.C. 16(b)-(h), files this Competitive Impact Statement relating to the proposed Final Judgment submitted for entry in this civil antitrust proceeding.

I. Nature and Purpose of the Proceedings

The United States brought this lawsuit against Defendant Morgan Stanley (''Morgan'') on September 30, 2011, to remedy a violation of Section 1 of the Sherman Act, 15 U.S.C. 1. In January 2006, Morgan Stanley Capital Group Inc. (''MSGC''), a subsidiary of defendant Morgan Stanley,[2]executed agreements with KeySpan Corporation (''KeySpan'') and Astoria Generating Company Acquisitions, L.L.C. (''Astoria'') that would effectively combine the economic interests of the two largest competitors in the New York City electric capacity market. By creating this combination, the likely effect of the agreements was to increase capacity prices for the retail electricity suppliers who must purchase capacity, and, in turn, to increase the prices consumers pay for electricity.

The proposed Final Judgment remedies this violation by requiring Morgan to disgorge profits obtained through the anticompetitive agreement. Under the terms of the proposed Final Judgment, Morgan will surrender $4.8 million to the Treasury of the United States. Disgorgement will deter Morgan and others from future violations of the antitrust laws.

The United States and Morgan have stipulated that the proposed Final Judgment may be entered after compliance with the APPA, unless the United States withdraws its consent. Entry of the proposed Final Judgment would terminate this action, except that this Court would retain jurisdiction to construe, modify, and enforce the proposed Final Judgment and to punish violations thereof.

II. Description of the Events Giving Rise to the Alleged Violation of the Antitrust Laws

A. The Defendant

Morgan Stanley is a Delaware corporation with its principal place of business in New York City. Morgan Stanley provides diversified financial services, operating a global asset

[2] MSCG and Morgan Stanley are collectively referred to hereinafter as ''Morgan.''

management business, investment banking services, and a global securities business, including a commodities trading division. In 2010, Morgan Stanley had revenues of $31.6 billion. Morgan Stanley Capital Group, Inc., a wholly owned subsidiary of Morgan Stanley, functions as and is publicly referred to as the commodities trading division for the parent company Morgan Stanley.

B. The Market

In the state of New York, sellers of retail electricity must purchase a product from generators known as installed capacity (''capacity'').[3] Electricity retailers are required to purchase capacity in an amount equal to their expected peak energy demand plus a share of reserve capacity. These payments assure that retail electric companies do not use more electricity than the system can deliver and encourage electric generating companies to build new facilities as needed. Because transmission constraints limit the amount of energy that can be imported into the New York City area from the power grid, the New York Independent System Operator (''NYISO'') requires retail providers of electricity to customers in New York City to purchase 80% of their capacity from generators in that region. Thus, the New York City Installed Capacity (''NYC Capacity'') Market constitutes a relevant geographic and product market.

The price for installed capacity has been set through auctions administered by the NYISO. The NYISO organizes the auctions to serve two distinct seasonal periods, summer (May though October) and winter (November through April). For each season, the NYISO conducts seasonal, monthly, and spot auctions in which capacity can be acquired for all or some of the seasonal period. Capacity suppliers offer price and quantity bids in each of these three auctions. Supplier bids are ''stacked'' from lowest-priced to highest. The stack is then compared to the amount of demand. The offering price of the last bid in the ''stack'' needed to meet requisite demand establishes the market price for all capacity sold into that auction. Any capacity bid at higher than this price is unsold, as is any excess capacity bid at what becomes the market price.

The NYC Capacity Market was highly concentrated during the relevant period, with three firms—Astoria, NRG Energy, Inc., and KeySpan—controlling a substantial portion of the market's generating capacity. These three were designated as pivotal suppliers by the Federal Energy Regulatory Commission, meaning that at least some of each of these three suppliers' output was required to satisfy demand. The three firms were subject to bid and price caps—KeySpan's being the highest—for nearly all of their generating capacity in New York City and were not allowed to sell their capacity outside of the NYISO auction process.

C. The Alleged Violation

1. KeySpan Assesses Plans for Changed Market Conditions

From June 2003 through December 2005, almost all installed capacity in the market was needed to meet demand. With these tight market conditions, KeySpan could sell almost all of its capacity into the market, even while bidding at its cap. KeySpan did so, and the market cleared at the price established by the cap, with only a small fraction of KeySpan's capacity remaining unsold.

KeySpan anticipated that the tight supply and demand conditions in the NYC Capacity Market would end in 2006 due to the entry into the market of approximately 1000 MW of generation capacity, and would not return until 2009 with the retirement of old generation units and demand growth.

KeySpan could no longer be confident that ''bid the cap'' would remain its best strategy during the 2006–2009 period. The ''bid the cap'' strategy would keep market prices high, but at a significant cost. KeySpan would have to withhold a significant additional amount of capacity to account for the new entry. The additional withholding would reduce KeySpan's revenues by as much as $90 million per year. Alternatively, KeySpan could compete with its rivals for sales by bidding more capacity at lower prices. KeySpan considered various competitive bidding strategies. These could potentially produce much higher returns for KeySpan than bidding the cap but carried the risk that competitors would undercut its price and take sales away, making the strategy potentially less profitable than bidding the cap.

KeySpan also considered acquiring Astoria's generating assets from Reliant Energy, Inc., which was putting them up for sale. This would have solved the problem that new entry posed for KeySpan's revenue stream, as Astoria's capacity would have provided KeySpan with sufficient additional revenues to make continuing to ''bid the cap'' its best strategy. Simultaneously, Morgan was interested in buying the same assets and seeking a strategic partner with whom to bid. Morgan and KeySpan discussed such a partnership and the market power issues of a bid involving KeySpan. KeySpan soon concluded that its acquisition of its largest competitor would raise serious market power issues and communicated that conclusion to Morgan.

2. Morgan Facilitates the Anticompetitive and Unlawful Agreement

Instead of purchasing the Astoria assets, KeySpan decided to acquire a financial interest in substantially all of Astoria's capacity. KeySpan would pay Astoria's owner a fixed revenue stream in return for the revenues generated from Astoria's capacity sales in the auctions.

KeySpan realized that it could not approach the owner of Astoria assets directly, so it turned to Morgan to act as a counter-party. Morgan agreed to serve as the counter-party but informed KeySpan that the agreement was contingent on it entering into an offsetting agreement with the owner of the Astoria generating assets.

On or about January 9, 2006, KeySpan and Morgan finalized the terms of a financial derivative arrangement between the two companies, ''the Morgan/KeySpan Swap.'' Under the agreement, if the market price for capacity was above $7.57 per kW-month, Morgan would pay KeySpan the difference between the market price and $7.57 times 1800 MW; if the market price was below $7.57, KeySpan would pay Morgan the difference times 1800 MW. The Morgan/KeySpan Swap was executed on January 18, 2006. The term of the Morgan/KeySpan Swap ran from May 2006 through April 2009.

On or about January 9, 2006, Morgan and Astoria finalized the terms of the offsetting agreement (''Morgan/Astoria Hedge''). Under that agreement, if the market price for capacity was above $7.07 per kW-month, Astoria would pay Morgan the difference times 1800 MW; if the market price was below $7.07, Astoria would be paid the difference times 1800 MW. The Morgan/Astoria Hedge was executed on January 11, 2006. The term of the Morgan/Astoria Hedge ran from May 2006 through April 2009, matching the duration of the Morgan/KeySpan Swap.

Morgan earned approximately $21.6 million in net revenues from the Morgan/KeySpan Swap and the Morgan/Astoria Hedge.

3. The Effect of the Morgan/KeySpan Swap

After the Morgan/KeySpan Swap went into effect in May 2006, KeySpan

[3] Except where noted otherwise, this description pertains to the market conditions that existed from May 2003 through March 2008.

consistently bid its capacity into the capacity auctions at its cap even though a significant portion of its capacity went unsold. Despite the addition of significant new generating capacity in New York City, the market price of capacity did not decline.

The clear tendency of the Morgan/KeySpan Swap was to alter KeySpan's bidding in the NYC Capacity Market auctions. The swap effectively eliminated KeySpan's incentive to compete for sales in the same way a purchase of Astoria or a direct agreement between KeySpan and Astoria would have done. By adding revenues from Astoria's capacity to KeySpan's own, the Morgan/KeySpan Swap made bidding the cap KeySpan's most profitable strategy regardless of its rivals' bids. Without the swap, KeySpan likely would have chosen from a range of potentially profitable competitive strategies in response to the entry of new capacity and, had it done so, the price of capacity would have declined. The swap produced no countervailing efficiencies.

III. United States v. *Keyspan Corporation*

On February 22, 2010, the United States filed suit against KeySpan for its role in the Morgan/KeySpan Swap. Simultaneous with the filing of its Complaint, the United States filed a proposed Final Judgment requiring KeySpan to pay to the United States $12 million as disgorgement of ill-gotten gains. *See Complaint, United States* v. *KeySpan Corp.,* No. 10–1415 (S.D.N.Y. Feb. 22, 2010). After completion of the procedures set forth in the Tunney Act, including public notice and comment, the United States moved for entry of the proposed Final Judgment. In the course of making its public interest determination, the Court found that disgorgement is available to remedy violations of the Sherman Act. *See United States* v. *KeySpan Corp.,* 763 F. Supp. 2d 633, 638–641. The KeySpan Final Judgment was entered on February 2, 2011.

IV. Explanation of the Proposed Final Judgment

The proposed Final Judgment requires Morgan to disgorge profits gained as a result of its unlawful agreement restraining trade. Morgan is to surrender $4.8 million to the Treasury of the United States.

KeySpan, pursuant to a Final Judgment sought by the United States, has surrendered $12 million as a result of its role in the Morgan/KeySpan Swap.[4] *See United States* v. *KeySpan Corp.,* 763 F. Supp. 2d 633, 637–38 (S.D.N.Y. 2011). Securing similar disgorgement from the other responsible party to the anticompetitive agreement will protect the public interest by depriving Morgan of a substantial portion of the fruits of the agreement. The effect of the swap agreement was to effectively combine the economic interests of KeySpan and Astoria, thereby permitting KeySpan to increase prices above competitive rates, and this result could not have been achieved without Morgan's participation in the swap agreement. Requiring disgorgement in these circumstances will thus protect the public interest by deterring Morgan and other parties from entering into similar financial agreements that result in anticompetitive effects in the underlying markets, or from otherwise engaging in similar anticompetitive conduct in the future.

The $4.8 million disgorgement amount is the product of settlement and accounts for litigation risks and costs. While the disgorged sum represents less than all of Morgan's net transaction revenues under the two agreements,[5] disgorgement will effectively fulfill the remedial goals of the Sherman Act to ''prevent and restrain'' antitrust violations as it will send a message of deterrence to those in the financial services community considering the use of derivatives for anticompetitive ends.

V. Remedies Available to Potential Private Litigants

Section 4 of the Clayton Act, 15 U.S.C. 15, provides that any person who has been injured as a result of conduct prohibited by the antitrust laws may bring suit in federal court to recover three times the damages the person has suffered, as well as costs and reasonable attorneys' fees. Entry of the proposed Final Judgment will neither impair nor assist the bringing of any private antitrust damage action. Under the provisions of Section 5(a) of the Clayton Act, 15 U.S.C. 16(a), the proposed Final Judgment has no *prima facie* effect in any subsequent private lawsuit that may be brought against Morgan.

VI. Procedures Available for Modification of the Proposed Final Judgment

The United States and the Defendant have stipulated that the proposed Final Judgment may be entered by the Court after compliance with the provisions of the APPA, provided that the United States has not withdrawn its consent. The APPA conditions entry upon the Court's determination that the proposed Final Judgment is in the public interest.

The APPA provides a period of at least sixty (60) days preceding the effective date of the proposed Final Judgment within which any person may submit to the United States written comments regarding the proposed Final Judgment. Any person who wishes to comment should do so within sixty (60) days of the date of publication of this Competitive Impact Statement in the **Federal Register**, or the last date of publication in a newspaper of the summary of this Competitive Impact Statement, whichever is later. All comments received during this period will be considered by the United States, which remains free to withdraw its consent to the proposed Final Judgment at any time prior to the Court's entry of judgment. The comments and the response of the United States will be filed with the Court and published in the **Federal Register**.

Written comments should be submitted to: William H. Stallings, Chief, Transportation, Energy & Agriculture Section, Antitrust Division, United States Department of Justice, 450 Fifth Street, NW.; Suite 8000, Washington, DC 20530.

The proposed Final Judgment provides that the Court retains jurisdiction over this action, and the parties may apply to the Court for any order necessary or appropriate for the modification, interpretation, or enforcement of the Final Judgment.

VII. Alternatives to the Proposed Final Judgment

The United States considered, as an alternative to the proposed Final Judgment, a full trial on the merits against the Defendant. The United States is satisfied, however, that the disgorgement of profits is an appropriate remedy in this matter. A disgorgement remedy should deter Morgan and others from engaging in similar conduct and thus achieves a significant portion of the relief the United States would have

[4] Had the *KeySpan* case proceeded to trial, the United States would have sought disgorgement of the approximately $49 million in net revenues that KeySpan received under the Swap, contending that these net revenues reflected the value that KeySpan received from trading the uncertainty of competing for the certainty of the bid-the-cap strategy. *See Plaintiff United States's Response to Public Comments* at 14–18, *United States* v. *KeySpan Corp.,* No. 10–1415 (S.D.N.Y. June 11, 2010).

[5] Had the case against Morgan proceeded to trial, the United States would have sought disgorgement of the $21.6 million in net transaction revenues Morgan earned under both the Morgan/KeySpan Swap and the Morgan/Astoria Hedge. At trial, Morgan—in addition to raising arguments as to its lack of liability in general—would have disputed that the entire $21.6 million earned under both agreements would be cognizable as ill-gotten gains.

obtained through litigation but avoids the time, expense, and uncertainty of discovery and a full trial on the merits of the Complaint.

VIII. Standard of Review Under the APPA for Proposed Final Judgment

The Clayton Act, as amended by the APPA, requires that proposed consent judgments in antitrust cases brought by the United States be subject to a sixty-day comment period, after which the court shall determine whether entry of the proposed Final Judgment ''is in the public interest.'' 15 U.S.C. 16(e)(1). In making that determination, the court is directed to consider:

(A) The competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and

(B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. 16(e)(1)(A) & (B); *see generally United States* v. *KeySpan Corp.,* 763 F. Supp. 2d 633, 637–38 (S.D.N.Y. 2011) (WHP) (discussing Tunney Act standards); *United States* v. *SBC Commc'ns, Inc.,* 489 F. Supp. 2d 1 (D.D.C. 2007) (assessing standards for public interest determination). In considering these statutory factors, the court's inquiry is necessarily a limited one as the United States is entitled to ''broad discretion to settle with the Defendant within the reaches of the public interest.'' *United States* v. *Microsoft Corp.,* 56 F.3d 1448, 1461 (D.C. Cir. 1995).

Under the APPA a court considers, among other things, the relationship between the remedy secured and the specific allegations set forth in the United States' complaint, whether the decree is sufficiently clear, whether enforcement mechanisms are sufficient, and whether the decree may positively harm third parties. *See Microsoft,* 56 F.3d at 1458–62. With respect to the adequacy of the relief secured by the decree, the court's function is ''not to determine whether the proposed [d]ecree results in the balance of rights and liabilities that is the one that will *best* serve society, but only to ensure that the resulting settlement is within the *reaches* of the public interest.'' *KeySpan,* 763 F. Supp. 2d at 637 (quoting *United States* v. *Alex Brown & Sons, Inc.,* 963 F. Supp. 235, 238 (S.D.N.Y. 1997) (internal quotations omitted). In making this determination, ''[t]he [c]ourt is not permitted to reject the proposed remedies merely because the court believes other remedies are preferable. [Rather], the relevant inquiry is whether there is a factual foundation for the government's decision such that its conclusions regarding the proposed settlement are reasonable.'' *Id.* at 637–38 (quoting *United States* v. *Abitibi–Consolidated Inc.,* 584 F. Supp. 2d 162, 165 (D.D.C. 2008).[6] The government's predictions about the efficacy of its remedies are entitled to deference.[7]

Courts have greater flexibility in approving proposed consent decrees than in crafting their own decrees following a finding of liability in a litigated matter. ''[A] proposed decree must be approved even if it falls short of the remedy the court would impose on its own, as long as it falls within the range of acceptability or is 'within the reaches of public interest.' '' *United States* v. *Am. Tel. & Tel. Co.,* 552 F. Supp. 131, 151 (D.D.C. 1982) (citations omitted) (quoting *United States* v. *Gillette Co.,* 406 F. Supp. 713, 716 (D. Mass. 1975)), *aff'd sub nom. Maryland* v. *United States,* 460 U.S. 1001 (1983); *see also United States* v. *Alcan Aluminum Ltd.,* 605 F. Supp. 619, 622 (W.D. Ky. 1985) (approving the consent decree even though the court would have imposed a greater remedy). To meet this standard, the United States ''need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms.'' *SBC Commc'ns,* 489 F. Supp. 2d at 17.

Moreover, the court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its Complaint, and does not authorize the court to ''construct [its] own hypothetical case and then evaluate the decree against that case.'' *Microsoft,* 56 F.3d at 1459; *KeySpan,* 763 F. Supp. 2d at 638 (''A court must limit its review to the issues in the complaint * * *.''). Because the ''court's authority to review the decree depends entirely on the government's exercising its prosecutorial discretion by bringing a case in the first place,'' it follows that ''the court is only authorized to review the decree itself,'' and not to ''effectively redraft the complaint'' to inquire into other matters that the United States did not pursue. *Microsoft,* 56 F.3d at 1459–60.

In its 2004 amendments, Congress made clear its intent to preserve the practical benefits of utilizing consent decrees in antitrust enforcement, adding the unambiguous instruction that ''[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.'' 15 U.S.C. 16(e)(2). This language effectuates what Congress intended when it enacted the Tunney Act in 1974, as Senator Tunney explained: ''[t]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process.'' 119 Cong. Rec. 24,598 (1973) (statement of Senator Tunney). Rather, the procedure for the public interest determination is left to the discretion of the court, with the recognition that the court's ''scope of review remains sharply proscribed by precedent and the nature of Tunney Act proceedings.'' *SBC Commc'ns,* 489 F. Supp. 2d at 11.[8]

IX. Determinative Documents

There are no determinative materials or documents within the meaning of the APPA that the United States considered in formulating the proposed Final Judgment.

Dated: September 30, 2011.

Respectfully submitted,

For Plaintiff
the United States of America.
Jade Alice Eaton,
Trial Attorney, United States Department of Justice, Antitrust Division, Transportation, Energy & Agriculture Section, 450 5th Street, NW., Suite 8000, Washington, DC 20530,

[6] *United States* v. *Bechtel Corp.,* 648 F.2d 660, 666 (9th Cir. 1981) (''The balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General.''). *See generally Microsoft,* 56 F.3d at 1461 (discussing whether ''the remedies [obtained in the decree are] so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest' '').

[7] *Microsoft,* 56 F.3d at 1461 (noting the need for courts to be ''deferential to the government's predictions as to the effect of the proposed remedies''); *United States* v. *Archer-Daniels-Midland Co.,* 272 F. Supp. 2d 1, 6 (D.D.C. 2003) (noting that the court should grant due respect to the United States' prediction as to the effect of proposed remedies, its perception of the market structure, and its views of the nature of the case).

[8] *See United States* v. *Enova Corp.,* 107 F. Supp. 2d 10, 17 (D.D.C. 2000) (noting that the ''Tunney Act expressly allows the court to make its public interest determination on the basis of the competitive impact statement and response to comments alone'').

Telephone: (202) 307–6316, jade.eaton@usdoj.gov.

United States of America, Plaintiff,

v.

Morgan Stanley, Defendant.

Civil Action No.

Final Judgment

Whereas Plaintiff United States of America filed its Complaint alleging that Defendant Morgan Stanley (''Morgan'') violated Section 1 of the Sherman Act, 15 U.S.C. 1, and Plaintiff and Morgan, through their respective attorneys, having consented to the entry of this Final Judgment without trial or adjudication of any issue of fact or law, for settlement purposes only, and without this Final Judgment constituting any evidence against or an admission by Morgan for any purpose with respect to any claim or allegation contained in the Complaint:

Now, Therefore, before the taking of any testimony and without trial or adjudication of any issue of fact or law herein, and upon the consent of the parties hereto, it is hereby *Ordered, Adjudged, and Decreed:*

I. Jurisdiction

This Court has jurisdiction of the subject matter herein and of each of the parties consenting hereto. The Complaint states a claim upon which relief may be granted to the United States against Morgan under Sections 1 and 4 of the Sherman Act, 15 U.S.C. 1 and 4.

II. Applicability

This Final Judgment applies to Morgan and each of its successors, assigns, and to all other persons in active concert or participation with it who shall have received actual notice of the Settlement Agreement and Order by personal service or otherwise.

III. Relief

A. Within thirty (30) days of the entry of this Final Judgment, Morgan shall pay to the United States the sum of four million eight hundred thousand dollars ($4,800,000.00).

B. The payment specified above shall be made by wire transfer. Before making the transfer, Morgan shall contact Janie Ingalls, of the Antitrust Division's Antitrust Documents Group, at (202) 514–2481 for wire transfer instructions.

C. In the event of a default in payment, interest at the rate of eighteen (18) percent per annum shall accrue thereon from the date of default to the date of payment.

IV. Retention of Jurisdiction

This Court retains jurisdiction to enable any party to this Final Judgment to apply to this Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify any of its provisions, to enforce compliance, and to punish violations of its provisions. Upon notification by the United States to the Court of Morgan's payment of the funds required by Section III above, this Section IV will have no further force or effect.

V. Public Interest Determination

Entry of this Final Judgment is in the public interest. The parties have complied with the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. 16, including making copies available to the public of this Final Judgment, the Competitive Impact Statement, and any comments thereon and Plaintiff's responses to comments. Based upon the record before the Court, which includes the Competitive Impact Statement and any comments and response to comments filed with the Court, entry of this Final Judgment is in the public interest.

Dated: _____

_____

United States District Judge.

[FR Doc. 2011–26161 Filed 10–7–11; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Foreign Claims Settlement Commission

[F.C.S.C. Meeting and Hearing Notice No. 10–11]

Sunshine Act Meeting

The Foreign Claims Settlement Commission, pursuant to its regulations (45 CFR part 503.25) and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of open meetings as follows:

Monday, October 17, 2011: 10:30 a.m.—Issuance of Proposed Decisions in claims against Libya; 3 p.m.—Oral hearings on objections to Commission's Proposed Decisions in Claim Nos.LIB–II–128, LIB–II–129, LIB–II–130 and LIB–II–131.

Status: Open.

All meetings are held at the Foreign Claims Settlement Commission, 600 E Street, NW., Washington, DC. Requests for information, or advance notices of intention to observe an open meeting, may be directed to: Judith H. Lock, Executive Officer, Foreign Claims Settlement Commission, 600 E Street, NW., Suite 6002, Washington, DC 20579. *Telephone:* (202) 616–6975.

Jaleh F. Barrett,

Chief Counsel.

[FR Doc. 2011–26305 Filed 10–6–11; 4:15 pm]

BILLING CODE 4410–BA–P

DEPARTMENT OF JUSTICE

National Institute of Corrections

Advisory Board Meeting

DATES: *Time and Date:* 8 a.m. to 4:30 p.m. on Wednesday, November 2, 2011, 8 a.m. to 4:30 p.m. on Thursday, November 28, 2011.

PLACE: National Corrections Academy, 11900 East Cornell Avenue, Aurora, CO 80014, 1 (303) 338–6600.

MATTERS TO BE CONSIDERED: Important trends in corrections-related policy, program, and practices; identifying and meeting the needs of the field of corrections; Performance Based Outcomes; Director's report; Federal Partners Reports; Presentations.

CONTACT PERSON FOR MORE INFORMATION: Thomas Beauclair, Deputy Director, 202–307–3106, ext. 44254.

Morris L. Thigpen,

Director.

[FR Doc. 2011–25880 Filed 10–7–11; 8:45 am]

BILLING CODE 4410–36–M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2010–0018]

Curtis-Straus LLC; Application for Renewal of Recognition

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: This notice announces the application of Curtis-Straus LLC for renewal of its recognition as a Nationally Recognized Testing Laboratory (NRTL) and presents the Agency's preliminary finding to deny this application for renewal of NRTL recognition.

DATES: Submit information or comments, or a request to extend the comment period, on or before November 10, 2011. All submissions must bear a postmark or provide other evidence of the submission date.

ADDRESSES: Submit comments by any of the following methods:

Electronically: Submit comments electronically at *http://www.regulations.gov*, which is the Federal eRulemaking Portal. Follow the instructions online for making electronic submissions.

Fax: If submissions, including attachments, are no longer than 10 pages, commenters may fax submissions to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, or messenger or courier service: Submit one copy of the comments to the OSHA Docket Office, Docket No. OSHA–2010–0018, U.S. Department of Labor, Room N–2625, 200 Constitution Avenue, NW., Washington, DC 20210. The Docket Office accepts deliveries (hand, express mail, and messenger and courier service) during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m.—4:45 p.m., E.T.

Instructions: All submissions must include the Agency name and the OSHA docket number (*i.e.,* OSHA–2010–0018). OSHA will place all submissions, including any personal information provided, in the public docket without revision, and will make these submissions available online at *http://www.regulations.gov*.

Docket: To read or download submissions or other material in the docket (*e.g.,* exhibits listed below), go to *http://www.regulations.gov* or the OSHA Docket Office at the address above. The *http://www.regulations.gov* index lists all documents in the docket; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through the Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office.

Extension of comment period: Submit requests for an extension of the comment period on or before November 10, 2011 to the Office of Technical Programs and Coordination Activities, NRTL Program, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue, NW., Room N–3655, Washington, DC 20210, or by fax to (202) 693–1644.

FOR FURTHER INFORMATION CONTACT: Bernard Pasquet, Acting Director, Office of Technical Programs and Coordination Activities, NRTL Program, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue, NW., Room N–3655, Washington, DC 20210; *telephone:* (202) 693–2110. For information about the NRTL Program, go to *http://www.osha.gov*, and select ''N'' in the site index.

SUPPLEMENTARY INFORMATION:

I. Notice of Application for Renewal of Recognition

The Occupational Safety and Health Administration (OSHA) is providing notice that Curtis-Straus LLC (CSL) applied for renewal of its recognition as a Nationally Recognized Testing Laboratory (NRTL). (See Ex. 2—CSL renewal application dated 06/04/2004.)[1] OSHA recognition of an NRTL signifies that the organization meets the legal requirements specified in 29 CFR 1910.7. Recognition is an acknowledgment by OSHA that the organization can perform independent safety testing and certification of the specific products covered within its scope of recognition, and is not a delegation or grant of government authority. As a result of recognition, employers may use products approved by the NRTL to meet OSHA standards that require product testing and certification.

The Agency processes applications by an NRTL for initial recognition, or for an expansion or renewal of this recognition, following requirements in Appendix A to 29 CFR 1910.7. This appendix requires that the Agency publish two notices in the **Federal Register** in processing an application. In the first notice, OSHA announces the application and provides its preliminary finding. In the second notice, the Agency provides its final decision on the application. These notices set forth the NRTL's scope of recognition or modifications of that scope. OSHA maintains an informational Web page for each NRTL that details its scope of recognition. Interested parties may access these pages from OSHA's Web site at *http://www.osha.gov/dts/otpca/nrtl/index.html*. Each NRTL's scope of recognition has three elements: (1) The type of products the NRTL may test, with each type specified by its applicable test standard; (2) the recognized site(s) that has/have the technical capability to perform the product testing and certification activities for test standards within the NRTL's scope; and (3) the supplemental program(s) that the NRTL may use, each of which allows the NRTL to rely on other parties to perform activities necessary for product testing and certification.

II. General Background on the Application

A. CSL's Application

CSL applied to OSHA for its initial recognition in February 1998 when it was a limited liability company chartered in the Commonwealth of Massachusetts. After processing the application, including performing the necessary on-site assessments, OSHA announced its preliminary finding on the application in a notice published in the **Federal Register** on December 13, 1999 (64 FR 69552). Following the requisite comment period, OSHA issued a notice in the **Federal Register** on May 8, 2000, announcing its final decision to recognize CSL as an NRTL (65 FR 26637). In May of 2005, Bureau Veritas Consumer Products Services, Inc. (BVCPS) acquired CSL; Bureau Veritas Holdings, Inc. owns BVCPS; Bureau Veritas SA (BVSA) owns Bureau Veritas Holding, Inc., and Wendel Investissement (Wendel) owns BVSA. Through various intermediaries, Wendel owns 58% of CSL. As of May 2011, Wendel also owns approximately 11% of Legrand (see Ex. 10—CSL letter to OSHA dated 08/01/2011), a manufacturer of electrical products based in France. Legrand has world-wide operations in many other European countries, Canada, Mexico, various South American countries, and China, as well as other parts of Asia (see Legrand Group ''Facts and Figures,'' *http://www.legrandgroup.com/EN/2010-facts-and-figures_12506.html).*

Wendel describes itself as ''one of the most prominent listed investment companies in Europe. Its philosophy is to invest for the long term, as a majority or principal shareholder, in listed or unlisted companies with leadership positions, so as to accelerate their own growth and business development'' (*http://www.wendel-investissement.com/en/profil-strategie_uk.html*). Wendel subsequently acquired additional manufacturers, such as Campagnie Deutsche, a manufacturer of industrial and automotive electrical connectors, some of which may require NRTL certification prior to use in the workplace. Wendel has the potential to acquire additional companies that manufacture products that require NRTL testing and certification.

On June 4, 2004, CSL submitted its renewal application. On April 27, 2007, OSHA informed CSL by letter that CSL appeared not to meet the NRTL Program policy on independence under

[1] A number of documents, or information within documents, described in this **Federal Register** notice are the applicant's internal, detailed procedures, or contain other confidential business or trade-secret information. These documents and information, designated by an ''NA'' at the end of, or within, the sentence or paragraph describing them, are not available to the public.

Appendix C of the NRTL Program Directive (OSHA Instruction CPL 01–00–003–CPL 1–0.3) due to BVSA's acquisition of CSL (see Ex. 3—OSHA letter to CSL, dated 04/27/2007). In that letter, OSHA asked CSL to provide clear and convincing evidence (NRTL Program Directive, Appendix C.V, OSHA Instruction CPL 01–00–003–CPL 1–0.3) that pressures (*i.e.,* undue influences) do not exist as a result of its organizational affiliation with Legrand that could compromise CSL's NRTL testing and certification processes. CSL responded to OSHA on August 27, 2007, and supplemented this response on January 31, 2008, (see Ex. 4—CSL letter to OSHA, dated 08/27/2007, and Ex. 5—CSL letter to OSHA, dated 01/31/2008). To rebut the presumption of pressures, CSL described the ''longstanding integrity'' of BVSA and CSL, and claimed an ''attenuated'' relationship existed between CSL and Legrand. It also argued that the Compliance Committee implemented by CSL, as well as the objectivity of CSL's testing program, would mitigate any undue influence. A follow-up response from CSL received by OSHA on January 31, 2008, argued that ''firewalls'' existed to assure the independence of CSL's testing and certification processes (Ex. 5, pp. 1–4). These ''firewalls'' were measures or factors that CSL claimed will mitigate or prevent undue influence on its NRTL activities. CSL's firewalls included a separation of its board of directors from other Legrand companies, use of independent auditors, and establishment of the Compliance Committee. The letter also asserted that the presence of common executives and board members between Legrand, Wendel, and BVSA does not compromise CSL's testing and certification because ''there is no reason to believe that [the board members] would seek to cause a complex international conspiracy to compromise CSL'' (Ex. 5, p. 2).

OSHA responded to CSL on August 14, 2008 (see Ex. 6—OSHA letter to CSL, dated 08/14/2008), and reiterated the following concerns about CSL's independence: (1) The substantial relationship [2] that arises from Wendel's common ownership of both Legrand, a manufacturer, and CSL, an NRTL; (2) the common executives and board members shared between BVSA, CSL, Wendel, and Legrand; (3) how CSL will monitor Wendel's future acquisitions; (4) how CSL can warrant to OSHA that it would not test or certify either Legrand's or its competitor's products; (5) how CSL will comply with the requirements of the International Federation of Inspection Agencies (IFIA) [3] that auditors be independent of the testing organization; and (6) how CSL will ensure the personnel performing the audits have the necessary qualifications.

On February 20, 2009, CSL responded by letter (see Ex. 7—CSL letter to OSHA, dated 02/20/2009) describing its efforts to: (1) Monitor Wendel's acquisitions; (2) perform enhanced certification procedures on products manufactured by subsidiaries and other companies organizationally affiliated with Wendel; and (3) use both external and internal audits to ensure that CSL maintains its independence. CSL asserted that it would accomplish these efforts through extensive procedures it has in place to identify public Wendel subsidiaries, its conflict management procedures that require additional witnessing and review of test data on products produced by Wendel subsidiaries, audits by internal compliance officers, and IFIA membership. It also informed OSHA that it was changing its executive leadership and augmenting its board of directors with additional independent directors to dilute the potential for undue influence upon the board. However, the mutual board members shared between BVSA, Legrand, and Wendel would remain on the board. OSHA fully considered CSL's efforts to rebut the presumption of undue influence. However, on January 19, 2010, the Agency responded with a negative finding of renewal (see Ex. 8—OSHA negative finding of renewal, dated 01/19/2010). OSHA based its decision, in part, on concerns that OSHA would not be able to effectively monitor CSL's efforts, even if CSL made good-faith efforts, because of the extent and complexity of Wendel and Legrand's operations. OSHA does not have the resources or expertise to monitor all of Wendel's and Legrand's acquisitions, products, and operations.

In response to the negative finding of renewal, CSL submitted a revised application on October 18, 2010 (see Ex. 9—CSL revised renewal application, dated 10/18/2010). The revised application reiterated its commitment to objective testing, the procedures of the CSL Compliance Committee, and requirements of the external audits. CSL also proposed a temporary limitation, in which CSL would limit its testing and certification to existing customers and products. On August 1, 2011, CSL notified OSHA that Wendel reduced its ownership of Legrand from 32% to 11.1% (Ex. 10). However, as described below, the revised application and reduction in ownership fail to address the fundamental violation of the NRTL independence requirement.

B. The NRTL Independence Policy

OSHA requires NRTLs and applicants to be ''completely independent'' of the manufacturers of the equipment the NRTLs are testing (see 29 CFR 1910.7(b)(3)). This independence requirement is fundamental to the third-party testing and certification system. Early in the NRTL Program, OSHA extended the practices that two NRTLs—Underwriters Laboratories (UL) and Factory Mutual Research Corporation (FMRC)—instituted in their testing and certification programs. These practices included having no affiliations with (*i.e.,* being independent of) the manufacturers of the equipment they certified. Therefore, independence is the cornerstone of the NRTL Program, the purpose of which is to ensure that the organizations testing and certifying specified products as safe have no affiliation with the manufacturers of the products or with employers that use the products in the workplace.

The NRTL Program Directive that was in effect when CSL applied for NRTL recognition stated that, to meet the independence requirement, NRTLs and applicants ''must be free from commercial, financial and other pressures that could compromise the results of its testing and certification processes'' (see NRTL Program Policies, Procedures, and Guidelines—CPL 01–00–003—CPL 1–0.3 (NRTL Program Directive), Appendix C.V). The Directive makes it clear that NRTLs and applicants must avoid these pressures from manufacturers of equipment.

Under its independence policy, OSHA presumes that ''pressures'' exist if there is a substantial relationship between the NRTL or applicant and a manufacturer ''of products that must be certified which could compromise the objectivity and impartiality in determining the results of its testing and certification processes.'' Substantial, for purposes of the policy, ''means of such a nature and extent as to exert undue influence on the testing and certification processes.''

[2] The definition of ''substantial relationship'' includes when a major owner of a supplier of products requiring NRTL certification has an ownership interest in excess of two percent in an NRTL (see NRTL Program Policies, Procedures, and Guidelines—CPL 01–00–003–CPL 1–0.3 (NRTL Program Directive), Appendix C.V(C)).

[3] The IFIA is a trade association that represents companies involved in international testing, inspection, and certification services. It requires members to adhere to a compliance code that includes independent auditing by IFIA for compliance with IFIA standards (see ''About Us'' IFIA, *http://www.ifia-federation.org/content/about-us*).

In some limited situations, the policy allows OSHA to prescribe ''conditions'' on NRTLs or applicants for initial or continued recognition, even when the Agency determines that pressures exist. Such conditions, however, ''must be consistent with the policy,'' in that they must effectively eliminate the pressures stemming from the substantial relationship. The Directive also provides examples of options OSHA may consider when imposing conditions: (1) Restricting the suppliers for whom the NRTL or applicant may test and certify products; or (2) restricting the type of products the NRTL or applicant may test and certify.

Whether imposing conditions on an NRTL or applicant is appropriate is a judgment made by the Agency on a case-by-case basis. OSHA has discretion whether to impose conditions in a particular case. The independence policy does not *require* OSHA to impose conditions; it only *allows* OSHA to impose conditions. When organizations cannot effectively eliminate pressures stemming from a substantial relationship, then OSHA cannot impose conditions ''consistent with the policy.'' Accordingly, OSHA can impose conditions only in those rare instances when the substantial relationships cause ''minimal'' pressures.

In analyzing these situations, OSHA must carefully examine the ownership situation; the types of products at issue; the scope and magnitude of the NRTL's or applicant's operations; the scope and magnitude of the operations of the manufacturers making, and the employers using, the products; and other factors. OSHA also must consider the degree to which it can monitor the NRTL or applicant's compliance with any imposed conditions, which is a particularly important factor. OSHA typically audits NRTLs once a year to ensure they continue to meet the NRTL requirements, including the independence requirement, and to maintain the quality of their testing and certification operations. If imposing conditions on an NRTL or applicant would be difficult or impossible for OSHA to audit effectively, imposing conditions on the NRTL or applicant would not be appropriate.

OSHA believes its policy on NRTL independence is a straightforward approach for judging an NRTL's or applicant's compliance with the Agency's independence requirement under 29 CFR 1910.7. OSHA cannot perform in-depth analyses of an NRTL's or applicant's ownership or financial relationship and interests. Therefore, the NRTL or applicant has the burden of showing it is independent, and that any relationship with a manufacturer or employer involves no, or only minor, pressures.

III. General Finding of Non-Independence

A. CSL Has a ''Substantial Relationship'' With Legrand

Wendel Investissement (Wendel) owns, at least in part, both CSL and Legrand (a manufacturer). Wendel owns 58% of CSL and 11% of Legrand through various intermediaries. Legrand is a manufacturer of various products, many of which require NRTL certification if used in the workplace. Under the NRTL independence policy, this relationship constitutes a ''substantial relationship,'' in which a major owner of a supplier of products requiring NRTL certification has an ownership interest in excess of two percent in CSL, an NRTL. Because of this substantial relationship, OSHA presumes that pressures exist on CSL that could compromise the results of its testing and certification processes and that CSL, therefore, is not independent.

B. CSL Failed To Rebut the Presumption of Pressures

CSL attempted to rebut the presumption of pressures. In various letters to the Agency, CSL explained why it believes it is not subject to pressures from Wendel or Legrand that could compromise the results of its testing and certification processes. CSL stated that its relationship to Legrand is highly attenuated and that its decision making is independent of both Wendel and Legrand (Ex. 9, p. 3). To rebut the presumption of pressures, CSL also proposed that it renew temporarily only product certifications for existing customers not associated with Wendel (Ex. 9 pp. 1, 10). Finally, CSL claimed that it took a variety of steps to ensure that it will not test or certify any products made by Legrand (Ex. 9, pp. 10–12). The Agency carefully considered this information, and finds that CSL did not adequately rebut the presumption of pressures, as discussed below.

1. CSL's Independence From Legrand and Wendel

To rebut the presumption of pressure, CSL contended that ''the relationship of Legrand or other Wendel holdings is highly attenuated'' (Ex. 9, p. 3) and, as such, does not result in undue pressure on CSL. CSL argues that Wendel is a long-term investor that does not manage CSL's day-to-day operations. CSL also noted that Wendel does not exert control over CSL, therefore assuring CSL's independence from Wendel and Legrand.

CSL's assertion that Wendel does not manage, or exert control over, CSL does not address the fundamental issue regarding the control that a parent company has over a subsidiary (*e.g.,* a majority-owned subsidiary). According to the Securities and Exchange Commission, the term ''control'' in this context means the ''possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract, or otherwise'' (see 17 CFR 230.405). The parent company of a majority-owned subsidiary, in this case CSL, has ultimate control over the subsidiary, even though the parent company may delegate some of that control to the subsidiary. A parent company can exert control by changing a subsidiary's policies and leadership, and even by selling the subsidiary. Therefore, because Wendel has the power to dictate and influence CSL's actions, CSL does not have decision-making independence.

Although CSL claims an ''attenuated'' connection to Wendel, CSL did not provide any assurances that Wendel will refrain from exerting control over CSL, or pressuring CSL through Bureau Veritas. To the contrary, Wendel has a corporate policy that encourages exerting control over Bureau Veritas and CSL. Wendel's Web site states that its ''policy is to be the key or controlling shareholder in its listed or unlisted investments on a long-term and hands-on basis. It expresses this commitment by actively participating in these companies' strategic decisions, based on the principle of direct, constructive and transparent give-and-take with their managers'' (*http://www.wendel-investissement.com/en/charte-de-lactionnaire_83.html*). Furthermore, although CSL notified OSHA that Wendel reduced its percentage ownership of Legrand from 32% to 11% in 2011 (Ex. 10), CSL did not provide any assurance that this reduction in ownership eliminated Wendel's control over CSL. Furthermore, Wendel can increase its ownership interest in CSL at any time. Although OSHA could impose a condition to limit such an increase in ownership, the fundamental issue of Wendel's control over CSL would remain.

2. CSL's Organizational Relationship to Wendel and Legrand

CSL also claims that, because no member of its Board of Managers has ''significant ties'' to any of BVSA's parent companies, there is little

opportunity for these companies to exert pressures on CSL (Ex. 9, p. 18). OSHA finds that the current organizational relationship between CSL and Wendel via BVSA does not rebut the presumption of pressures. When Wendel first purchased CSL, BVSA and CSL shared two key executives (Mr. Piedelievre, who was a member of BVSA's management board, as well as CSL's chairman, and Mr. Tardan, who also was on BVSA's management board and is CSL's treasurer). To date, Wendel and BVSA share one board member. According to the Web site of Wendel and BVSA, Ernest-Antoine Seillière is the Chairman of Wendel's Supervisory Board, as well as a member of BVSA's Board of Directors (see *http://www.bureauveritas.com/wps/wcm/connect/bv_com/Group/Home/Investors/Corporate_governance* and *http://www.wendel-investissement.com/en/members_32.html*).

Furthermore, CSL asserted that individuals affiliated with Wendel and Legrand are no longer members of its Board of Managers (see Ex. 7). However, based on the information CSL provided, several BVSA-affiliated members remain on CSL's board: John Beisheim is Vice President of Acquisitions and Risk Management at BVCPS and Oliver Butler is a Senior Vice President of BVCPS (Ex. 7, p. 2). BVCPS is a subsidiary of BVSA, which is a subsidiary of Wendel. This arrangement perpetuates a direct line of communication and influence between Wendel and CSL by way of BVSA and senior officers at BVCPS. CSL provided no information to OSHA regarding the removal of members of its board who also were members of Legrand's, Wendel's, and BVSA's boards. These associations make Wendel privy to the BVSA's Board of Director's deliberations on behalf of CSL. Because of the close linkages, the potential remains for Wendel to influence CSL's testing and certification operations. Furthermore, since Wendel benefits from Legrand's success as a manufacturer of NRTL-certified products, the presumption is that pressures from Wendel could compromise CSL's testing and certification processes with regard to these Legrand products. In summary, the modifications CSL made to its Board of Managers provided little organizational separation between CSL and Wendel and, therefore, do not adequately rebut the presumption of pressures.

3. Missing Information Regarding Ownership and Subsidiaries

OSHA has concerns regarding entities that own intermediary companies between Legrand and Wendel, the companies these intermediaries own, and the business lines of these companies. The organizational chart provided by CSL on January 31, 2008 (Ex. 5; Ex. 1), fails to show the part owners of a number of these intermediaries. CSL also provided no information on the new intermediate owner of BVSA. Also missing is the name of intermediate companies owned by Wendel's subsidiaries. OSHA requested this information on August 14, 2008, but CSL repeatedly failed to provide the information required to address OSHA's concerns.

4. Temporary Limitation to Certifications

In its revised application, submitted October 18, 2010 (see Ex. 9), CSL requested that OSHA renew CSL's recognition by imposing a limitation that would restrict CSL to ''only renew existing NRTL product certifications for existing customers * * * until the matter of ownership of [CSL] is resolved to OSHA's satisfaction.'' CSL argued that this limitation would eliminate the presumption of pressure or other concerns regarding Wendel's ownership of CSL or the content of Wendel's holdings. CSL claimed that this approach would address OSHA's concerns regarding undue pressure because none of its existing customers had affiliations with Wendel. This limitation does not address OSHA's concerns adequately. The Agency must examine carefully the ownership situation; the types of products at issue; the scope and magnitude of the NRTL's and applicant's operations; the scope and magnitude of the operations of manufacturers making, and the employers using, the products; and other factors. OSHA also must consider the degree to which it can monitor NRTL compliance with such a condition.

As proposed by CSL, the limitation would be temporary and, therefore, would not resolve the ultimate independence issue. CSL would remain organizationally affiliated with Wendel, a situation in which Wendel could exert undue pressure on CSL. For instance, CSL's current NRTL certifications include testing for the standard UL 60950, which covers products made by Legrand. Under CSL's proposal, Wendel could still exert pressure on CSL to reject similar products made by Legrand's competitors.

Furthermore, CSL claimed that the proposed condition is a ''self regulating'' limitation that OSHA could audit easily. However, Wendel's operations are so vast that OSHA seriously doubts that CSL could effectively enforce the proposed condition. In this regard, Legrand is a world-wide enterprise with operations and affiliates in the U.S., Europe, Canada, Mexico, South America, China, and other Asian countries. One of these affiliates, Bticino, has operations in 60 countries. Wendel's 2007 annual report states that Legrand acquired 15 suppliers or manufacturers during the preceding three years, and the 2008 annual report describes Legrand as having a 19% market share of products and systems for electrical installations, and offering nearly 170,000 products. Moreover, CSL reports that it currently has 203 outstanding certifications distributed among 78 customers. Accordingly, it is infeasible for either OSHA or CSL to monitor every merger and acquisition of CSL's customers to ensure that none of these transactions involve a Wendel subsidiary. This infeasibility, along with the temporary status of this proposed condition, makes it an unacceptable option to resolve CSL's independence issue.

5. Corporate-Compliance Program

CSL established a compliance program that includes participation in various ethics programs, as well as formation of a Compliance Committee of CSL's Board consisting of independent managers to ''assure that there are no pressures to distort its NRTL testing and certifications'' (Ex. 9, p. 10). CSL also noted that Bureau Veritas is a member of the IFIA, which CSL claimed ''assure[s] independence with respect to * * * certifications'' as a part of the IFIA's ethical requirements (Ex. 9, p. 12). The ethical programs include both internal and external audits. Furthermore, CSL claimed that its conflict-management procedures require that it test and certify all products ''independently of all of its clients. It does not design or manufacture products that it tests or certifies'' (Ex. 9, p. 10). However, implementation of this compliance program does not rebut the presumption of pressures.

First, OSHA does not allow an NRTL to ''self certify'' its independence. Second, CSL's policy does not address the fundamental ownership conflict (*i.e.,* that Wendel still can assert control over CSL's operations). Regardless of the ethical and auditing programs in place, Wendel can revise CSL's policies and operations, including its corporate-compliance program. A corporate-compliance program will not mitigate this relationship and the control that Wendel can assert on CSL. Furthermore, as noted above, Wendel's operations are so vast that OSHA believes that CSL

cannot self regulate its independence effectively through a corporate-compliance program. Moreover, OSHA does not have the resources to audit the effectiveness of such a program because the vast scope of Wendel's and Legrand's operations, including intermediary owners of Wendel and Legrand and the subsidiary companies of these intermediary owners.

C. OSHA Cannot Impose Conditions on CSL

As described above, OSHA's independence policy permits OSHA to impose conditions only when minimal pressures exist, and the conditions are consistent with the NRTL independence requirement. The extent to which OSHA may impose conditions on a manufacturer-owned NRTL depends in part on the ownership arrangement, the scope of the NRTL's recognition, and the scope of the products manufactured.

In this case, Wendel owns a substantial share of CSL and a manufacturer, rather than a small minority interest in either organization, which would severely limit the pressure it could exert on the NRTL. Furthermore, Wendel owns and operates an enormous variety of companies. Wendel could own companies that produce numerous types of products that require NRTL certification. In such cases, OSHA cannot impose conditions on CSL that are consistent with the fundamental requirement that NRTLs be independent of ''any manufacturers or vendors of equipment or material being tested for [equipment requirements]'' (see 29 CFR 1910.7(b)(3)). In this regard, OSHA must consider whether it can reasonably monitor an NRTL's compliance with the conditions. OSHA cannot monitor reliably the various CSL and Wendel ownership relationships and affiliations with the numerous subsidiaries of Wendel. As noted earlier, the Agency's policy on independence must provide a straightforward, practical approach to determining whether an organization meets the requirement for independence. Accordingly, OSHA is not requiring its staff to analyze actual or potential business activities that could cause actual or potential conflicts and pressures. When these activities are extensive, which is the case for the world-wide operations of Legrand, this information is far beyond OSHA's auditing capabilities under the NRTL Program. In summary, OSHA cannot reasonably determine with its existing resources the extent to which Wendel-affiliated companies contribute to the sale and manufacture of products submitted to CSL for NRTL testing and certification.

D. OSHA Has a Consistent Position on Conditions

CSL contended that OSHA permitted other NRTLs in positions similar to CSL's to adopt conditions that rebut the presumption of pressures (Ex. 9, p. 6). In particular, CSL argued that OSHA permitted such conditions in the cases of Intertek Testing Services NA, Inc. (Intertek), National Technical Systems, Inc. (NTS), and Wyle Laboratories, Inc. (Wyle), and that those cases indicate that OSHA also should apply conditions in CSL's case (Ex. 9, pp. 7–9). OSHA disagrees with this argument because CSL's case differs from these other cases. As mentioned above, OSHA applies conditions only in circumstances in which minimal pressures exist, and OSHA can reasonably determine and monitor the effectiveness of the conditions, and the conditions are consistent with OSHA's independence requirement.

In the Intertek case, Intertek's parent acquired, and merged into Intertek's overall laboratory operations, a small manufacturer of laboratory test equipment, Compliance Design. Consequently, Intertek lost its independence because its parent company owned a manufacturer of equipment that needed NRTL approval. OSHA, however, imposed a condition on Intertek's recognition that effectively eliminated the pressures stemming from Intertek's relationship with Compliance Design (66 FR 29178). This condition included a no-testing policy for Compliance Design and for any other manufacturer affiliated with Intertek. Although OSHA received no information showing that Intertek or its parent owned any other manufacturing interest, the Agency imposed the broader condition as a precaution. OSHA could impose this condition because, unlike CSL's situation, Compliance Design was a small company that produced just one type of product; therefore, Intertek could enforce the no-testing policy. Because of Compliance Design's limited operations, OSHA could monitor effectively Intertek's compliance with the independence policy. As noted earlier, CSL's situation is much different than Intertek's because Wendel's and Legrand's operations involve multiple products manufactured and sold by numerous and various subsidiaries, making it impossible for OSHA to impose conditions on CSL's recognition that would mitigate all of the pressures and that OSHA could monitor reasonably and effectively.

OSHA also imposed a condition on Wyle (59 FR 37509). When OSHA granted Wyle NRTL recognition, Wyle was part of an organization with a division that manufactured and distributed electronic enclosure cabinets. As with Intertek, the condition imposed on Wyle required that Wyle not test or certify any equipment that used electronic enclosures manufactured by the affiliated division. Unlike CSL's situation, this condition was easy for Wyle and OSHA to monitor because the only product at issue was electrical enclosure cabinets.

Lastly, OSHA imposed conditions on NTS (63 FR 68306). NTS was a public company that ''could conceivably perform the design and engineering services * * * for manufacturers or vendors of the products covered within the scope of the test standards for which OSHA has recognized NTS'' (63 FR 68306). Because NTS is a public company, OSHA had a concern that manufacturers or vendors could acquire ownership of NTS. Accordingly, OSHA imposed a condition on NTS that restricted it from testing and certifying products for a client to which it sells design or similar services. OSHA also required NTS to provide OSHA an opportunity to review NTS's NRTL Quality Manual, Quality Assurance Procedures, and other procedures within 30 days of certifying its first products under the NRTL Program (63 FR 68306, 68309). OSHA imposed these conditions only as a preemptive measure because there was no evidence in the record that any manufacturers or vendors owned NTS, or that NTS was providing design and engineering services to manufacturers or vendors. However, this is not the case for CSL, in which a manufacturer's direct ownership interest and the potential for indirect affiliation with numerous other manufacturers and vendors, results in a presumption of pressure that violates the NRTL independence policy.

Thus, OSHA's determination regarding the imposition of conditions on CSL's NRTL recognition is consistent with the Agency's previous actions on this issue. Although OSHA provided CSL with several opportunities to rebut the presumption of pressures, CSL did not meet its burden of demonstrating by clear and convincing evidence that pressures do not, and will not, exist that could compromise the results of its testing and certification process.

IV. Request for Renewal of Recognition

CSL seeks renewal of its recognition for the one site that OSHA previously recognized. CSL also is requesting that OSHA renew its recognition to use the

following five test standards for testing and certification of products: UL 544 Electric Medical and Dental Equipment; UL 60601–1 Medical Electrical Equipment, Part 1: General Requirements for Safety; UL 60950 Information Technology Equipment; UL 61010A–1 Electrical Equipment for Laboratory Use, Part 1: General Requirements; and UL 61010B–1 Electrical Measuring and Test Equipment, Part 1: General Requirements.[4]

V. Preliminary Finding

Following a thorough review of the application file and other pertinent information, and for the reasons stated above, OSHA determined that CSL does not meet all of the requirements for renewal of its NRTL recognition. The NRTL Program staff, therefore, recommends preliminarily that the Assistant Secretary deny CSL's application for renewal of its NRTL recognition.

OSHA welcomes public comment as to whether CSL meets the requirements of 29 CFR 1910.7 for renewal of its recognition as an NRTL. Comments should consist of pertinent written documents and exhibits. Commenters needing more time to comment must submit a request in writing, stating the reasons for the request. OSHA must receive the written request for an extension by the due date for comments (see **DATES** above). OSHA will limit any extension to 30 days unless the requester justifies a longer period. OSHA may deny a request for an extension if the requester does not adequately justify it. To obtain or review copies of the publicly available information in CSL's application and other pertinent documents (including exhibits), and all submitted comments, contact the Docket Office, Room N–2625, Occupational Safety and Health Administration, U.S. Department of Labor, at the address listed above under **ADDRESSES**; these materials also are available online at *http://www.regulations.gov* under Docket No. OSHA–2010–0018.

The NRTL Program staff will review all comments submitted to the docket in a timely manner, and, after addressing the issues raised by the comments, will recommend whether to grant the renewal of NRTL recognition to CSL. The Assistant Secretary will make the final decision on granting NRTL recognition, and, in making this decision, may undertake other proceedings prescribed in Appendix A to 29 CFR 1910.7. OSHA will publish a public notice of this final decision in the **Federal Register**.

Authority and Signature

David Michaels, PhD, MPH, Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue, NW., Washington, DC 20210, authorized the preparation of this notice. Accordingly, the Agency is issuing this notice pursuant to Sections 6(b) and 8(g) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655 and 657), Secretary of Labor's Order No. 4–2010 (75 FR 55355), and 29 CFR 1911.

Signed at Washington, DC on October 4, 2011.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2011–26067 Filed 10–7–11; 8:45 am]

BILLING CODE 4510–26–P

[4] Each of these standards is an ''appropriate test standard'' within the meaning of 29 CFR 1910.7(c). The designations and titles of these test standards were current when OSHA prepared this notice.

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Nixon Presidential Historical Materials: Opening of Materials

AGENCY: National Archives and Records Administration.

ACTION: Notice of opening of additional materials.

SUMMARY: This notice announces the opening of Nixon Presidential Historical Materials by the Richard Nixon Presidential Library and Museum, a division of the National Archives and Records Administration. Notice is hereby given that the Agency has identified, inventoried, and prepared for public access additional textual materials and sound recordings from among the Nixon Presidential Historical Materials. Furthermore, in response to the July 29, 2011, court order in the case of *In Re Petition of Stanley Kutler, et al.,* the National Archives and Records Administration (NARA) will be separately opening the transcript of President Richard M. Nixon's grand jury testimony of June 23–24, 1975, and associated materials from Record Group 460, Records of the Watergate Special Prosecution Force (WSPF); with certain information redacted as required by law, including the PRMPA. The materials associated with President Nixon's grand jury testimony include segments of five transcripts of Nixon White House taped conversations recorded in May 1971, October 1971 and April 1973 that were previously withheld under the PRMPA when the WSPF transcripts were released in June 1991. Those segments, which no longer need to be withheld, will also be released on November 10, 2011 at the National Archives at College Park, Maryland, as well as at the Nixon Library in Yorba Linda, California.

DATES: The Richard Nixon Presidential Library and Museum intends to make the materials described in this notice available to the public on Thursday, November 10, 2011, at the Richard Nixon Library and Museum's primary location in Yorba Linda, California, beginning at 9 a.m. P.S.T./12 p.m. E.S.T. In accordance with 36 CFR 1275.44, any person who believes it necessary to file a claim of legal right or privilege concerning access to Nixon Presidential Historical Materials must notify the Archivist of the United States in writing of the claimed right, privilege, or defense within 30 days of the publication of this notice. The formerly redacted segments of the WSPF tape transcripts associated with the grand jury testimony of President Nixon will be made available to the public in the research room of the National Archives at College Park, located at 8601 Adelphi Road, College Park, Maryland, beginning at 12 p.m. E.S.T.

ADDRESSES: The Richard Nixon Presidential Library and Museum, a division of the National Archives, is located at 18001 Yorba Linda Boulevard., Yorba Linda, California. The National Archives at College Park is located at 8601 Adelphi Road, College Park, Maryland. Researchers must have a NARA researcher card, which they may obtain when they arrive at either facility. Selections from the materials described in paragraphs 1 through 5 of this notice will be available at *http://www.nixonlibrary.gov.* The transcript of President Nixon's grand jury testimony and associated materials, which include the formerly redacted segments of the WSPF tape transcripts, will be available at *http://www.archives.gov.* Petitions asserting a legal or constitutional right or privilege that would prevent or limit public access to Nixon Presidential Historical Materials must be sent to the Archivist of the United States, National Archives at College Park, 8601 Adelphi Road., College Park, Maryland 20740–6001.

FOR FURTHER INFORMATION CONTACT: Timothy Naftali, Director, Richard Nixon Presidential Library and Museum, 714–983–9120.

SUPPLEMENTARY INFORMATION: In accordance with section 104 of Title I of the Presidential Recordings and Materials Preservation Act (PRMPA, 44 U.S.C. 2111 note) and 1275.42(b) of the PRMPA Regulations implementing the

Act (36 CFR part 1275), NARA has identified, inventoried, and prepared for public access additional textual materials and sound recordings from among the Nixon Presidential Historical Materials.

The following materials will be made available in accordance with this notice:

1. Previously restricted textual materials. *Volume:* 1 cubic foot. A number of textual materials previously withheld from public access have been reviewed for release and/or declassified under the systematic declassification review provisions and under the mandatory review provisions of Executive Order 13526, the Freedom of Information Act (5 U.S.C. 552), or in accordance with 36 CFR 1275 (Public Access regulations). The materials are from integral file segments for the National Security Council (NSC Files and NSC Institutional Files); the Henry A. Kissinger (HAK) Office Files, including HAK telephone conversation transcripts; White House Special Files, Staff Member and Office Files, John D. Ehrlichman; and White House Central Files, Staff Member and Office Files, Anne L. Armstrong.

2. White House Central Files, Staff Member and Office Files. *Volume:* 18 cubic feet. The White House Central Files Unit was a permanent organization within the White House complex that maintained a central filing and retrieval system for the records of the President and his staff. The Staff Member and Office Files consist of materials that were transferred to the Central Files but were not incorporated into the Subject Files. The following file groups will be made available: Kenneth Cole (Accretion).

3. White House Central Files, Name Files: *Volume:* <1 cubic foot. The Name Files were used for routine materials filed alphabetically by the name of the correspondent; copies of documents in the Name Files were usually filed by subject in the Subject Files. The following Name Files folders will be made available: Burroughs, U–Z; Silberman, Laurence.

4. White House Special Files, Staff Member and Office Files. Volume: <60 minutes of audio recordings from the following collections: President's Personal File (PPF).

5. Record Group 460, Records of the Watergate Special Prosecution Force (WSPF). *Volume:* <1 cubic foot. The segments of five transcripts of White House taped conversations from 1971 and 1973, which are part of the materials associated with President Richard M. Nixon's June 23–24, 1975 grand jury testimony, were formerly redacted as required by law, including the PRMPA.

Dated: October 5, 2011.

David Ferriero,

Archivist of the United States.

[FR Doc. 2011–26165 Filed 10–7–11; 8:45 am]

BILLING CODE 7515–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 70–7021; NRC–2011–0232]

Notice of Acceptance of Application for Special Nuclear Materials Licensen From Rapiscan Laboratories, Inc., Opportunity To Request a Hearing, and Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information for Contention Preparation

AGENCY: Nuclear Regulatory Commission.

ACTION: License application; opportunity for hearing and order.

DATES: Requests for a hearing or Leave to Intervene must be filed by December 12, 2011. Any potential party as defined in Title 10 of the *Code of Federal Regulations* (10 CFR) 2.4 who believes access to SUNSI information is necessary to respond to this notice must request document access by October 21, 2011.

ADDRESSES: You can access publicly available documents related to this document using the following methods:

- *NRC's Public Document Room (PDR):* The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* Publicly available documents created or received at the NRC are available online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* From this page, the public can gain entry into ADAMS, which provides text and image files of the NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr.resource@nrc.gov.*
- *Federal Rulemaking Web Site:* Public comments and supporting materials related to this final rule can be found at *http://www.regulations.gov* by searching on Docket ID NRC–2011–0232. Address questions about NRC dockets to Carol Gallagher, *telephone:* 301–492–3668; *e-mail: Carol.Gallagher@nrc.gov.*

FOR FURTHER INFORMATION CONTACT: Marilyn Diaz, Project Manager, Fuel Manufacturing Branch, Division of Fuel Cycle Safety and Safeguards, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Mailstop: EBB2–C40M, Rockville, Maryland 20852; *telephone:* 301–492–3172; *e-mail: Marilyn.Diaz@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC has accepted for detailed technical review an application for a new license for the possession and use of special nuclear material (SNM) for performance testing of radiation detection systems for locating SNM, under a project sponsored by the Domestic Nuclear Detection Office (DNDO) of the U.S. Department of Homeland Security (DHS). Rapiscan Laboratories, Inc. (the Applicant) requested the new license for a period of 10 years. This license application, if approved, would authorize the Applicant to possess and use special nuclear materials under 10 CFR Part 70, ''Domestic Licensing of Special Nuclear Material.''

II. Discussion

In its application, dated October 22, 2010, the Applicant requested a license to possess and use SNM to conduct tests of new technology for use in detection systems. The SNM would be used as test objects for concept demonstrations and characterization testing. Following an administrative review, the NRC requested the Applicant to revise its application to include elements essential to conducting a detailed technical review. The Applicant submitted a revised license application, dated February 9, 2011, and supplemental information on March 10, 2011. By letter dated March 10, 2011, the NRC staff found the revised license application acceptable to begin a detailed technical review. The application has been docketed in Docket No. 70–7021.

If the NRC approves the license application, the basis for approval will be documented in a Safety Evaluation Report (SER) supporting the issuance of a new NRC license. The SER would contain the findings required by the Atomic Energy Act of 1954, as amended (the Act), and the NRC's regulations, for issuing an SNM license. The SER would also include a determination of the need to complete an environmental

assessment based on the proposed action.

III. Opportunity To Request a Hearing

Requirements for submitting hearing requests and petitions for Leave to Intervene are found in 10 CFR 2.309, ''Hearing Requests, Petitions to Intervene, Requirements for Standing, and Contentions.'' Interested persons should consult 10 CFR Part 2, Section 2.309, which is available at the NRC's PDR, located at One White Flint North, 11555 Rockville Pike, O1–F21, Rockville, MD 20852. You may also call the PDR at 1–800–397–4209 or 301–415–4737. The NRC regulations are also accessible electronically from the NRC's Web site at *http://www.nrc.gov.*

Any person whose interest may be affected by this proceeding, and who desires to participate as a party in the proceeding must file a written petition for Leave to Intervene. As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding and how that interest may be affected by the results of the proceeding. The petition must provide the name, address, and telephone number of the petitioner; and specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order that may be entered in the proceeding on the petitioner's interest.

A petition for Leave to Intervene must also include a specification of the contentions that the petitioner seeks to have litigated in the hearing. For each contention, the petitioner must provide a specific statement of the issue of law or fact to be raised or controverted, as well as a brief explanation of the basis for the contention. Additionally, the petitioner must demonstrate that the issue raised by each contention is within the scope of the proceeding, and is material to the findings that the NRC must make to support the granting of a license in response to the application. The petition must also include a concise statement of the alleged facts or expert opinions which support the position of the petitioner, and on which the petitioner intends to rely at the Hearing—together with references to the specific sources and documents on which the petitioner intends to rely. Finally, the petition must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact, including references to specific portions of the license application that the petitioner disputes and the supporting reasons for each dispute, or, if the petitioner believes that the license application fails to contain information on a relevant matter as required by law, the identification of each failure, and the supporting reasons for the petitioner's belief. Each contention must be one that, if proven, would entitle the petitioner to relief.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting Leave to Intervene, and have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that person's admitted contentions, including the opportunity to present evidence and to submit a cross-examination plan for cross-examination of witnesses, consistent with the NRC's regulations, policies, and procedures. The Atomic Safety and Licensing Board (the Licensing Board) will set the time and place for any pre-hearing conferences and evidentiary hearings, and the appropriate notices will be provided.

Petitions for leave to intervene must be submitted no later than 60 days from October 11, 2011. Non-timely petitions for Leave to Intervene and contentions, amended petitions, and supplemental petitions will not be entertained, absent a determination by the Commission, the Licensing Board or a Presiding Officer that the petition should be granted and/or the contentions should be admitted based upon a balancing of the factors specified in 10 CFR 2.309(c)(1)(i)–(viii).

A State, county, municipality, Federally recognized Indian Tribe, or agencies thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(d)(2). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission by December 12, 2011. The petition must be filed in accordance with the filing instructions in Section IV of this document, and should meet the requirements for petitions for Leave to Intervene set forth in this section, except that State and Federally recognized Indian tribes do not need to address the standing requirements in 10 CFR 2.309(d)(1) if the facility is located within its boundaries. The entities listed above could also seek to participate in a hearing as a non-party, pursuant to 10 CFR 2.315(c).

Any person who does not wish, or is not qualified, to become a party to this proceeding may request permission to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of position on the issues, but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any pre-hearing conference, subject to such limits and conditions as may be imposed by the Licensing Board. Persons desiring to make a limited appearance are requested to inform the Secretary of the Commission by December 12, 2011.

IV. Electronic Submissions (E-Filing)

All documents filed in NRC's adjudicatory proceedings, including a request for hearing, a petition for Leave to Intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and any document filed by interested Governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC E-Filing rule (72 FR 49139, August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the Internet—or in some cases, to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the petitioner/requestor should contact the Office of the Secretary by e-mail at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to request: (1) A digital ID certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the petitioner/requestor, or its counsel or representative, already holds an NRC-issued digital ID certificate.) Based on this information, the Secretary will establish an electronic docket for the hearing in this proceeding, if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/apply-certificates.html.* System requirements for accessing the E-Submittal server are detailed in NRC's,

''Guidance for Electronic Submission,'' which is available on the agency's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software; and the NRC's Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a petitioner/requestor has obtained a digital ID certificate and a docket has been created, the petitioner/requestor can then submit a request for hearing or petition for Leave to Intervene. Submissions should be in Portable Document Format (PDF) in accordance with the NRC's guidance available on the NRC public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the filer submits its documents through EIE. To be timely, an electronic filing must be submitted to the EIE system no later than 11:59 p.m., Eastern Standard Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The EIE system also distributes an e-mail notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a Hearing Request/Petition to Intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the agency's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the ''Contact Us'' link located on the NRC Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by e-mail at*MSHD.Resource@nrc.gov,* or by calling 800–672–7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m. Eastern Standard Time, Monday through Friday, excluding Federal holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file a motion, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First-class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, 16th Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, *Attention:* Rulemakings and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket, which is available to the public at *http://ehd1.nrc.gov/EHD/,* unless excluded pursuant to an order of the Commission or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home telephone numbers in their filings, unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information for Contention Preparation

A. This Order contains instructions regarding how potential parties to this proceeding may request access to documents containing Sensitive Unclassified Non-Safeguards Information (SUNSI).

B. Within 10 days after publication of this notice of hearing and opportunity to petition for leave to intervene, any potential party who believes access to SUNSI is necessary to respond to this notice may request such access. A ''potential party'' is any person who intends to participate as a party by demonstrating standing and filing an admissible contention under 10 CFR 2.309. Requests for access to SUNSI submitted later than 10 days after publication will not be considered absent a showing of good cause for the late filing, addressing why the request could not have been filed earlier.

C. The requester shall submit a letter requesting permission to access SUNSI to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, *Attention:* Rulemakings and Adjudications Staff, and provide a copy to the Associate General Counsel for Hearings, Enforcement and Administration, Office of the General Counsel, Washington, DC 20555–0001. The expedited delivery or courier mail address for both offices is: U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852. The e-mail address for the Office of the Secretary and the Office of the General Counsel are *Hearing.Docket@nrc.gov* and *OGCmailcenter@nrc.gov,* respectively.[1] The request must include the following information:

(1) A description of the licensing action with a citation to this Federal Register notice;

(2) The name and address of the potential party and a description of the potential party's particularized interest that could be harmed by the action identified in C.(1);

(3) The identity of the individual or entity requesting access to SUNSI and the requester's basis for the need for the information in order to meaningfully participate in this adjudicatory proceeding. In particular, the request must explain why publicly-available versions of the information requested would not be sufficient to provide the basis and specificity for a proffered contention;

D. Based on an evaluation of the information submitted under paragraph C.(3) the NRC staff will determine within 10 days of receipt of the request whether:

(1) There is a reasonable basis to believe the petitioner is likely to

[1] While a request for hearing or petition to intervene in this proceeding must comply with the filing requirements of the NRC's ''E-Filing Rule,'' the initial request to access SUNSI under these procedures should be submitted as described in this paragraph.

establish standing to participate in this NRC proceeding; and

(2) The requestor has established a legitimate need for access to SUNSI.

E. If the NRC staff determines that the requestor satisfies both D.(1) and D.(2) above, the NRC staff will notify the requestor in writing that access to SUNSI has been granted. The written notification will contain instructions on how the requestor may obtain copies of the requested documents, and any other conditions that may apply to access to those documents. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order [2] setting forth terms and conditions to prevent the unauthorized or inadvertent disclosure of SUNSI by each individual who will be granted access to SUNSI.

F. Filing of Contentions. Any contentions in these proceedings that are based upon the information received as a result of the request made for SUNSI must be filed by the requestor no later than 25 days after the requestor is granted access to that information. However, if more than 25 days remain between the date the petitioner is granted access to the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.

G. Review of Denials of Access.

(1) If the request for access to SUNSI is denied by the NRC staff either after a determination on standing and need for access, or after a determination on trustworthiness and reliability, the NRC staff shall immediately notify the requestor in writing, briefly stating the reason or reasons for the denial.

(2) The requester may challenge the NRC staff's adverse determination by filing a challenge within 5 days of receipt of that determination with: (a) The presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an administrative law judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) if another officer has been designated to rule on information access issues, with that officer.

H. Review of Grants of Access. A party other than the requester may challenge an NRC staff determination granting access to SUNSI whose release would harm that party's interest independent of the proceeding. Such a challenge must be filed with the Chief Administrative Judge within 5 days of the notification by the NRC staff of its grant of access.

If challenges to the NRC staff determinations are filed, these procedures give way to the normal process for litigating disputes concerning access to information. The availability of interlocutory review by the Commission of orders ruling on such NRC staff determinations (whether granting or denying access) is governed by 10 CFR 2.311.[3]

I. The Commission expects that the NRC staff and presiding officers (and any other reviewing officers) will consider and resolve requests for access to SUNSI, and motions for protective orders, in a timely fashion in order to minimize any unnecessary delays in identifying those petitioners who have standing and who have propounded contentions meeting the specificity and basis requirements in 10 CFR part 2. Attachment 1 to this Order summarizes the general target schedule for processing and resolving requests under these procedures.

It Is So Ordered.

Dated at Rockville, Maryland, this 4th day of October, 2011.

For the Commission.

Annette L. Vietti-Cook.

Secretary of the Commission.

ATTACHMENT 1—GENERAL TARGET SCHEDULE FOR PROCESSING AND RESOLVING REQUESTS FOR ACCESS TO SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION IN THIS PROCEEDING

Day	Event/activity
0	Publication of **Federal Register** notice of hearing and opportunity to petition for leave to intervene, including order with instructions for access requests.
10	Deadline for submitting requests for access to Sensitive Unclassified Non-Safeguards Information (SUNSI) with information: Supporting the standing of a potential party identified by name and address; describing the need for the information in order for the potential party to participate meaningfully in an adjudicatory proceeding.
60	Deadline for submitting petition for intervention containing: (i) Demonstration of standing; (ii) all contentions whose formulation does not require access to SUNSI (+25 Answers to petition for intervention; +7 petitioner/requestor reply).
20	Nuclear Regulatory Commission (NRC) staff informs the requester of the staff's determination whether the request for access provides a reasonable basis to believe standing can be established and shows need for SUNSI. (NRC staff also informs any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information.) If NRC staff makes the finding of need for SUNSI and likelihood of standing, NRC staff begins document processing (preparation of redactions or review of redacted documents).
25	If NRC staff finds no "need" or no likelihood of standing, the deadline for petitioner/requester to file a motion seeking a ruling to reverse the NRC staff's denial of access; NRC staff files copy of access determination with the presiding officer (or Chief Administrative Judge or other designated officer, as appropriate). If NRC staff finds "need" for SUNSI, the deadline for any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information to file a motion seeking a ruling to reverse the NRC staff's grant of access.
30	Deadline for NRC staff reply to motions to reverse NRC staff determination(s).
40	(Receipt +30) If NRC staff finds standing and need for SUNSI, deadline for NRC staff to complete information processing and file motion for Protective Order and draft Non-Disclosure Affidavit. Deadline for applicant/licensee to file Non-Disclosure Agreement for SUNSI.
A	If access granted: Issuance of presiding officer or other designated officer decision on motion for protective order for access to sensitive information (including schedule for providing access and submission of contentions) or decision reversing a final adverse determination by the NRC staff.
A + 3	Deadline for filing executed Non-Disclosure Affidavits. Access provided to SUNSI consistent with decision issuing the protective order.

[2] Any motion for Protective Order or draft Non-Disclosure Affidavit or Agreement for SUNSI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 30 days of the deadline for the receipt of the written access request.

[3] Requesters should note that the filing requirements of the NRC's E–Filing Rule (72 FR 49139; August 28, 2007) apply to appeals of NRC staff determinations (because they must be served on a presiding officer or the Commission, as applicable), but not to the initial SUNSI request submitted to the NRC staff under these procedures.

ATTACHMENT 1—GENERAL TARGET SCHEDULE FOR PROCESSING AND RESOLVING REQUESTS FOR ACCESS TO SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION IN THIS PROCEEDING—Continued

Day	Event/activity
A + 28	Deadline for submission of contentions whose development depends upon access to SUNSI. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.
A + 53	(Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI.
A + 60	(Answer receipt +7) Petitioner/Intervenor reply to answers.
>A + 60	Decision on contention admission.

[FR Doc. 2011–26172 Filed 10–7–11; 8:45 am]
BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–498 and 50–499; NRC–2011–0238]

STP Nuclear Operating Company, South Texas Project, Units 1 and 2; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of an exemption from Title 10 of the *Code of Federal Regulations* (10 CFR), part 50, Section 50.46 ''Acceptance criteria for emergency core cooling systems [ECCSs] for light-water nuclear power reactors,'' and Appendix K to 10 CFR Part 50, ''ECCS Evaluation Models,'' to allow the use of Optimized ZIRLO™ fuel rod cladding in future core reload applications for South Texas Project (STP), Units 1 and 2, Facility Operating License Nos. NPF–76 and NPF–80, respectively, issued to STP Nuclear Operating Company (the licensee) for operation of STP, Units 1 and 2, located Matagorda County, Texas. Therefore, as required by 10 CFR 51.21, the NRC is issuing this environmental assessment and finding of no significant impact.

Environmental Assessment

Identification of the Proposed Action:

The proposed action would issue an exemption from Section 50.46 and Appendix K to 10 CFR 50, regarding fuel cladding material, and revise the Technical Specifications document, which is part of the Facility Operating Licenses for STP, Units 1 and 2, to permit use of Optimized ZIRLO™ fuel. The NRC staff has previously issued an exemption to STP, Units 1 and 2, to allow use of up to eight lead test assemblies (LTAs) containing fuel rods with Optimized ZIRLO™ cladding (69 FR 64113; November 3, 2004). Westinghouse has provided the NRC staff with information related to test data and models for the LTAs. LTA measured data and favorable results from visual examinations of once, twice, and thrice-burned LTAs confirm, for three cycles of operation, that the current performance models are applicable for Optimized ZIRLO™ clad fuel rods. The purpose of this exemption request is to allow fuel rods with Optimized ZIRLO™ cladding to be used in future core reloads for STP, Units 1 and 2.

The proposed action is in accordance with the licensee's application dated December 21, 2010, which is publicly available in the Agencywide Documents Access and Management System (ADAMS) under Accession No. ML103630408.

The Need for the Proposed Action:

The proposed action is needed because the regulation in 10 CFR 50.46 contains acceptance criteria for the ECCS for reactors that have fuel rods clad either with Zircaloy or ZIRLO. Appendix K to 10 CFR part 50, paragraph I.A.5, requires the Baker-Just equation to be used to predict the rates of energy release, hydrogen concentration, and cladding oxidation for the metal-water reaction. The Baker-Just equation assumed the use of a zirconium alloy different than Optimized ZIRLO™; therefore, an exemption is required.

Environmental Impacts of the Proposed Action:

The NRC has completed its evaluation of the proposed action and concludes that the exemption does not present undue risk to public health and safety, and is consistent with common defense and security.

The proposed action will not significantly increase the probability or consequences of accidents. No changes are being made in the types of effluents that may be released offsite. There is no significant increase in the amount of any effluent released offsite. There is no significant increase in occupational or public radiation exposure. Therefore, there are no significant radiological environmental impacts associated with the proposed action.

Based on the nature of the exemption, the proposed action does not result in changes to land use or water use, or result in changes to the quality or quantity of non-radiological effluents. No changes to the National Pollution Discharge Elimination System permit are needed. No effects on the aquatic or terrestrial habitat in the vicinity of the plant, or to threatened, endangered, or protected species under the Endangered Species Act, or impacts to essential fish habitat covered by the Magnuson-Stevens Act are expected. There are no impacts to the air or ambient air quality. There are no impacts to historic and cultural resources. There would be no noticeable effect on socioeconomic conditions in the region.

Accordingly, the NRC concludes that there are no significant environmental impacts associated with the proposed action.

Environmental Impacts of the Alternatives to the Proposed Action:

As an alternative to the proposed action, the NRC staff considered denial of the proposed actions (*i.e.,* the ''no-action'' alternative). Denial of the application would result in no change in current environmental impacts. Thus, the environmental impacts of the proposed actions and the alternative action are similar.

Alternative Use of Resources:

The action does not involve the use of any different resources than those previously considered in the Final Environmental Statement for the STP, Units 1 and 2, NUREG–1171, dated August 1986.

Agencies and Persons Consulted:

In accordance with its stated policy, on September 1, 2011, the staff consulted with the Texas State official regarding the environmental impact of the proposed action. The State official had no comments.

Finding of No Significant Impact

On the basis of the environmental assessment, the NRC concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the NRC has determined not to prepare an environmental impact statement for the proposed action.

For further details with respect to the proposed action, see the licensee's letter dated December 21, 2010. Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room (PDR), located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available documents created or received at the NRC are accessible electronically through ADAMS in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html*. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC PDR Reference staff by telephone at 1–800–397–4209 or 301–415–4737, or send an e-mail to *pdr.resource@nrc.gov.*

Dated at Rockville, Maryland, this 4th day of October 2011.

For the Nuclear Regulatory Commission.

Balwant K. Singal,

Senior Project Manager, Plant Licensing Branch IV, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2011–26181 Filed 10–7–11; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2011–0226]

Notice; Applications and Amendments to Facility Operating Licenses Involving Proposed No Significant Hazards Considerations and Containing Sensitive Unclassified Non-Safeguards Information and Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of license amendment request, opportunity to comment, opportunity to request a hearing.

DATES: Comments must be filed by November 10, 2011. A request for a hearing must be filed by December 12, 2011. Any potential party as defined in Title 10 of the Code of Federal Regulations (10 CFR) 2.4 who believes access to Sensitive Unclassified Non-Safeguards Information is necessary to respond to this notice must request document access by October 21, 2011.

ADDRESSES: Please include Docket ID NRC–2011–0226 in the subject line of your comments. For additional instructions on submitting comments and instructions on accessing documents related to this action, see ''Submitting Comments and Accessing Information'' in the **SUPPLEMENTARY INFORMATION** section of this document. You may submit comments by any one of the following methods:

- *Federal Rulemaking Web Site:* Go to *http://www.regulations.gov* and search for documents filed under Docket ID NRC–2011–0226. Address questions about NRC dockets to Carol Gallagher, telephone: 301–492–3668; e-mail: *Carol.Gallagher@nrc.gov.*
- *Mail comments to:* Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Office of Administration, Mail Stop: TWB–05–B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.
- *Fax comments to:* RADB at 301–492–3446.

SUPPLEMENTARY INFORMATION:

Submitting Comments and Accessing Information

Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal rulemaking Web site, *http://www.regulations.gov.* Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed.

The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed.

You can access publicly available documents related to this document using the following methods:

- *NRC's Public Document Room (PDR):* The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* Publicly available documents created or received at the NRC are available online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* From this page, the public can gain entry into ADAMS, which provides text and image files of the NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr.resource@nrc.gov.*
- *Federal Rulemaking Web Site:* Public comments and supporting materials related to this notice can be found at *http://www.regulations.gov* by searching on Docket ID NRC–2011–0226.

Background

Pursuant to section 189a.(2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (NRC or the Commission) is publishing this notice. The Act requires the Commission publish notice of any amendments issued, or proposed to be issued and grants the Commission the authority to issue and make immediately effective any amendment to an operating license upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This notice includes notices of amendments containing sensitive unclassified non-safeguards information (SUNSI).

Notice of Consideration of Issuance of Amendments to Facility Operating Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment

involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example in derating or shutdown of the facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish in the Federal Register a notice of issuance. Should the Commission make a final No Significant Hazards Consideration Determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

Within 60 days after the date of publication of this notice, any person(s) whose interest may be affected by this action may file a request for a hearing and a petition to intervene with respect to issuance of the amendment to the subject facility operating license. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10 CFR part 2. Interested person(s) should consult a current copy of 10 CFR 2.309, which is available at the Commission's PDR, located at One White Flint North, Public File Area O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland. The NRC regulations are accessible electronically from the NRC Library on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.* If a request for a hearing or petition for leave to intervene is filed within 60 days, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also set forth the specific contentions which the requestor/petitioner seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the requestor/petitioner shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the requestor/petitioner intends to rely in proving the contention at the hearing. The requestor/petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the requestor/petitioner intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the requestor/petitioner to relief. A requestor/petitioner who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing.

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC E-Filing rule (72 FR 49139, August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten (10) days prior to the filing deadline, the participant should contact the Office of the Secretary by e-mail at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to request (1) a digital ID certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E–Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/apply-certificates.html.* System requirements for accessing the E-Submittal server are detailed in NRC's ''Guidance for Electronic Submission,'' which is available on the agency's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve

documents through EIE, users will be required to install a Web browser plug-in from the NRC Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The E-Filing system also distributes an e-mail notice that provides access to the document to the NRC Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the agency's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the ''Contact Us'' link located on the NRC Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by e-mail at *MSHD.Resource@nrc.gov,* or by a toll-free call at 866–672–7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket which is available to the public at *http://ehd1.nrc.gov/EHD/,* unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

Petitions for leave to intervene must be filed no later than 60 days from the date of publication of this notice. Non-timely filings will not be entertained absent a determination by the presiding officer that the petition or request should be granted or the contentions should be admitted, based on a balancing of the factors specified in 10 CFR 2.309(c)(1)(i)–(viii).

South Carolina Electric & Gas Company, South Carolina Public Service Authority, Docket No. 50–395, Virgil C. Summer Nuclear Station, Unit No. 1, Fairfield County, South Carolina

Date of amendment request: August 11, 2011.

Description of amendment request: This amendment request contains sensitive unclassified non-safeguards information (SUNSI). The proposed change would revise the Technical Specifications to allow the use of updated core monitoring methodology including the use of the three-dimensional Advanced Nodal Code (ANC) neutronic model.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The Technical Specification change represents a change in approved methodology. The change has no impact on the probability of occurrence or consequences of any design basis accident. The change in approved methodology does not involve any alterations to plant equipment or procedures which would affect any operational modes or accident precursors.

Therefore, the change has no effect on the probability of occurrence of previously evaluated accidents and has no effect on the consequences of previously evaluated accidents.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The Technical Specifications changes represent a change in approved methodology and will not create the possibility of a new or different type of accident from any accident previously evaluated. All design and performance criteria will continue to be met and no new single-failure mechanisms will be created. The change in methodology does not involve any alterations to plant equipment or procedures which would introduce any new or unique operational modes or accidents precursors.

Therefore, a new or different type of accident from any accident previously evaluated is not created.

3. Does the proposed change involve a significant reduction in the margin of safety?

Response: No.

The change in methodology does not change the proposed reload design or safety analysis limits for each cycle reload core. The associated margin of safety will be specifically evaluated using approved reload design methods. Since the safety analysis limits are unaffected, and cycle specific analyses will show that the analysis limits are met, the change in methodology will have no impact on the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: J. Hagood Hamilton, Jr., South Carolina Electric & Gas Company, Post Office Box 764, Columbia, South Carolina 29218.

NRC Branch Chief: Gloria Kulesa

Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information for Contention Preparation.

South Carolina Electric & Gas Company, South Carolina Public Service Authority, Docket No. 50–395, Virgil C. Summer Nuclear Station, Unit No. 1, Fairfield County, South Carolina

A. This Order contains instructions regarding how potential parties to this proceeding may request access to documents containing Sensitive Unclassified Non-Safeguards Information (SUNSI).

B. Within 10 days after publication of this notice of hearing and opportunity to petition for leave to intervene, any potential party who believes access to SUNSI is necessary to respond to this notice may request such access. A ''potential party'' is any person who intends to participate as a party by demonstrating standing and filing an admissible contention under 10 CFR 2.309. Requests for access to SUNSI submitted later than 10 days after publication will not be considered absent a showing of good cause for the late filing, addressing why the request could not have been filed earlier.

C. The requestor shall submit a letter requesting permission to access SUNSI to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, and provide a copy to the Associate General Counsel for Hearings, Enforcement and Administration, Office of the General Counsel, Washington, DC 20555–0001. The expedited delivery or courier mail address for both offices is: U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852. The e-mail address for the Office of the Secretary and the Office of the General Counsel are *Hearing.Docket@nrc.gov* and *OGCmailcenter@nrc.gov,* respectively.[1] The request must include the following information:

(1) A description of the licensing action with a citation to this Federal Register notice;

(2) The name and address of the potential party and a description of the potential party's particularized interest that could be harmed by the action identified in C.(1);

(3) The identity of the individual or entity requesting access to SUNSI and the requestor's basis for the need for the information in order to meaningfully participate in this adjudicatory proceeding. In particular, the request must explain why publicly-available versions of the information requested would not be sufficient to provide the basis and specificity for a proffered contention;

D. Based on an evaluation of the information submitted under paragraph C.(3) the NRC staff will determine within 10 days of receipt of the request whether:

(1) There is a reasonable basis to believe the petitioner is likely to establish standing to participate in this NRC proceeding; and

(2) The requestor has established a legitimate need for access to SUNSI.

E. If the NRC staff determines that the requestor satisfies both D.(1) and D.(2) above, the NRC staff will notify the requestor in writing that access to SUNSI has been granted. The written notification will contain instructions on how the requestor may obtain copies of the requested documents, and any other conditions that may apply to access to those documents. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order[2] setting forth terms and conditions to prevent the unauthorized or inadvertent disclosure of SUNSI by each individual who will be granted access to SUNSI.

F. Filing of Contentions. Any contentions in these proceedings that are based upon the information received as a result of the request made for SUNSI must be filed by the requestor no later than 25 days after the requestor is granted access to that information. However, if more than 25 days remain between the date the petitioner is granted access to the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.

G. Review of Denials of Access.

(1) If the request for access to SUNSI is denied by the NRC staff either after a determination on standing and need for access, or after a determination on trustworthiness and reliability, the NRC staff shall immediately notify the requestor in writing, briefly stating the reason or reasons for the denial.

(2) The requestor may challenge the NRC staff's adverse determination by filing a challenge within 5 days of receipt of that determination with: (a) The presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an administrative law judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) if another officer has been designated to rule on information access issues, with that officer.

H. Review of Grants of Access. A party other than the requestor may challenge an NRC staff determination granting access to SUNSI whose release would harm that party's interest independent of the proceeding. Such a challenge must be filed with the Chief Administrative Judge within 5 days of the notification by the NRC staff of its grant of access.

If challenges to the NRC staff determinations are filed, these procedures give way to the normal process for litigating disputes concerning access to information. The availability of interlocutory review by the Commission of orders ruling on such NRC staff determinations (whether granting or denying access) is governed by 10 CFR 2.311.[3] The Commission expects that the NRC staff and presiding officers (and any other reviewing officers) will consider and resolve requests for access to SUNSI, and motions for protective orders, in a timely fashion in order to minimize any unnecessary delays in identifying those petitioners who have standing and who have propounded contentions meeting the specificity and basis requirements in 10 CFR part 2. Attachment 1 to this Order summarizes the general target schedule for processing and resolving requests under these procedures.

It is so ordered.

Dated at Rockville, Maryland, this 4th day of October, 2011.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[1] While a request for hearing or petition to intervene in this proceeding must comply with the filing requirements of the NRC's ''E-Filing Rule,'' the initial request to access SUNSI under these procedures should be submitted as described in this paragraph.

[2] Any motion for Protective Order or draft Non-Disclosure Affidavit or Agreement for SUNSI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 30 days of the deadline for the receipt of the written access request.

[3] Requestors should note that the filing requirements of the NRC's E-Filing Rule (72 FR 49139; August 28, 2007) apply to appeals of NRC staff determinations (because they must be served on a presiding officer or the Commission, as applicable), but not to the initial SUNSI request submitted to the NRC staff under these procedures.

ATTACHMENT 1—GENERAL TARGET SCHEDULE FOR PROCESSING AND RESOLVING REQUESTS FOR ACCESS TO SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION IN THIS PROCEEDING

Day	Event/activity
0	Publication of **Federal Register** notice of hearing and opportunity to petition for leave to intervene, including order with instructions for access requests.
10	Deadline for submitting requests for access to Sensitive Unclassified Non-Safeguards Information (SUNSI) with information: Supporting the standing of a potential party identified by name and address; describing the need for the information in order for the potential party to participate meaningfully in an adjudicatory proceeding.
60	Deadline for submitting petition for intervention containing: (i) Demonstration of standing; (ii) all contentions whose formulation does not require access to SUNSI (+25 Answers to petition for intervention; +7 requestor/petitioner reply).
20	Nuclear Regulatory Commission (NRC) staff informs the requestor of the staff's determination whether the request for access provides a reasonable basis to believe standing can be established and shows need for SUNSI. (NRC staff also informs any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information.) If NRC staff makes the finding of need for SUNSI and likelihood of standing, NRC staff begins document processing (preparation of redactions or review of redacted documents).
25	If NRC staff finds no ''need'' or no likelihood of standing, the deadline for requestor/petitioner to file a motion seeking a ruling to reverse the NRC staff's denial of access; NRC staff files copy of access determination with the presiding officer (or Chief Administrative Judge or other designated officer, as appropriate). If NRC staff finds ''need'' for SUNSI, the deadline for any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information to file a motion seeking a ruling to reverse the NRC staff's grant of access.
30	Deadline for NRC staff reply to motions to reverse NRC staff determination(s).
40	(Receipt +30) If NRC staff finds standing and need for SUNSI, deadline for NRC staff to complete information processing and file motion for Protective Order and draft Non-Disclosure Affidavit. Deadline for applicant/licensee to file Non-Disclosure Agreement for SUNSI.
A	If access granted: Issuance of presiding officer or other designated officer decision on motion for protective order for access to sensitive information (including schedule for providing access and submission of contentions) or decision reversing a final adverse determination by the NRC staff.
A + 3	Deadline for filing executed Non-Disclosure Affidavits. Access provided to SUNSI consistent with decision issuing the protective order.
A + 28	Deadline for submission of contentions whose development depends upon access to SUNSI. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.
A + 53	(Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI.
A + 60	(Answer receipt +7) Petitioner/Intervenor reply to answers.
>A + 60	Decision on contention admission.

[FR Doc. 2011–26235 Filed 10–7–11; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS) Meeting of the ACRS Subcommittee on Economic Simplified Boiling Water Reactor; Notice of Meeting

The ACRS Subcommittee on Economic Simplified Boiling Water Reactor (ESBWR) will hold a meeting on October 21, 2011, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance with the exception for portions that may be closed to protect proprietary information pursuant to 5 U.S.C. 552b(c)(3).

The agenda for the subject meeting shall be as follows:

Friday, October 21, 2011—8:30 a.m. Until 5 p.m.

The Subcommittee will review Chapters 5, 6, 16, 17, 19, and Loss of Large Areas (LOLA) of the Fermi Reference Combined License Application (RCOLA) Safety Evaluation Report (SER). 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), Christopher Brown (Telephone 301–415–7111 or *E-mail: Christopher.Brown@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 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 though 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.

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: October 4, 2011.

Yoira Diaz-Sanabria,

Technical Assistant, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2011–26170 Filed 10–7–11; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on AP1000; Notice of Meeting

The ACRS Subcommittee on AP1000 will hold a meeting on October 18–19, 2011, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance with the exception for portions that may be closed to protect proprietary information pursuant to 5 U.S.C. 552b(c)(4).

The agenda for the subject meeting shall be as follows:

Tuesday, October 18, 2011—8:30 a.m. until 5 p.m. and Wednesday, October 19, 2011—8:30 a.m. until 5 p.m.

The Subcommittee will review the AP1000 Subsequent Combined License Application (SCOLA) associated with Levy Unit 2. The Subcommittee will hear presentations by and hold discussions with representatives of 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), Weidong Wang (Telephone 301–415–6279 or *E-mail: Weidong.Wang@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: October 3, 2011.

Yoira Diaz-Sanabria,

Technical Assistant, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2011–26178 Filed 10–7–11; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS) Meeting of the ACRS Subcommittee on U.S. Advanced Pressurized Power Reactor; Notice of Meeting

The ACRS Subcommittee on U.S. Advanced Pressurized Power Reactor (US–APWR) will hold a meeting on October 20, 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:

Thursday, October 20, 2011–8:30 a.m. until 5 p.m.

The Subcommittee will review Chapter 11, ''Radioactive Waste Management,'' and Chapter 12, ''Radiation protection'' of the Safety Evaluation Report (SER) associated with the Comanche Peak Combined License Application (COLA). The staff will provide an information briefing regarding the risk managed technical specifications. The Subcommittee will hear presentations by and hold discussions with the NRC staff, Luminant Generation Company LLC 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), 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 e-mailed 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 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: October 4, 2011.

Yoira Diaz-Sanabria,

Technical Assistant, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2011–26177 Filed 10–7–11; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2011–0006]

Sunshine Federal Register Notice

AGENCY HOLDING THE MEETINGS: Nuclear Regulatory Commission.

DATE: Week of October 10, 2011.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

ADDITIONAL ITEMS TO BE CONSIDERED:

Week of October 10, 2011

Wednesday, October 12, 2011

8:55 a.m. Affirmation Session (Public Meeting) (Tentative)

a. *Pacific Gas and Electric Company* (Diablo Canyon Nuclear Power Plant, Units 1 and 2), Applicant's Notice of Appeal, Brief in Support of Appeal, of LBP–10–15 (Aug. 16, 2010); NRC Staff's Petition for Interlocutory Review of Atomic Safety and Licensing Board Decision (LBP–10–15) Admitting an Out of Scope Safety Contention and Improperly Recasting an Environmental Contention (Aug. 19, 2010); Certified Question and Referred Ruling in LBP–10–15 (Aug. 4, 2010) (Tentative)

b. *Shieldalloy Metallurgical Corporation Site* (NRC–NJ Section 274 Agreement) –Commission Decision on Remand from Court of Appeals (Tentative)

This meeting will be webcast live at the Web address—*http://www.nrc.gov*.

* * * * *

* The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings, call (recording)—(301) 415–1292. Contact person for more information: Rochelle Bavol, (301) 415–1651.

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/about-nrc/policy-making/schedule.html*.

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The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.* braille, large print), please notify Bill Dosch, Chief, Work Life and Benefits Branch, at 301–415–6200, TDD: 301–415–2100, or by e-mail at *william.dosch@nrc.gov*. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

This notice is distributed electronically to subscribers. If you no longer wish to receive it, or would like to be added to the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301–415–1969), or send an e-mail to *darlene.wright@nrc.gov.*

Dated: October 5, 2011.

Rochelle C. Bavol,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2011–26303 Filed 10–6–11; 4:15 pm]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–027, NRC–2011–0083]

Washington State University; Notice of Issuance of Renewed Facility Operating License No. R–76

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of issuance of renewed facility operating license No. R–76.

ADDRESSES: You can access publicly available documents related to this notice using the following methods:

NRC's Public Document Room (PDR): The public may examine and have copied for a fee, publicly available documents at the NRC's PDR, Room O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

NRC's Agencywide Documents Access and Management System (ADAMS): Publicly available documents created or received at the NRC are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html.* From this page, the public can gain entry into ADAMS, which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr.resource@nrc.gov.* For details with respect to the application for renewal, see the licensee's letter dated June 24, 2002 (ADAMS Accession No. ML092390202), as supplemented on April 7 (two letters) (ADAMS Accession Nos. ML101031097 and ML101030215), May 3 (ADAMS Accession No. ML101310231), May 24 (ADAMS Accession No. ML101530139), June 30 (ADAMS Accession No. ML101890720), July 30 (ADAMS Accession No. 102230406), August 4 (ADAMS Accession No. ML 102230415), August 10 (ADAMS Accession No. ML102300722), August 17 (ADAMS Accession No. ML102360194), and September 22, 2010 (ADAMS Accession No. ML102780440), and March 23 (ADAMS Accession No. ML110900059), July 15 (ADAMS Accession No. ML11202A095), July 18, (ADAMS Accession No. ML11207A068), August, (ADAMS Accession No. ML11221A162), and August 26, 2011 (ADAMS Accession No. ML112430148).

FOR FURTHER INFORMATION CONTACT: Linh N. Tran, Senior Project Manager, Research and Test Reactor Licensing Branch, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Rockville, MD 20852. *Telephone:* 301–415–4103; *fax number:* (301) 415–3031; *e-mail: Lihn.Tran@nrc.gov.*

SUPPLEMENTARY INFORMATION: The U.S. Nuclear Regulatory Commission (NRC, the Commission) has issued renewed Facility Operating License No. R–76, held by the Washington State University (WSU, the licensee), which authorizes continued operation of the WSU Modified TRIGA Nuclear Reactor, located in Pullman, Whitman County, Washington. The WSU Modified TRIGA Nuclear Reactor is a pool-type, natural convection, light-water cooled, and shielded reactor that was converted to the use of TRIGA (Training, Research, Isotope Production, General Atomics) fuel. The WSU NRCR is licensed to operate at a steady-state power level of 1 megawatt thermal power and pulse mode operation with a peak pulse power of 2,000 megawatt. The renewed Facility Operating License No. R–76 will expire 20 years from its date of issuance.

The renewed facility operating license complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's regulations in Title 10, Chapter 1, ''Nuclear Regulatory Commission,'' of the *Code of Federal Regulations* (10 CFR), and sets forth those findings in the renewed facility

operating license. The agency afforded an opportunity for hearing in the Notice of Opportunity for Hearing published in the **Federal Register** on June 28, 2010 (75 FR 36717–36721). The NRC received no request for a hearing or petition for leave to intervene following the notice.

The NRC staff prepared a safety evaluation report for the renewal of Facility Operating License No. R–76 and concluded, based on that evaluation, the licensee can continue to operate the facility without endangering the health and safety of the public. The NRC staff also prepared an Environmental Assessment and Finding of No Significant Impact for the renewal of the facility operating license, noticed in the **Federal Register** on April 19, 2011 (76 FR 2192821931), and concluded that renewal of the facility operating license will not have a significant impact on the quality of the human environment.

Dated at Rockville, Maryland, this 30th day of September, 2011.

For The Nuclear Regulatory Commission.

Patricia A. Silva,

Acting Chief, Research and Test Reactors Licensing Branch, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation.

[FR Doc. 2011–26180 Filed 10–7–11; 8:45 am]

BILLING CODE 7590–01–P

OVERSEAS PRIVATE INVESTMENT CORPORATION

Sunshine Notice—October 27, 2011 Board of Directors Meeting

TIME AND DATE: Thursday, October 27, 2011, 10 a.m. (Open Portion) 10:15 a.m. (Closed Portion).

PLACE: Offices of the Corporation, Twelfth Floor Board Room, 1100 New York Avenue, NW., Washington, DC.

STATUS: Meeting OPEN to the Public from 10 a.m. to 10:15 a.m. Closed portion will commence at 10:15 a.m. (approx.).

MATTERS TO BE CONSIDERED:

1. President's Report
2. Tribute—Christopher J. Hanley

FURTHER MATTERS TO BE CONSIDERED: (Closed to the Public 10:15 a.m.)

1. Reports
2. Revisions to OPIC Bylaws
3. Revised Delegation of Authority
4. Finance Project—Egypt and South Sudan (upon the opening of OPIC Programs)
5. Finance Project—Guatemala
6. Finance Project—Peru
7. Finance Project—Mexico
8. Finance Project—Global
9. Finance Project—Mexico, Ukraine, Brazil, Colombia, Jamaica, Egypt, Vietnam, India and Nigeria
10. Finance Project—Sierra Leone, Liberia, other West Africa countries
11. Finance Project—Sub-Saharan Africa
12. Finance Project—Global
13. Pending Major Projects

Written summaries of the projects to be presented will be posted on OPIC's Web site on or about October 7, 2011.

CONTACT PERSON FOR INFORMATION: Information on the meeting may be obtained from Connie M. Downs at (202) 336–8438.

Dated: October 5, 2011.

Connie M. Downs,

Corporate Secretary, Overseas Private Investment Corporation.

[FR Doc. 2011–26302 Filed 10–6–11; 4:15 pm]

BILLING CODE 3210–01–P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Request for Information: Building A 21st Century Bioeconomy

ACTION: Notice of Request for Information (RFI).

SUMMARY: The purpose of this Request for Information (RFI) is to solicit input from all interested parties regarding recommendations for harnessing biological research innovations to meet national challenges in health, food, energy, and the environment while creating high-wage, high-skill jobs.

The public input provided through this Notice will inform the Office of Science and Technology Policy (OSTP) as it works with Federal agencies and other stakeholders to develop a National Bioeconomy Blueprint.

DATES: October 7, 2011—December 6, 2011.

ADDRESSES: *BIOECONOMY@OSTP.GOV.*

SUPPLEMENTARY INFORMATION:

Purpose

The purpose of this Request for Information (RFI) is to solicit input from all interested parties regarding recommendations for harnessing biological research innovations to meet national challenges in health, food, energy, and the environment while creating high-wage, high-skill jobs.

The public input provided through this Notice will inform the Office of Science and Technology Policy as it works with Federal agencies and other stakeholders to develop a National Bioeconomy Blueprint.

Background

On September 16, 2011, President Obama announced that his Administration will develop a National Bioeconomy Blueprint detailing Administration-wide steps to harness biological research innovations to address national challenges in health, food, energy, and the environment. Biological research underpins the foundation of a significant portion of our economy. By better leveraging our national investments in biological research and development, the Administration will grow the jobs of the future and improve the lives of all Americans.

Twenty-first century advances in biological research and technologies are poised to return tremendous public benefits. For example, advances in human genome-informed personalized medicine and data analytics could be combined to improve human health in novel ways. In bio-based industry, biological design can create new opportunities for biofuels, chemicals, materials, and energy-efficient manufacturing processes.

The National Bioeconomy Blueprint will identify strategies to meet grand challenges, promote commercialization and entrepreneurship, focus research and development investments in areas that will provide the foundation for the bioeconomy, expand workforce training to prepare the next generation of scientists and engineers for the bioeconomy jobs of the future, identify regulatory reforms that will reduce unnecessary burdens on innovators while protecting health and safety, and describe appropriate public-private partnerships to accelerate innovation in key areas.

OSTP seeks comment on the questions listed below to inform the development of the National Bioeconomy Blueprint:

Grand challenges: President Obama has identified ''grand challenges'' as an important element of his innovation strategy, such as ''smart anti-cancer therapeutics that kill cancer cells and leave their normal neighbors untouched; early detection of dozens of diseases from a saliva sample; personalized medicine that enables the prescription of the right dose of the right drug for the right person; a universal vaccine for influenza that will protect against all future strains; and regenerative medicine that can end the agonizing wait for an organ transplant.''

(1) Identify one or more grand challenges for the bioeconomy in areas such as health, energy, the environment, and agriculture, and suggest concrete

steps that would need to be taken by the Federal government, companies, non-profit organizations, foundations, and other stakeholders to achieve this goal.

Research and development: R&D investments, particularly in platform technologies, can support advances in health, energy, the environment, and agriculture, and accelerate the pace of discovery in fundamental life sciences research.

(2) Constrained Federal budgets require a focus on high-impact research and innovation opportunities. With this in mind, what should be the Federal funding priorities in research, technologies, and infrastructure to provide the foundation for the bioeconomy?

(3) What are the critical technical challenges that prevent high throughput approaches from accelerating bioeconomy-related research? What specific research priorities could address those challenges? Are there particular goals that the research community and industry could rally behind (e.g., NIH $1,000 genome initiative [1])?

(4) The speed of DNA sequencing has outstripped advances in the ability to extract information from genomes given the large number of genes of unknown function in genomes; as many as 70% of genes in a genome have poorly or unknown functions. All areas of scientific inquiry that utilize genome information could benefit from advances in this area. What new multidisciplinary funding efforts could revolutionize predictions of protein function for genes?

Moving life sciences breakthroughs from lab to market: It is a challenge to commercialize advances in the life sciences because of the risk, expense, and need for many years of sustained investment. The Administration is interested in steps that it can take directly, but is also interested in encouraging experimentation with new private-sector-led models for funding commercialization of life sciences research.

(5) What are the barriers preventing biological research discoveries from moving from the lab to commercial markets? What specific steps can Federal agencies take to address these shortcomings? Please specify whether these changes apply to academic labs, government labs, or both.

(6) What specific changes to Federal Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs [2] would help accelerate commercialization of federally-funded bioeconomy-related research?

(7) What high-value data might the government release in the spirit of its open government agenda that could spur the development of new products and services in the bioeconomy?

(8) What are the challenges associated with existing private-sector models (e.g. venture funding) for financing entrepreneurial bioeconomy firms and what specific steps can agencies take to address those challenges?

Workforce development: Investment in education and training is essential to creating a technically-skilled 21st century American bioeconomy workforce.

(9) The majority of doctorate recipients will accept jobs outside of academia. What modifications should be made to professional training programs to better prepare scientists and engineers for private-sector bioeconomy jobs?

(10) What roles should community colleges play in training the bioeconomy workforce of the future?

(11) What role should the private sector play in training future bioeconomy scientists and engineers?

(12) What role might government, industry, and academia play in encouraging successful entrepreneurship by faculty, graduate students, and postdocs?

Reducing regulatory barriers to the bioeconomy: As President Obama has stated, our regulatory system must ''identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends'' and ''protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation.''

(13) What specific regulations are unnecessarily slowing or preventing bioinnovation? Please cite evidence that the identified regulation(s) are a) slowing innovation, and b) could be reformed or streamlined while protecting public health, safety, and the environment.

(14) What specific steps can Federal agencies take to improve the predictability and transparency of the regulatory system? (Please specify the relevant agency.)

(15) What specific improvements in the regulatory processes for drugs, diagnostics, medical devices, and agricultural biotechnology should federal agencies implement? What challenges do new or emerging technologies pose to the existing regulatory structure and what can agencies do to address those challenges?

Public-private partnerships: The Administration is interested in serving as a catalyst for public-private partnerships that build the bioeconomy and address important unmet needs in areas such as health, energy, agriculture, and environment.

(16) What are the highest impact opportunities for public-private partnerships related to the bioeconomy? What shared goals would these partnerships pursue, which stakeholders might participate, and what mutually reinforcing commitments might they make to support the partnership?

(17) What are the highest impact opportunities for pre-competitive collaboration in the life sciences, and what role should the government play in developing them? What can be learned from existing models for pre-competitive collaboration both inside and outside the life-sciences sector? What are the barriers to such collaborations and how might they be removed or overcome?

Response to this RFI is voluntary. Responders are free to address any or all the above items, as well as provide additional information that they think is relevant to the development of a National Bioeconomy Blueprint.

Please note that the Government will not pay for response preparation or for the use of any information contained in the response.

How To Submit a Response

All comments must be submitted electronically to: *bioeconomy@ostp.gov.*

Responses to this RFI will be accepted through December 6, 2011. You will receive an electronic confirmation acknowledging receipt of your response, but will not receive individualized feedback on any suggestions. No basis for claims against the U.S. Government shall arise as a result of a response to this request for information or from the Government's use of such information.

Responses received after the deadline will be considered during implementation of the activities of the National Bioeconomy Blueprint if not received before finalization of the National Bioeconomy Blueprint.

Responses to the RFI, including the names of the authors and their institutional affiliations, will be posted at *http://www.whitehouse.gov/ostp/bioeconomy.*

Inquiries

Specific questions about this RFI should be directed to the following e-mail address: *bioeconomy@ostp.gov.*

Form should include:

[Assigned ID #]

[1] *http://www.genome.gov/27541190*

[2] *http://www.sbir.gov/*

[Assigned Entry date]
Name/E-mail
Affiliation/Organization
City, State
Comment 1
Comment 2
Comment 3
Comment 4
Comment 5
Attachment

Ted Wackler,

Deputy Chief of Staff.

[FR Doc. 2011–26088 Filed 10–7–11; 8:45 am]

BILLING CODE P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

President's Council of Advisors on Science and Technology Meeting

AGENCY: Office of Science and Technology Policy.

ACTION: Notice of meeting.

SUMMARY: This notice sets forth the schedule and summary agenda for a partially closed meeting of the President's Council of Advisors on Science and Technology (PCAST), and describes the functions of the Council. Notice of this meeting is required under the Federal Advisory Committee Act (FACA), 5 U.S.C., App.

DATES: November 2, 2011.

ADDRESSES: The meeting will be held at the Marriott Metro Center, 775 12th Street NW., Ballroom Salon A, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Information regarding the meeting agenda, time, location, and how to register for the meeting is available on the PCAST Web site at: *http://whitehouse.gov/ostp/pcast.* A live video webcast and an archive of the webcast after the event are expected to be available at *http://whitehouse.gov/ostp/pcast.* The archived video will be available within one week of the meeting. Questions about the meeting should be directed to Dr. Deborah D. Stine, PCAST Executive Director, at *dstine@ostp.eop.gov,* (202) 456–6006. Please note that public seating for this meeting is limited and is available on a first-come, first-served basis.

SUPPLEMENTARY INFORMATION: The President's Council of Advisors on Science and Technology (PCAST) is an advisory group of the nation's leading scientists and engineers, appointed by the President to augment the science and technology advice available to him from inside the White House and from cabinet departments and other Federal agencies. *See* the Executive Order at *http://www.whitehouse.gov/ostp/pcast.* PCAST is consulted about and provides analyses and recommendations concerning a wide range of issues where understandings from the domains of science, technology, and innovation may bear on the policy choices before the President. PCAST is administered by the Office of Science and Technology Policy (OSTP). PCAST is co-chaired by Dr. John P. Holdren, Assistant to the President for Science and Technology, and Director, Office of Science and Technology Policy, Executive Office of the President, The White House; and Dr. Eric S. Lander, President, Broad Institute of the Massachusetts Institute of Technology and Harvard.

Type of Meeting: Open and Closed.

Proposed Schedule and Agenda: The President's Council of Advisors on Science and Technology (PCAST) is scheduled to meet in open session on November 2, 2011 from 10 a.m. to 5 p.m.

Open Portion of Meeting: During this open meeting, PCAST is tentatively scheduled to hear from speakers who will provide an overview of two reports—one on innovation and job creation, and another on government-held spectrum. In addition, several agencies will update PCAST on the implementation status of the recommendations it made in its report on nanotechnology. PCAST will also receive an update on the status of several of its studies. Additional information and the agenda, including any changes that arise, will be posted at the PCAST Web site at: *http://whitehouse.gov/ostp/pcast.*

Closed Portion of the Meeting: PCAST may hold a closed meeting of approximately 1 hour with the President on November 2, 2011, which must take place in the White House for the President's scheduling convenience and to maintain Secret Service protection. This meeting will be closed to the public because such portion of the meeting is likely to disclose matters that are to be kept secret in the interest of national defense or foreign policy under 5 USC 552b(c)(1).

Public Comments: It is the policy of the PCAST to accept written public comments of any length, and to accommodate oral public comments whenever possible. The PCAST expects that public statements presented at its meetings will not be repetitive of previously submitted oral or written statements.

The public comment period for this meeting will take place on November 2, 2011 at a time specified in the meeting agenda posted on the PCAST Web site at *http://whitehouse.gov/ostp/pcast.* This public comment period is designed only for substantive commentary on PCAST's work, not for business marketing purposes.

Oral Comments: To be considered for the public speaker list at the meeting, interested parties should register to speak at *http://whitehouse.gov/ostp/pcast,* no later than 12 p.m. Eastern Time on October 24, 2011. Phone or e-mail reservations will not be accepted. To accommodate as many speakers as possible, the time for public comments will be limited to two (2) minutes per person, with a total public comment period of 30 minutes. If more speakers register than there is space available on the agenda, PCAST will randomly select speakers from among those who applied. Those not selected to present oral comments may always file written comments with the committee. Speakers are requested to bring at least 25 copies of their oral comments for distribution to the PCAST members.

Written Comments: Although written comments are accepted until the date of the meeting, written comments should be submitted to PCAST no later than 12 p.m. Eastern Time on October 17, 2011, so that the comments may be made available to the PCAST members prior to the meeting for their consideration. Information regarding how to submit comments and documents to PCAST is available at *http://whitehouse.gov/ostp/pcast* in the section entitled ''Connect with PCAST.''

Please note that because PCAST operates under the provisions of FACA, all public comments and/or presentations will be treated as public documents and will be made available for public inspection, including being posted on the PCAST Web site.

Meeting Accomodations: Individuals requiring special accommodation to access this public meeting should contact Dr. Stine at least ten business days prior to the meeting so that appropriate arrangements can be made.

Ted Wackler,

Deputy Chief of Staff.

[FR Doc. 2011–26151 Filed 10–7–11; 8:45 am]

BILLING CODE 3170–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65478; File No. SR–Phlx–2011–130]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to the SQT Fees

October 4, 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 27, 2011, NASDAQ OMX PHLX LLC (''Phlx'' or ''Exchange'') 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 the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Streaming Quote Trader[3] (''SQT'') Fees.

While changes to the Fee Schedule pursuant to this proposal are effective upon filing, the Exchange has designated these changes to be operative on October 3, 2011.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqtrader.com/micro.aspx?id=PHLXfilings,* at the principal office of the Exchange, on the Commission's Web site at *http://www.sec.gov/* 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 aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the SQT Fees in Section VI of the Exchange's Fee Schedule, entitled ''Access Service, Cancellation, Membership, Regulatory and Other Fees.'' The Exchange proposes to simplify the SQT Fees by amending certain text, without changing the fees, for ease of reference. Additionally, the Exchange proposes to amend the calculation of the SQT Fees to incentivize trading in equity options, excluding currencies and indexes. The Exchange believes that the proposed SQT Fees will continue to incentivize SQTs to remain on the Exchange's options floor and thereby provide liquidity for floor-brokered orders traded in-crowd.

Currently, a member organization is assessed per month an SQT Fee based on the total number of options in which all SQTs in the same member organization are assigned. A member organization is assessed an SQT Fee based on the aggregate amount of equity options and index options traded by the SQTs in that member organization. The highest applicable SQT Fee is assessed based on the highest SQT category level in which the SQT was qualified at any time during a particular calendar month.[4] For example, if an SQT was eligible to trade at any time in a given calendar month as a Category I SQT, and sometime during that same calendar month became qualified and eligible to trade as a Category II SQT, the SQT member organization would be assessed the fee applicable to a Category II SQT, regardless of when such SQT became eligible to trade at the Category II level, and regardless if, during that same calendar month, the SQT resumed eligibility as a Category I SQT.[5]

The Exchange proposes to amend the verbiage of the current SQT Fees to simplify the fees as follows:

Number of option class assignments	SQT fees
Up to 200 classes	$0.00 per calendar month.
Up to 400 classes	$2,200 per calendar month.
Up to 600 classes	$3,200 per calendar month.
Up to 800 classes	$4,200 per calendar month.
Up to 1000 classes	$5,200 per calendar month.
Up to 1200 classes	$6,200 per calendar month.
All equity issues	$7,500 per calendar month.

The Exchange is proposing to remove the references to ''SQT is Eligible to trade:'' and ''equity and index options issues'' and instead use the term ''classes.'' The Exchange proposes to amend the calculation of the SQT Fees as well. In calculating the SQT Fees, the Exchange will calculate the number of option class assignments for equity options including exchange-traded funds (''ETFs''), exchange-traded notes (''ETNs'')[6] and HOLDRS[7]. The Exchange will not include and therefore not assess a fee for currencies or indexes in calculating the number of option class assignments. The Exchange proposes to amend the Fee Schedule to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] An SQT is defined in Exchange Rule 1014(b)(ii)(A) as an ROT who has received permission from the Exchange to generate and submit option quotations electronically in options to which such SQT is assigned.

[4] *See* Exchange Rules 1014(b) and 507 for qualifications relating to assignments.

[5] For example, if a member organization's SQT is eligible to trade up to 200 equity and index options issues at any time in a given month, and is thus qualified as a Category I SQT, and sometime during that month becomes eligible to trade up to 400 equity and index options issues during that same month, and is thus qualified as a Category II SQT, the member organization employing that SQT would be assessed the fee applicable to a Category II SQT, regardless of when, during that month, the SQT became eligible to trade at the Category II level.

[6] ETNs are also known as ''Index-Linked Securities,'' which are designed for investors who desire to participate in a specific market segment by providing exposure to one or more identifiable underlying securities, commodities, currencies, derivative instruments or market indexes of the foregoing. Index-Linked Securities are the non-convertible debt of an issuer that have a term of at least one (1) year but not greater than thirty (30) years. Despite the fact that Index-Linked Securities are linked to an underlying index, each trade as a single, exchange-listed security. Accordingly, rules pertaining to the listing and trading of standard equity options apply to Index-Linked Securities.

[7] HOLDRS are Holding Company Depository Receipts.

note the method of calculation as follows:

''In calculating the number of option class assignments, equity options including ETFs, ETNs and HOLDRS will be counted. Currencies and indexes will not be counted in the number of option class assignments.''

While changes to the Fee Schedule pursuant to this proposal are effective upon filing, the Exchange has designated these changes to be operative on October 3, 2011.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act [8] in general, and furthers the objectives of Section 6(b)(4) of the Act [9] in particular, in that it is an equitable allocation of reasonable fees and other charges among Exchange members and other persons using its facilities.

The Exchange believes that the proposed amendments to the SQT Fees are reasonable because the fees remain the same, except the verbiage is simplified. The Exchange believes that the fees continue to be reasonable because SQT Fees are lower than RSQT Fees. This is because SQTs have more out-of-pocket costs associated with their streaming quote systems as compared to RSQTs. For example, SQTs generally have to purchase additional software programs and hardware from outside vendor to support their streaming quote systems, in addition to incurring additional costs associated with market data to enable them to price options within their particular options pricing model. Furthermore, the Exchange believes that excluding currencies and indexes from the basis of the calculation of the SQT Fees is reasonable because the Exchange is seeking to incentivize SQTs to transact equity options including ETFs, ETNs and HOLDRs.[10]

The Exchange believes that the proposed calculation of the SQT Fees is equitable and not unfairly discriminatory because the calculation will be uniformly applied to all SQTs. The exclusion of the currencies and indexes from the calculation of option class assignments to determine the amount of SQT Fees will apply equally to all SQTs.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[11] 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 No. SR–Phlx–2011–130 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 No. SR–Phlx-2011–130. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–Phlx–2011–130 and should be submitted on or before November 1, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–26134 Filed 10–7–11; 8:45 am]

BILLING CODE 8011–01–P

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(4).

[10] The Exchange is excluding currencies and indexes.

[11] 15 U.S.C. 78s(b)(3)(A)(ii).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65468; File No. SR–NYSEArca–2011–51]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Granting Approval of Proposed Rule Change To List and Trade Managed Fund Shares of TrimTabs Float Shrink ETF Under NYSE Arca Equities Rule 8.600

October 3, 2011.

I. Introduction

On July 29, 2011, NYSE Arca, Inc. (''Exchange'' or ''NYSE Arca'') 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 list and trade shares (''Shares'') of TrimTabs Float Shrink ETF (''Fund'') under NYSE Arca Equities Rule 8.600. The proposed rule change was published for comment in the **Federal Register** on August 18,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

2011.[3] The Commission received no comments on the proposal [CONFIRM]. This order grants approval of the proposed rule change.

II. Description of the Proposed Rule Change

The Exchange proposes to list and trade the Shares of the Fund pursuant to NYSE Arca Equities Rule 8.600, which governs the listing and trading of Managed Fund Shares on the Exchange. The Shares will be offered by AdvisorShares Trust (''Trust''), a statutory trust organized under the laws of the State of Delaware and registered with the Commission as an open-end management investment company.[4] The investment adviser to the Fund is AdvisorShares Investments, LLC (''Adviser''). Trim Tabs Asset Management, LLC (''TrimTabs'' or ''Sub-Adviser'') is the Fund's sub-adviser and provides day-to-day portfolio management of the Fund. Foreside Fund Services, LLC is the principal underwriter and distributor of the Fund's Shares. The Exchange states that neither the Adviser nor the Sub-Adviser is affiliated with a broker-dealer.[5]

Description of the Fund

The Fund is an actively-managed exchange-traded fund that seeks to achieve its investment objective primarily by investing in the broad U.S. equity market, as represented by the Russell 3000® Index (''Index''). The Fund seeks to achieve this goal by investing in stocks with liquidity and fundamental characteristics that are historically associated with superior long-term performance. The Sub-Adviser designed the following quantitative stock selection rules to make allocation decisions and to protect against dramatic over or under weighting of individual securities in the Fund's portfolio.

The Sub-Adviser will rank stocks in the Index based on the following criteria:

I. The decrease in their outstanding shares over approximately the past 120 days (''float shrink'');

II. The increase in free cash flow (the money available to the company that is not used to pay for its daily operations) over approximately the past 120 days; and

III. The decrease in leverage over approximately the past 120 days. Leverage is measured as the ratio of total liabilities to total assets. The Sub-Adviser will use the relative decrease in leverage, rather than amount of leverage itself, as a criterion because the degree of leverage varies across industries.

The top decile of each respective ranking will consist of the stocks of the companies with (I) the strongest reduction in shares outstanding, (II) the strongest growth in free cash flow, and (III) the largest decrease in leverage, respectively.

Stock Selection Algorithm

The Sub-Adviser will use an algorithm to give a relative weight to the three decile rankings, combining them in a single ranking (combined ranking). The algorithm will place a higher weight on the float shrink ranking, followed by the free cash flow ranking, followed by the leverage ranking. The Fund, under normal circumstances,[6] will invest in 80 to 120 stocks from among the top 10% of stocks in the combined ranking. The Sub-Adviser's investment process is quantitative. The Sub-Adviser designed the following stock selection rules, which involve liquidity, weighting, rebalancing, and trading considerations:

Liquidity Screening

Before trading, the Fund will estimate the liquidity impact of its suggested trades. Specifically, the Fund will avoid stocks whose average trading volume over the past 30 days would be less than 50% of the size of the Fund's proposed trades. As a result, the Fund will not invest in stocks that meet its investment criteria in terms of float shrink, free cash flow growth, and leverage if their trading volume is below such levels. As such, the Fund will not invest in stocks that it deems to be illiquid.

Weighting and Sector Allocation

Although the Fund initially will invest an equal dollar amount in the stocks that meet its investment criteria, the Fund is not market capitalization weighted. Thus, the Fund will overweight small-cap stocks and mid-cap stocks relative to traditional, market cap weighted indices.[7]

The relative weights of the sectors in the Fund may vary significantly from those of traditional, market cap weighted indices. Stocks with favorable liquidity characteristics may be concentrated in certain sectors. Sector concentration might increase the Fund's volatility over the short term. The Fund will not correct these sector effects because the Sub-Adviser's research shows that historically they are a source of long-term outperformance.

Other Investments

To respond to adverse market, economic, political, or other conditions, the Fund may invest 100% of its total assets, without limitation, in short-term, high-quality debt securities and money market instruments. The Fund may invest in these instruments for extended periods, depending on the Sub-Adviser's assessment of market conditions. These debt securities and money market instruments include shares of other mutual funds, commercial paper, certificates of deposit, bankers' acceptances, U.S. Government securities, including U.S. Treasury zero-coupon bonds, repurchase and reverse repurchase agreements,[8] and bonds that are BBB or higher.

The Fund will seek to qualify for treatment as a Regulated Investment Company under Subchapter M of the

[3] *See* Securities Exchange Act Release No. 65126 (August 12, 2011), 76 FR 51442 (''Notice'').

[4] The Trust is registered under the Investment Company Act of 1940 (''1940 Act''). On January 19, 2011, the Trust filed with the Commission Form N–1A under the Securities Act of 1933 (15 U.S.C. 77a) and under the 1940 Act relating to the Fund (File Nos. 333–157876 and 811–22110) (''Registration Statement''). In addition, the Commission has issued an order granting certain exemptive relief to the Trust under the1940 Act. *See* Investment Company Act Release No. 29291 (May 28, 2010) (File No. 812–13677) (''Exemptive Order'').

[5] *See* Commentary .06 to NYSE Arca Equities Rule 8.600. The Exchange represents that in the event (a) The Adviser or the Sub-Adviser becomes newly affiliated with a broker-dealer, or (b) any new adviser or sub-adviser becomes affiliated with a broker-dealer, it will implement a fire wall with respect to such broker-dealer regarding access to information concerning the composition and/or changes to the portfolio, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio.

[6] The term ''under normal market circumstances'' includes, but is not limited to, the absence of extreme volatility or trading halts in the fixed income markets or the financial markets generally; operational issues causing dissemination of inaccurate market information; or force majeure type events such as systems failure, natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption or any similar intervening circumstance.

[7] Mid-sized companies may be more volatile than large-capitalization companies, and returns on investments in stocks of mid-sized companies could trail the returns on investments in stocks of larger or smaller companies. Stock prices of small capitalization companies may be more volatile than those of larger companies and, therefore, the Fund's Share price may be more volatile than those of funds that invest a larger percentage of their assets in stocks issued by larger-capitalization companies.

[8] The Fund may enter into repurchase agreements with financial institutions, which may be deemed to be loans. The Fund follows certain procedures designed to minimize the risks inherent in such agreements. These procedures include effecting repurchase transactions only with large, well-capitalized and well-established financial institutions whose condition will be continually monitored by the Sub-Adviser. The Fund may enter into reverse repurchase agreements without limit as part of the Fund's investment strategy. Reverse repurchase agreements involve sales by the Fund of portfolio assets concurrently with an agreement by the Fund to repurchase the same assets at a later date at a fixed price.

Internal Revenue Code. The Fund may not (i) With respect to 75% of its total assets, purchase securities of any issuer (except securities issued or guaranteed by the U.S. Government, its agencies or instrumentalities or shares of investment companies) if, as a result, more than 5% of its total assets would be invested in the securities of such issuer; or (ii) acquire more than 10% of the outstanding voting securities of any one issuer. In addition, the Fund may not invest 25% or more of its total assets in the securities of one or more issuers conducting their principal business activities in the same industry or group of industries (this limitation does not apply to investments in securities issued or guaranteed by the U.S. Government, its agencies or instrumentalities, or shares of investment companies). The Fund will not invest 25% or more of its total assets in any investment company that so concentrates.

Pursuant to the terms of the Exemptive Order, the Fund will not invest in options contracts, futures contracts or swap agreements. The Fund's investments will be consistent with the Fund's investment objective and will not be used to enhance leverage. The Fund will not purchase illiquid securities. In addition, the Fund will not invest in non-U.S.-registered equity securities, loan participation agreements, and Rule 144A securities.

Additional information regarding the Trust, Fund, Shares, Fund's investment strategies, risks, creation and redemption procedures, fees, portfolio holdings and disclosure policies, distributions and taxes, availability of information, trading rules and halts, and surveillance procedures, among other things, can be found in the Notice and the Registration Statement, as applicable.[9]

III. Discussion and Commission's Findings

The Commission has carefully reviewed the proposed rule change and finds that it is consistent with the requirements of Section 6 of the Act and the rules and regulations thereunder applicable to a national securities exchange.[10] In particular, the Commission finds that the proposal is consistent with Section 6(b)(5) of the Act,[11] which requires, among other things, that the Exchange's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, 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 notes that the Shares must comply with the requirements of NYSE Arca Equities Rule 8.600 to be listed and traded on the Exchange.

The Commission finds that the proposal to list and trade the Shares on the Exchange is consistent with Section 11A(a)(1)(C)(iii) of the Act,[12] which sets forth Congress' finding that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers, and investors of information with respect to quotations for, and transactions in, securities. Quotation and last-sale information for the Shares will be available via the Consolidated Tape Association high-speed line. In addition, the Portfolio Indicative Value, as defined in NYSE Arca Equities Rule 8.600(c)(3), will be updated and disseminated by one or more major market data vendors at least every 15 seconds during the Core Trading Session on the Exchange. On each business day, before commencement of trading in Shares in the Core Trading Session on the Exchange, the Fund will disclose on its Web site the Disclosed Portfolio, as defined in NYSE Arca Equities Rule 8.600(c)(2), that will form the basis for the Fund's calculation of the net asset value (''NAV'') at the end of the business day.[13] The Fund will calculate NAV once each business day as of the regularly scheduled close of trading on the Exchange (normally 4 p.m. Eastern Time). In addition, information regarding market price and trading volume of the Shares is and will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services, and the previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers. The intra-day, closing, and settlement prices of the portfolio securities are also readily available from the national securities exchanges trading such securities, automated quotation systems, published or other public sources, or on-line information services such as Bloomberg or Reuters. The Fund's website will also include a form of the prospectus for the Fund, information relating to NAV, and other quantitative and trading information.

The Commission further believes that the proposal to list and trade the Shares is reasonably designed to promote fair disclosure of information that may be necessary to price the Shares appropriately and to prevent trading when a reasonable degree of transparency cannot be assured. The Commission notes that the Exchange will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time.[14] In addition, the Exchange will halt trading in the Shares under the specific circumstances set forth in NYSE Arca Equities Rule 8.600(d)(2)(D), and may halt trading in the Shares if trading is not occurring in the securities and/or the financial instruments comprising the Disclosed Portfolio of the Fund, or if other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present.[15] The Exchange will consider the suspension of trading in or removal from listing of the Shares if the Portfolio Indicative Value is no longer calculated or available or the Disclosed Portfolio is not made available to all market participants at the same time.[16] The Exchange represents that neither the Adviser nor the Sub-Adviser is affiliated with a broker-dealer.[17] The

[9] *See* Notice and Registration Statement, *supra* notes 3 and 4, respectively.

[10] 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).

[11] 17 U.S.C. 78f(b)(5).

[12] 15 U.S.C. 78k–1(a)(1)(C)(iii).

[13] On a daily basis, the Adviser will disclose on the Fund's Web site for each portfolio security or other financial instrument of the Fund the following information: Ticker symbol (if applicable), name of security or financial instrument, number of shares or dollar value of financial instruments held in the portfolio, and percentage weighting of the security or financial instrument in the portfolio. The Web site information will be publicly available at no charge.

[14] *See* NYSE Arca Equities Rule 8.600(d)(1)(B).

[15] With respect to trading halts, the Exchange may consider other relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Fund. Trading in Shares of the Fund will be halted if the circuit breaker parameters in NYSE Arca Equities Rule 7.12 have been reached. Trading also may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable.

[16] *See* NYSE Arca Equities Rule 8.600(d)(2)(C)(ii).

[17] *See supra* note 5 and accompanying text. The Commission notes that an investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (''Advisers Act''). As a result, the Adviser and Sub-Adviser and their related personnel are subject to the provisions of Rule 204A–1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent

Continued

Commission notes that the Reporting Authority that provides the Disclosed Portfolio must implement and maintain, or be subject to, procedures designed to prevent the use and dissemination of material non-public information regarding the actual components of the portfolio.[18]

The Exchange further represents that the Shares are deemed to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. In support of this proposal, the Exchange has made representations, including:

(1) The Shares will conform to the initial and continued listing criteria under NYSE Arca Equities Rule 8.600.

(2) The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions.

(3) The Exchange's surveillance procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws.

(4) Prior to the commencement of trading, the Exchange will inform its Equity Trading Permit (''ETP'') Holders in an Information Bulletin of the special characteristics and risks associated with trading the Shares. Specifically, the Information Bulletin will discuss the following: (a) The procedures for purchases and redemptions of Shares in Creation Unit aggregations (and that Shares are not individually redeemable); (b) NYSE Arca Equities Rule 9.2(a), which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Shares; (c) the risks involved in trading the Shares during the Opening and Late Trading Sessions when an updated Portfolio Indicative Value will not be calculated or publicly disseminated; (d) how information regarding the Portfolio Indicative Value is disseminated; (e) the requirement that ETP Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (f) trading information.

(5) For initial and/or continued listing, the Fund will be in compliance with Rule 10A–3 under the Act,[19] as provided by NYSE Arca Equities Rule 5.3.

(6) The Fund will not invest in non-U.S. equity securities, loan participation agreements, and Rule 144A securities. In addition, pursuant to the terms of the Exemptive Order, the Fund will not invest in options contracts, futures contracts, or swap agreements. The Fund's investments will be consistent with the Fund's investment objective and will not be used to enhance leverage. The Fund will not purchase illiquid securities.

(7) A minimum of 100,000 Shares of the Fund will be outstanding at the commencement of trading on the Exchange.

This approval order is based on the Exchange's representations.

For the foregoing reasons, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act[20] and the rules and regulations thereunder applicable to a national securities exchange.

IV. Conclusion

It Is Therefore Ordered, pursuant to Section 19(b)(2) of the Act,[21] that the proposed rule change (SR–NYSEArca–2011–51) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–26135 Filed 10–7–11; 8:45 am]

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the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A–1 under the Advisers Act. In addition, Rule 206(4)–7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) Adopted and implemented written policies and procedures reasonably designed to prevent violation, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) Above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

[18] *See* NYSE Arca Equities Rule 8.600(d)(2)(B)(ii).

[19] *See* 17 CFR 240.10A–3.

[20] 15 U.S.C. 78f(b)(5).

[21] 15 U.S.C. 78s(b)(2).

[22] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65479; File No. SR–FICC–2011–06]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Order Approving Proposed Rule Change To Eliminate Two Rules of the Mortgage-Backed Securities Division That FICC Believes Are No Longer Utilized or Necessary

October 4, 2011.

I. Introduction

On August 17, 2011, Fixed Income Clearing Corporation (''FICC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change SR–FICC–2011–06 pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder.[2] The proposed rule change was published for comment in the Federal Register on August 31, 2011.[3] The Commission received no comment letters. For the reasons discussed below, the Commission is granting approval of the proposed rule change.

II. Description

This rule change will eliminate two Mortgage-Backed Securities Division (''MBSD'') rules which FICC believes are no longer utilized or necessary. The first rule that will be eliminated is Article II, Rule 1, Section 3, which was put in place to stem certain abuses of cash adjustments taking place in the mid to late 1990s (specifically, traders were manipulating pricing on their submission of trades in order to maximize their cash adjustments). Because cash adjustments were deleted from the rules via the approved rule filing FICC 2010–08,[4] FICC believes the rule imposing trade restrictions between accounts is no longer necessary.

The second rule that will be eliminated relates to the ''match modes'' currently referenced in the MBSD rules. Currently, the rules provide that dealers may elect to have the comparison of their transactions governed in either ''Exact Match Mode'' or ''Net Position Match Mode.'' In Exact Match Mode, trade input that matches in all other respects will be compared only if the par amount of the eligible securities reported to have been sold or purchased

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 34–65198 (August 25, 2011), 76 FR 54268 (August 31, 2011).

[4] *See* Securities Exchange Act Release No. 34–63611 (December 28, 2010), 76 FR 408 (January 4, 2011) (SR–FICC–2010–08).

by the dealer for a particular transaction is identical to the par amount for a particular transaction reported by the broker. In a Net Position Match Mode, trade input that matches in all other respects will be compared only if the aggregate par amount for one or more transactions in eligible securities reported to have been sold or purchased by the dealer equals the aggregate par amount for one or more transactions reported by the broker. Currently, no participants have elected to have their transactions governed in Exact Match Mode. FICC believes there is no need to provide participants with a choice of match mode because MBSD's system already attempts to find an exact match for trade input and, only if an exact match is not found, will the system revert to Net Position Match Mode. This change will require the deletion of subpart (a) of Article II, Rule 3, Section 4 and conforming changes to the definitions (in Article I) and in Article II, Rule 3, Sections 3 and 4 to reflect that Net Position Match Mode will be the only available match mode.

Given that FICC believes these rules have no utility for MBSD's participants, MBSD proposed to eliminate these rules. FICC believes elimination of these rules will also promote efficiency. MBSD is currently undertaking a rewrite of its internal software applications and operating systems to promote efficiency and streamline its operations. Approval of the elimination of these rules will allow MBSD to avoid writing unnecessary coding during the rewrite process.

III. Discussion

Section 17A(b)(3)(F) of the Act [5] requires, among other things, that the rules of a clearing agency be designed to remove impediments to and perfect the mechanism of a national system for the prompt and accurate clearance and settlement of securities transactions. The Commission believes that because the proposed rule change removes outdated rules that no longer have utility for participants and conserves resources by avoiding the writing of unnecessary code during MBSD's software rewrite process, it is consistent with the requirements of Section 17A(b)(3)(F) of the Act.

IV. Conclusion

On the basis of the foregoing, the Commission finds that the proposal is consistent with the requirements of the Act and in particular with the requirements of Section 17A of the Act [6] and the rules and regulations thereunder.

It Is Therefore Ordered, pursuant to Section 19(b)(2) of the Act,[7] that the proposed rule change (File No. SR–FICC–2011–06) be, and hereby is, approved.[8]

For the Commission by the Division of Trading and Markets, pursuant to delegated authority.[9]

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–26136 Filed 10–7–11; 8:45 am]

BILLING CODE 8011–01–P

[5] 15 U.S.C. 78q–1(b)(3)(F).

[6] 15 U.S.C. 78q–1.

[7] 15 U.S.C. 78s(b)(2).

[8] In approving the proposed rule change, the Commission considered the proposal's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[9] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65480; File No. SR–CBOE–2011–091]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend CBOE Stock Exchange Transaction Fees

October 4, 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 30 2011, the Chicago Board Options Exchange, Incorporated (''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend CBOE Stock Exchange (''CBSX'') transaction fees. The text of the proposed rule change is available on the Exchange's Web site (*http://www.cboe.org/legal*), at the Exchange's Office of the Secretary, and at the Commission.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

CBSX proposes to modify its fees for transactions in securities priced $1 or greater. The Exchange proposes to adopt a Maker fee of $0.0017 per share and a Taker rebate of $0.0015 per share. For a Maker that adds more than two million shares of liquidity to CBSX in a single day, the Exchange proposes a fee of $0.0015 per share. This lower rate will be calculated on a daily basis. Market participants who share a trading acronym or MPID may aggregate their trading activity for purposes of this rate. Qualification for this rate will require that a market participant appropriately indicate his trading acronym and/or MPID in the appropriate field on the order. CBSX will promulgate an information circular to direct market participants on how to accurately qualify and aggregate their trading activity in order to receive this reduced rate. CBSX also proposes to change the language on the Fees Schedule describing the execution type for transactions in securities priced below $1 from ''Single-sided execution'' to ''Maker or Taker'' in order to achieve consistency on the Fee Schedule and make clear that such fee applies to either the Maker or the Taker in transactions in securities priced below $1.

The proposed fee change for transactions in securities priced at $1 or greater is intended to encourage increased trading activity and liquidity on CBSX, which would benefit all market participants. By encouraging market participants to hit a threshold of executing at least two million shares a day (at which point such market participants would receive the lower Maker fee for all shares executed by the market participant that day), the Exchange incentivizes market

participants who may be able to meet that threshold to add more volume and liquidity to the CBSX marketplace. This increased volume and liquidity would benefit all CBSX market participants, including those who do not trade at that level, by providing them with more opportunities for execution. If the lower rate did not exist for market participants who execute at least two million shares a day, even those market participants who do not hit that threshold will not receive the benefit of this added volume and liquidity. The threshold is applied on a daily basis in order to encourage market participants to add volume and liquidity on a consistent basis. The Exchange seeks market participants who will be active on CBSX on a regular basis, as the liquidity that such larger-volume participants provide will be attractive to all investors and benefit all market participants.

The proposed rule change is to take effect October 1, 2011.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act [3] in general, and furthers the objectives of Section 6(b)(4) [4] of the Act in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among CBOE Trading Permit Holders and other persons using Exchange facilities. The proposed Maker fees of $0.0017 per share or $0.0015 per share for a Maker that adds more than two million shares of liquidity in a single day and Taker Rebate of $0.0015 are reasonable because they are within the range of fees assessed for similar transactions in securities priced $1 or greater on other exchanges.[5] The fees are equitable and not unfairly discriminatory because they will apply to all market participants, and all market participants will have the opportunity to qualify for the reduced rate for a Maker that adds more than two million shares of liquidity in a single day.

Further, the reduced fee for market participants that execute at least two million shares a day is equitable and not unfairly discriminatory because it will encourage market participants to trade on CBSX and bring greater liquidity to CBSX, which will benefit all market participants. By encouraging market participants to hit a threshold of executing at least two million shares a day (at which point such market participants would receive the lower Maker fee for all shares executed by the market participant that day), the Exchange incentivizes market participants who may be able to meet that threshold to add more volume and liquidity to the CBSX marketplace. This increased volume and liquidity would benefit all CBSX market participants, including those who do not trade at that level, by providing them with more opportunities for execution. Orders that provide liquidity increase the likelihood that members seeking to access liquidity will have their orders filled. If the lower rate did not exist for market participants who execute at least two million shares a day, even those market participants who do not hit that threshold will not receive the benefit of this added volume and liquidity. Applying the two million share threshold on a daily basis will encourage these larger-volume market participants to add volume and liquidity on a consistent basis, and the resulting consistently-available executions will benefit all market participants. As such, the Exchange believes that it is reasonable and equitable to use pricing incentives, such as a lower fee for creating large amounts of liquidity, to encourage market participants to increase their participation in the market.

Finally, changing the language on the Fees Schedule describing the execution type for transactions in securities priced below $1 from ''Single-sided execution'' to ''Maker or Taker'' furthers the objectives of Section 6(b)(5) [6] of the Act in particular in that the change is designed to 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 by achieving consistency in the language of the Fees Schedule, thereby eliminating any potential confusion.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The proposed rule change is designated by the Exchange as establishing or changing a due, fee, or other charge, thereby qualifying for effectiveness on filing pursuant to Section 19(b)(3)(A) of the Act [7] and subparagraph (f)(2) of Rule 19b–4 [8] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–CBOE–2011–091 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2011–091. 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

[3] 15 U.S.C. 78f(b).

[4] 15 U.S.C. 78f(b)(4).

[5] *See* NASDAQ OMX BX, Inc. (''BX'') Fee Schedule regarding trading of shares executed at or above $1.00. The BX rebate for removing liquidity is $0.0005 per share, or $0.0014 per share for MPIDs removing greater than 3.5 million shares per day or adding greater than 25,000 shares per day. The proposed CBSX rebate is $0.0015 per share. The BX fee for adding liquidity is $0.0018 per share, or $0.0015 for MPIDs meeting BX's Qualified Liquidity Provider Program criteria. The proposed CBSX fee is $0.0017 per share, or $0.0015 per share for a Maker that adds more than two million shares of liquidity in a single day.

[6] 15 U.S.C. 78f(b)(5).

[7] 15 U.S.C. 78s(b)(3)(A).

[8] 17 C.F.R. 240.19b–4(f)(2).

communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2011–091 and should be submitted on or before November 1, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–26137 Filed 10–7–11; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65482; File No. SR–C2–2011–028]

Self-Regulatory Organizations; C2 Options Exchange, Incorporated: Notice of Filing and Immediate Effectiveness of Proposed Rule ChangeRelating to PULSe Fees

October 4, 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 October 3, 2011, C2 Options Exchange, Incorporated (''Exchange'' or ''C2'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, Ii and III below, which Items have been prepared by the Exchange. The Exchange has designated this proposal as one establishing or changing a 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] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing to amend its Fees Schedule as it relates to the PULSe workstation. The text of the proposed rule change is available on the Exchange's Web site (*http://www.c2exchange.com*), at the Exchange's Office of the Secretary and at the Commission.

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 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 aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, Proposed Rule Change

1. Purpose

The purpose of this proposed rule change is to adopt a PULSe routing fee for executions of orders on C2 that originate from non-Trading Permit Holder (''TPH'') PULSe workstations. The Exchange is also proposing some non-substantive changes to the fees schedule text to clarify the existing operation of the Routing Intermediary fee. These changes, which are described in more detail below, will be effective October 3, 2011.[5]

By way of background, the PULSe workstation is a front-end order entry system designed for use with respect to orders that may be sent to the trading systems of C2. In addition, the PULSe workstation provides a user with the capability to send options orders to other U.S. options exchanges and stock orders to other U.S. stock exchanges and trading centers (''away market routing'').[6] To use the away-market routing functionality, a C2 TPH must either be a PULSe Routing Intermediary or establish a relationship with a third party PULSe Routing Intermediary. A ''PULSe Routing Intermediary'' is a C2 TPH that has connectivity to, and is a member of, other options and/or stock exchanges and trading centers. If a TPH sends an order from the PULSe workstation, the PULSe Routing Intermediary will route that order to the designated market on behalf of the entering TPH.[7]

The first purpose of this proposed rule change is to adopt a C2 Routing fee. This fee would be payable by a TPH that makes the PULSe workstation available to non-TPHs and would only be applicable for routing to C2 from such non-TPH PULSe workstations. The fee would be $0.02 per contract or share equivalent for the first 1 million contracts or share equivalent executed in a month on C2 that originate from non-TPH PULSe workstations made available by the TPH, and $0.03 per contract or share equivalent for each additional contract or share equivalent executed on C2 in the same month from the non-TPH PULSe workstations made available by the TPH.[8]

[9] 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] *See* e-mail from Jennifer M. Lamie, Assistant Secretary, C2, to Steve L. Kuan, Attorney, Division of Trading and Markets, Commission, on October 3, 2011.

[6] For a more detailed description of the PULSe workstation and its other functionalities, *see, e.g.,* Securities Exchange Act Release Nos. 63246 (November 4, 2010), 75 FR 69478 (November 12, 2010) (SR–C2–2010–007) and 65279 (September 7, 2011), 76 FR 56824 (September 14, 2011) (SR–C2–2011–020).

[7] The PULSe workstation offers the ability to route orders to any market including, among others, C2 affiliates Chicago Board Options Exchange, Incorporated (''CBOE'') and CBOE Stock Exchange, LLC (''CBSX,'' CBOE's stock execution facility). To the extent a C2 TPH that is also a CBOE/CBSX TPH obtains a PULSe workstation through CBOE, it is not necessary for that TPH to obtain a separate PULSe workstation through CBOE or CBSX to route orders to CBOE or CBSX, as applicable. *See, e.g.,* SR–C2–2010–007, note 5, *supra.* It is also not necessary for that TPH to utilize the services of a Routing Intermediary to route orders to CBOE or CBSX, as applicable. As such, to the extent a C2 TPH is also a CBOE TPH or a CBSX TPH, the ''Away-Market Routing'' and ''Routing Intermediary'' fees detailed in the Exchange Fees Schedule are not be applicable because the fees are only applicable for away-market routing. The TPH would not be away-market routing, but instead would be submitting orders directly to C2 as a C2 TPH, CBOE as a CBOE TPH or CBSX as a CBSX TPH, as applicable, where the TPH's activity would be subject to the transaction fee schedule of C2, CBOE or CBSX, respectively. To the extent a C2 TPH is not a CBOE TPH or a CBSX TPH, the Away-Market Routing and Routing Intermediary fees would apply for the TPH's executions on CBOE or CBSX, as applicable.

[8] The Exchange notes that CBOE is submitting a similar rule change to introduce a ''CBOE/CBSX Routing'' fee that will be applicable to CBOE TPHs and CBSX TPHs. See SR–CBOE–2011–092. To the extent that a C2 TPH making the non-TPH PULSe workstations available is not also a CBOE TPH or a CBSX TPH, routing from the non-TPH workstations to CBOE or CBSX would not be considered ''CBOE/CBSX Routing'' and, therefore, would not be subject to that fee (it would instead be considered ''away-market routing'' and subject to the Away-Market Routing and Routing Intermediary fees described above). To the extent that a C2 TPH

Continued

The C2 Routing fee will allow for the recoupment of the costs of developing, maintaining, and supporting the PULSe workstation and for income from the value-added services being provided through use of the PULSe workstation. The Exchange believes the fee structure represents an equitable allocation of reasonable fees in that the same fees will be applicable to all TPHs that make PULSe workstations available to non-TPHs. The Exchange also believes that the establishment of the fee, which is payable by TPHs only for transactions originating from non-TPH workstations, is equitable and not unfairly discriminatory because non-TPHs are able to obtain the benefits of utilizing the PULSe workstation—including the ability to route orders to the Exchange—without becoming a TPH (and incurring the associated costs of TPH membership). In addition, the Exchange believes that the $0.02/$0.03 C2 Routing fee is reasonable and appropriate in light of the facts that it is small in relation to the total costs typically incurred in routing and executing orders and that the amount is comparable to the Exchange's existing Routing Intermediary fee for away-market routing. The Exchange notes that the lower $0.02 rate for the first 1 million contracts or share equivalent (as compared to the $0.03 rate for each additional contract or share equivalent) is reasonable in that it is designed to help attract and encourage use of the PULSe workstation. The Exchange also notes that use of the PULSe workstation, and the routing technology available through the PULSe workstation, are not compulsory. The service is offered as a convenience and is not the exclusive means available to send or route orders to C2 (or another market).

The second purpose of this proposed rule change is to revise and expand on the description in the Fees Schedule text of the ''Routing Intermediary'' fee.[9] In particular, the Exchange is renaming the fee from ''Routing Intermediary'' fee to ''Away-Market Routing Intermediary'' fee. Because this fee is only applicable when a Routing Intermediary is routing to away markets, the Exchange believes this change in title will be more descriptive and helpful to persons reading the Fees Schedule. Likewise, the Exchange is expanding on the description in the text to make clear that the ''Away-Market Routing Intermediary'' fee is payable by a Routing Intermediary and is only applicable for away-market routing from any PULSe workstation. The expanded description also makes clear that the fee rates are determined based on the aggregate level of transactions across all away-markets and across all PULSe workstations for which firm serves as the Routing Intermediary. This level of detail on the meaning and application of the fee was previously included in the discussion section of prior rule filings and is consistent with the Exchange's original intent and understanding the fee structure.[10] The Exchange is simply proposing to include the clarifying information within the text of the Fees Schedule.

2 Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[11] in general, and furthers the objectives of Section 6(b)(4) of the Act,[12] in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among TPHs in that the same fees are applicable to all TPHs that utilize the PULSe workstation or make it available to non-TPHs.

With respect to the C2 Routing fee in particular, the Exchange believes that the establishment of the C2 Routing fee, which is payable by TPHs only for transactions originating from non-TPH workstations, is equitable and not unfairly discriminatory because, from the TPH perspective, as indicated above, the same fees are applicable to all TPHs that make the PULSe workstation available to non-TPHs. In addition, because non-TPHs are able to obtain the benefits of utilizing the PULSe workstation—including the ability to route orders to the Exchange—without becoming a TPH (and incurring the associated costs of TPH membership), the Exchange believes it is equitable and not unfairly discriminatory for the Exchange to assess the C2 Routing fee to TPHs for executions of orders originating from non-TPH PULSe workstations. The Exchange believes that the $0.02/$0.03 C2 Routing fee rate itself—which will allow for the recoupment of the costs of developing, maintaining, and supporting the PULSe workstation and for income from the value-added services being provided through use of the PULSe workstation—is reasonable and appropriate in light of the facts that it is small in relation to the total costs typically incurred in routing and executing orders and that the amount is comparable to the Exchange's existing Routing Intermediary fee for away-market routing. The Exchange also believes that the lower $0.02 rate for the first 1 million contracts or share equivalent (as compared to the $0.03 rate for each additional contract or share equivalent) is reasonable in that it is designed to help attract and encourage use of the PULSe workstation. Finally, in our consideration that the fee is equitable and not unfairly discriminatory, the Exchange note that use of the PULSe workstation, and the routing technology available through the PULSe workstation, are not compulsory. The service is offered as a convenience and is not the exclusive means available to send or route orders to C2 (or another market).

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The proposed rule change is designated by the Exchange as establishing or changing a due, fee, or other charge, thereby qualifying for

making the non-TPH PULSe workstations available *is* also a CBOE TPH or CBSX TPH, routing from the non-TPH workstations to CBOE or CBSX would be considered ''CBOE/CBSX Routing'' and therefore would be subject to that fee.

Example 1: Assume a *C2 TPH* that is *not* a *CBOE TPH* makes a PULSe workstation available to Non-TPH User A. To the extent that orders originating from Non-TPH User A's PULSe workstation are routed to *C2,* any resulting executions would be subject to the C2 Routing fee. To the extent that orders originating from Non-TPH User A's PULSe workstation are routed to *CBOE,* any resulting executions would be considered away-market routing and subject to the Away-Market Routing and Routing Intermediary fees (and not subject to the CBOE/CBSX Routing fee).

Example 2: Assume a *C2 TPH* that *is* also a *CBOE TPH* makes a PULSe workstation available to Non-TPH User A. To the extent that orders originating from Non-TPH User A's PULSe workstation are routed to *C2,* any resulting executions would be subject to the C2 Routing fee. To the extent that orders originating from Non-TPH User A's PULSe workstation are routed to *CBOE,* any resulting executions would be subject to the CBOE/CBSX Routing fee. (Given the C2 TPH's status as a CBOE TPH, such orders are not considered away-market routing and therefore are not subject to the Away-Market Routing and Routing Intermediary fees.)

[9] This fee is currently $0.02 per contract or share equivalent for the first 1 million contracts or share equivalent executed in a month and $0.03 per contract or share equivalent for each additional contract or share equivalent executed in the same month.

[10] *See, e.g.,* SR–C2–2011–020, note 5, *supra.*

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(4).

effectiveness on filing pursuant to Section 19(b)(3)(A)(ii) of the Act[13] and subparagraph (f)(2) of Rule 19b–4[14] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

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–C2–2011–028 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–C2–2011–028. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–C2–2011–028 and should be submitted on or before November 1, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Elizabeth M. Murphy,

Secretary.

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[13] 15 U.S.C. 78s(b)(3)(A)(ii).

[14] 17 CFR 240.19b–4(f)(2).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65481; File No. SR–CBOE–2011–092

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated: Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to PULSe Fees

October 4, 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 October 3, 2011, the Chicago Board Options Exchange, Incorporated (''CBOE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by CBOE. The Exchange has designated this proposal as one establishing or changing a due, fee, or other charge imposed by CBOE under Section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing to amend its Fees Schedule as it relates to the PULSe workstation. The text of the proposed rule change is availableon the Exchange's Web site *http://www.cboe.org/legal*), at the Exchange's Office of the Secretary and at the Commission.

[1] 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).

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, CBOE 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 examined at the places specified in Item IV below. CBOE 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, Proposed Rule Change

1. Purpose

The purpose of this proposed rule change is to adopt a PULSe routing fee for executions of orders on CBOE and CBOE Stock Exchange, LLC (''CBSX,'' CBOE's stock execution facility) that originate from non-Trading Permit Holder (''TPH'') PULSe workstations. The Exchange is also proposing some non-substantive changes to the fees schedule text to clarify the existing operation of the Routing Intermediary fee. These changes, which are described in more detail below, will be effective October 3, 2011.[5]

By way of background, the PULSe workstation is a front-end order entry system designed for use with respect to orders that may be sent to the trading systems of CBOE and CBSX. In addition, the PULSe workstation provides a user with the capability to send options orders to other U.S. options exchanges and stock orders to other U.S. stock exchanges and trading centers (''away-market routing'').[6] To use the away-market routing functionality, a CBOE or CBSX TPH must either be a PULSe Routing Intermediary or establish a relationship with a third party PULSe Routing Intermediary. A ''PULSe Routing Intermediary'' is a CBOE or CBSX TPH that has connectivity to, and is a member of, other options exchanges and/or stock exchanges and trading

[5] *See* e-mail from Jennifer M. Lamie, Assistant Secretary, CBOE, to Steve L. Kuan, Attorney, Division of Trading and Markets, Commission, on October 3, 2011.

[6] For a more detailed description of the PULSe workstation and its other functionalities, *see, e.g.,* Securities Exchange Act Release Nos. 62286 (June 11, 2010), 75 FR 34799 (June 18, 2010) (SR–CBOE–2010–051); 63244 (November 4, 2010), 75 FR 69148 (November 10, 2010) (SR–CBOE–2010–100); 63721 (January 14, 2011), 76 FR 3929 (January 21, 2011) (SR–CBOE–2011–001); and 65280 (September 7, 2011), 76 FR 56838 (September 14, 2011) (SR–CBOE–2011–083).

centers. If a TPH sends an order from the PULSe workstation, the PULSe Routing Intermediary will route that order to the designated market on behalf of the entering TPH.[7]

The first purpose of this proposed rule change is to adopt a CBOE/CBSX Routing fee. This fee would be payable by a TPH that makes the PULSe workstation available to non-TPHs and would only be applicable for routing to CBOE/CBSX from such non-TPH PULSe workstations. The fee would be $0.02 per contract or share equivalent for the first 1 million contracts or share equivalent executed in a month on CBOE/CBSX that originate from the non-TPH PULSe workstations made available by the TPH, and $0.03 per contract or share equivalent for each additional contract or share equivalent executed on CBOE/CBSX in the same month from the non-TPH PULSe workstations made available by the TPH.[8]

The CBOE/CBSX Routing fee will allow for the recoupment of the costs of developing, maintaining, and supporting the PULSe workstation and for income from the value-added services being provided through use of the PULSe workstation. The Exchange believes the fee structure represents an equitable allocation of reasonable fees in that the same fees will be applicable to all TPHs that make PULSe workstations available to non-TPHs. The Exchange also believes that the establishment of the fee, which is payable by TPHs only for transactions originating from non-TPH workstations, is equitable and not unfairly discriminatory because non-TPHs are able to obtain the benefits of utilizing the PULSe workstation—including the ability to route orders to the Exchange—without becoming a TPH (and incurring the associated costs of TPH membership). In addition, the Exchange believes that the $0.02/$0.03 CBOE/CBSX Routing fee is reasonable and appropriate in light of the facts that it is small in relation to the total costs typically incurred in routing and executing orders and that the amount is comparable to the Exchange's existing Routing Intermediary fee for away-market routing. The Exchange notes that the lower $0.02 rate for the first 1 million contracts or share equivalent (as compared to the $0.03 rate for each additional contract or share equivalent) is reasonable in that it is designed to help attract and encourage use of the PULSe workstation. The Exchange also notes that use of the PULSe workstation, and the routing technology available through the PULSe workstation, are not compulsory. The service is offered as a convenience and is not the exclusive means available to send or route orders to CBOE or CBSX (or another market).

The second purpose of this proposed rule change is to revise and expand on the description in the Fees Schedule text of the ''Routing Intermediary'' fee.[9] In particular, the Exchange is renaming the fee from ''Routing Intermediary'' fee to ''Away-Market Routing Intermediary'' fee. Because this fee is only applicable when a Routing Intermediary is routing to away markets, the Exchange believes this change in title will be more descriptive and helpful to persons reading the Fees Schedule. Likewise, the Exchange is expanding on the description in the text to make clear that the ''Away-Market Routing Intermediary'' fee is payable by a Routing Intermediary and is only applicable for away-market routing from any PULSe workstation. The expanded description also makes clear that the fee rates are determined based on the aggregate level of transactions across all away-markets and across all PULSe workstations for which firm serves as the Routing Intermediary. This level of detail on the meaning and application of the fee was previously included in the discussion section of prior rule filings and is consistent with the Exchange's original intent and understanding the fee structure.[10] The Exchange is simply proposing to include the clarifying information within the text of the Fees Schedule.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[11] in general, and furthers the objectives of Section 6(b)(4) of the Act,[12] in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among TPHs in that the same fees are applicable to all TPHs that utilize the PULSe workstation or make it available to non-TPHs.

With respect to the CBOE/CBSX Routing fee in particular, the Exchange believes that the establishment of the CBOE/CBSX Routing fee, which is payable by TPHs only for transactions originating from non-TPH workstations, is equitable and not unfairly discriminatory because, from the TPH perspective, as indicated above, the same fees are applicable to all TPHs that make the PULSe workstation available to non-TPHs. In addition, because non-TPHs are able to obtain the benefits of utilizing the PULSe workstation—including the ability to route orders to the Exchange—without becoming a TPH (and incurring the associated costs of TPH membership), the Exchange believes it is equitable and not unfairly

[7] The PULSe workstation offers the ability to route orders to any market including, among others, CBOE/CBSX affiliate C2 Options Exchange, Incorporated (''C2''). To the extent a CBOE/CBSX TPH that is also a C2 TPH obtains a PULSe workstation through CBOE, it is not necessary for that TPH to obtain a separate PULSe workstation through C2 to route orders to C2. *See, e.g.,* SR–CBOE–2010–100 and SR–CBOE–2011–083, note 5, *supra.* It is also not necessary for that TPH to utilize the services of a Routing Intermediary to route orders to C2. As such, to the extent a CBOE/CBSX TPH is also a C2 TPH, the ''Away-Market Routing'' and ''Routing Intermediary'' fees detailed in the Exchange Fees Schedule are not be applicable because the fees are only applicable for away-market routing. The TPH would not be away-market routing, but instead would be submitting orders directly to CBOE as a CBOE TPH, CBSX as a CBSX TPH or C2 as a C2 TPH, as applicable, where the TPH's activity would be subject to the transaction fee schedule of CBOE, CBSX or C2, respectively. To the extent a CBOE/CBSX TPH is not a C2 TPH, the Away-Market Routing and Routing Intermediary fees would apply for the CBOE/CBSX TPH's executions on C2.

[8] The Exchange notes that C2 is submitting a similar rule change to introduce a ''C2 Routing'' fee that will be applicable to C2 TPHs. *See* SR–C2–2011–028. To the extent that a CBOE TPH making the non-TPH PULSe workstations available is not also a CBSX TPH or a C2 TPH, routing from the non-TPH workstations to CBSX or C2 would not be considered ''CBOE/CBSX Routing'' or ''C2 Routing,'' respectively, and, therefore, would not be subject to those fees (it would instead be considered ''away-market routing'' and subject to the Away-Market Routing and Routing Intermediary fees described above). To the extent that a CBOE TPH making the non-TPH PULSe workstations available is also a CBSX TPH or C2 TPH, routing from the non-TPH workstations to CBSX or C2 would be considered ''CBOE/CBSX Routing'' or ''C2 Routing,'' respectively, and therefore would be subject to the respective fee.

Example 2: Assume a *CBOE TPH* that is *not* a *C2 TPH* makes a PULSe workstation available to Non-TPH User A. To the extent that orders originating from Non-TPH User A's PULSe workstation are routed to *CBOE,* any resulting executions would be subject to the CBOE/CBSX Routing fee. To the extent that orders originating from Non-TPH User A's PULSe workstation are routed to *C2,* any resulting executions would be considered away-market routing and subject to the Away-Market Routing and Routing Intermediary fees (and not subject to the C2 Routing fee).

Example 1: Assume a *CBOE TPH* that *is* also a *C2 TPH* makes a PULSe workstation available to Non-TPH User A. To the extent that orders originating from Non-TPH User A's PULSe workstation are routed to *CBOE,* any resulting executions would be subject to the CBOE/CBSX Routing fee. To the extent that orders originating from Non-TPH User A's PULSe workstation are routed to *C2,* any resulting executions would be subject to the C2 Routing fee. (Given the CBOE TPH's status as a C2 TPH, such orders are not considered away-market routing and therefore are not subject to the Away-Market Routing and Routing Intermediary fees.)

[9] This fee is currently $0.02 per contract or share equivalent for the first 1 million contracts or share equivalent executed in a month and $0.03 per contract or share equivalent for each additional contract or share equivalent executed in the same month.

[10] *See, e.g.,* SR–CBOE–2011–083, note 5, *supra.*

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(4).

discriminatory for the Exchange to assess the CBOE/CBSX Routing fee to TPHs for executions of orders originating from non-TPH PULSe workstations. The Exchange believes that the $0.02/$0.03 CBOE/CBSX Routing fee rate itself—which will allow for the recoupment of the costs of developing, maintaining, and supporting the PULSe workstation and for income from the value-added services being provided through use of the PULSe workstation—is reasonable and appropriate in light of the facts that it is small in relation to the total costs typically incurred in routing and executing orders and that the amount is comparable to the Exchange's existing Routing Intermediary fee for away-market routing. The Exchange also believes that the lower $0.02 rate for the first 1 million contracts or share equivalent (as compared to the $0.03 rate for each additional contract or share equivalent) is reasonable in that it is designed to help attract and encourage use of the PULSe workstation. Finally, in our consideration that the fee is equitable and not unfairly discriminatory, the Exchange note that use of the PULSe workstation, and the routing technology available through the PULSe workstation, are not compulsory. The service is offered as a convenience and is not the exclusive means available to send or route orders to CBOE or CBSX (or another market).

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The proposed rule change is designated by the Exchange as establishing or changing a due, fee, or other charge, thereby qualifying for effectiveness on filing pursuant to Section 19(b)(3)(A)(ii) of the Act [13] and subparagraph (f)(2) of Rule 19b–4 [14] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–CBOE–2011–092 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2011–092. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2011–092 and should be submitted on or before November 1, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–26139 Filed 10–7–11; 8:45 am]

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[13] 15 U.S.C. 78s(b)(3)(A)(ii).

[14] 17 CFR 240.19b–4(f)(2).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65484 File No. SR–OCC–2011–14]

Self-Regulatory Organizations; Options Clearing Corporation; Notice of Filing of Proposed Rule Relating to Clearing Options on the CBOE Silver Volatility Index

October 4, 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 27, 2011, The Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared primarily by OCC. 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 proposed rule change would allow OCC to add an interpretation following the introduction in Article XVII of OCC's By-Laws, clarifying that OCC will clear and treat as securities options any option contracts on the CBOE Silver ETF Volatility Index.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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

The purpose of the proposed rule change is to remove any potential cloud on the jurisdictional status of options on the CBOE Silver ETF Volatility Index, which is an index that measures the implied volatility of options on the iShares Silver Trust, an exchange-traded fund designed to reflect the performance of the price of silver.[3] To accomplish this purpose, OCC is proposing to amend the interpretation and policy following the introduction in Article XVII of OCC's By-Laws to clarify that OCC will clear and treat as securities options any option contracts on the CBOE Silver ETF Volatility Index. On December 29, 2010, the Commission approved rule filing SR–OCC–2010–07, which added the existing interpretation, which relates to the treatment and clearing of options on the CBOE Gold ETF Volatility Index.

In its capacity as a ''derivatives clearing organization'' registered as such with the CFTC, OCC is filing this proposed rule change for prior approval by the CFTC pursuant to provisions of the Commodity Exchange Act (the ''CEA'') in order to foreclose any potential liability under the CEA based on an argument that the clearing by OCC of such options as securities options constitutes a violation of the CEA.

OCC believes that the proposed interpretation of OCC's By-Laws is consistent with the purposes and requirements of Section 17A of the Exchange Act because it is designed to promote the prompt and accurate clearance and settlement of transactions in securities options, to foster cooperation and coordination with persons engaged in the clearance and settlement of such transactions, to remove impediments to and perfect the mechanism of a national system for the prompt and accurate clearance and settlement of such transactions, and, in general, to protect investors and the public interest. It accomplishes this purpose by reducing the likelihood of a dispute as to the Commission's jurisdiction over options based on the CBOE Silver ETF Volatility Index. The proposed rule change is not inconsistent with the By-Laws and Rules of OCC.

(B) Self-Regulatory Organization's Statement on Burden on Competition

OCC does not believe that the proposed rule change would impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were not and are not intended to be solicited with respect to the proposed rule change and none have been received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) As the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve or disapprove the proposed rule change or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

• Use the Commissions 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–OCC–2011–14 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–OCC–2011–14. 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 Section, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 pm. Copies of such filings will also be available for inspection and copying at the principal office of OCC and on OCC's Web site at*http://www.optionsclearing.com/components/docs/legal/rules_and_bylaws/sr_occ_11_14.pdf.*

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–OCC–2011–14 and should be submitted on or before November 1, 2011.

For the Commission by the Division of Trading and Markets, pursuant to delegated authority.[4]

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–26140 Filed 10–7–11; 8:45 am]

BILLING CODE 8011–01–P

[3] The staff notes that on August 11, 2011, the Commission issued an Order granting approval of a proposed rule change to trade options on the CBOE Silver ETF Volatility Index. *See* Securities Exchange Act Release No. 34–65116, 76 FR 51099 (August 17, 2011).

[4] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65473; File No. SR–BATS–2011–043]

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.

October 3, 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 30, 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, II, and III below, which Items have been prepared by the Exchange.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 October 3, 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 the ''Options Pricing'' section of its fee schedule to: (i) Decrease the fees applicable to Customer [6] orders that remove liquidity from the BATS options market (''BATS Options''); (ii) eliminate a pricing structure that provides a Firm [7] or Market Maker [8] a reduced fee to remove liquidity if such Firm or Market Maker satisfies certain volume thresholds; (iii) increase the rebate applicable to Customer orders that add liquidity to BATS Options; (iv) modify the rebates paid, subject to average daily volume requirements, for orders that set either the national best bid (the ''NBB'') or the national best offer (the ''NBO''); and (v) modify a program intended to incentivize sustained, aggressive quoting in certain specified options series (the ''Quoting Incentive Program'' or ''QIP'').

(i) Decrease to Customer Liquidity Removal Fees

The Exchange currently charges standard fees of $0.32 per contract for Customer orders that remove liquidity from BATS Options. The Exchange proposes to decrease this fee to $0.30 per contract, subject to potential reduction for any Member with an ADV of 0.30% or more of average TCV on BATS Options, as described below.

The Exchange currently maintains a tiered pricing structure through which Members can realize lower liquidity removal fees if such Members have an average daily volume (''ADV'') [9] equal to or greater than 0.30% of average total consolidated volume (''TCV'').[10] For Members reaching this volume threshold, the Exchange currently charges a fee of $0.29 per contract for Customer orders. Thus, such Members currently save $0.03 per contract as compared to the standard fee to remove liquidity. While the Exchange proposes to maintain this $0.03 savings per contract for Customer orders for Members that reach the volume tier, due to the proposed decrease described above for standard liquidity removal, the Exchange proposes to decrease liquidity removal fees for Members that reach the volume tier by $0.02 per contract for Customer orders. Accordingly, for Members reaching the volume threshold, the Exchange will charge a fee of $0.27 per contract for Customer orders.

(ii) Elimination of Liquidity Removal Discount for Firms and Market Makers

As explained above, the Exchange currently maintains a tiered pricing structure through which Members can realize lower liquidity removal fees if such Members have an ADV equal to or greater than 0.30% of average TCV. For Members reaching this volume threshold, the Exchange currently charges a fee of $0.39 per contract for Firm and Market Maker orders, which is $0.03 less than the standard fee of $0.42 for such orders. The Exchange proposes to eliminate the reduced liquidity removal fee for Firm and Market Maker orders of Members that reach the volume threshold. Accordingly, the Exchange proposes to charge a fee of $0.42 per contract for all Firm and Market Maker orders that remove liquidity from BATS Options.

(iii) Increase to Customer Rebates to Add Liquidity

The Exchange currently provides a rebate of $0.22 per contract for Customer orders. The Exchange proposes to increase this rebate to $0.30 per contract. As is the case under the current pricing structure, the removing Member's fee will be determined without regard to the capacity of the adding party.

(iv) Modified Rebates for NBBO Setter Rebate Program

The Exchange currently offers a rebate upon execution for all orders that add liquidity that sets either the NBB or NBO (the ''NBBO Setter Rebate''),[11] subject to certain volume requirements. The NBBO Setter Rebate currently offered by the Exchange to such Members is $0.35 per contract for Members with an ADV equal to or greater than 0.30% of average TCV but less than 1% of average TCV and $0.45 per contract for Members with an ADV equal to or greater than 1% of TCV. The NBBO Setter Rebate is currently an exclusive rebate structure, in that qualifying executions receive the applicable rebate irrespective of any other condition. For instance, an execution that qualifies for both the NBBO Setter Rebate and the Quoting Incentive Program (as described below), would simply receive the NBBO Setter

[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] As defined on the Exchange's fee schedule, a ''Customer'' order is any transaction identified by a Member for clearing in the Customer range at the Options Clearing Corporation (''OCC'').

[7] As defined on the Exchange's fee schedule, a ''Firm'' order is any transaction identified by a Member for clearing in the Firm range at the OCC.

[8] As defined on the Exchange's fee schedule, a ''Market Maker'' order is any transaction identified by a Member for clearing in the Market Maker range at the OCC.

[9] As defined on the Exchange's fee schedule, ADV is average daily volume calculated as the number of contracts added or removed, combined, per day on a monthly basis. The fee schedule also provides that routed contracts are not included in ADV calculation.

[10] As defined on the Exchange's fee schedule, TCV is total consolidated volume calculated as the volume reported by all exchanges to the consolidated transaction reporting plan for the month for which the fees apply.

[11] An order that is entered at the most aggressive price both on the BATS Options book and according to then current OPRA data will be determined to have set the NBB or NBO for purposes of the NBBO Setter Rebate without regard to whether a more aggressive order is entered prior to the original order being executed.

Rebate and the Quoting Incentive Program would not alter the amount of the rebate. The Exchange proposes to modify the NBBO Setter Rebate such that it is additive, and thus, can be combined with other incentives and structures offered by the Exchange. Specifically, the Exchange proposes to provide an additional $0.06 per contract for executions that qualify for the NBBO Setter Rebate by Members with an ADV equal to or greater than 0.30% of average TCV but less than 1% of average TCV and an additional $0.10 per contract for qualifying executions by Members with an ADV equal to or greater than 1% of TCV. Accordingly, a Member with an execution in an option that qualifies for both an NBBO Setter Rebate and a QIP rebate (as described below) will receive the applicable initial rebate of $0.22, $0.30, or $0.32 (depending on the capacities of the party or parties to the trade), plus the proposed QIP rebate of $0.05 per contract plus the applicable NBBO Setter Rebate of either $0.06 per contract or $0.10 per contract. As such, whether the NBBO Setter Rebate is an increase or decrease for any particular Member or any particular transaction depends on a number of factors, including the level of a Member's monthly trading activity on the Exchange, whether such Member qualifies for the QIP in the applicable option, the capacity of the orders sent by the Member and, in the case of Firms and Market Makers, the capacity of the party against which such orders execute.

(v) Modification of Quoting Incentive Program (QIP)

BATS Options currently offers a Quoting Incentive Program (QIP), through which Members receive a rebate of $0.03 per contract, in addition to any other liquidity rebate other than an NBBO Setter Program liquidity rebate, for executions subject to the QIP. The QIP currently applies only to executions in options overlying XLF, CSCO, PFE, ORCL, and XRT. To qualify for the QIP a BATS Options Market Maker must be at the NBB or NBO 70% of the time for series trading between $0.03 and $5.00 for the front three (3) expiration months in that underlying during the current trading month. A Member not registered as a BATS Options Market Maker can also qualify for the QIP by quoting at the NBB or NBO 80% of the time in the same series.

The Exchange proposes two changes to the QIP. First, the Exchange proposes to increase the rebate provided pursuant to the QIP from $0.03 per contract to $0.05 per contract. Second, the Exchange proposes to expand the QIP from executions in options overlying specified securities (XLF, CSCO, PFE, ORCL, and XRT) to all options traded on BATS Options. All other aspects of the QIP currently in place will remain the same, though the Exchange does propose changing the description of the QIP on the Exchange's fee schedule because, as described above, the Exchange proposes to permit QIP rebates to be combined with NBBO Setter Rebates. Accordingly, a Member with an execution in an option that qualifies for both the QIP and an NBBO Setter Rebate will receive the applicable initial rebate of $0.22, $0.30, or $0.32 (depending on the capacities of the party or parties to the trade), plus the $0.05 per contract QIP rebate plus the applicable NBBO Setter Rebate of either $0.06 per contract or $0.10 per contract.

As is true under the current operation of the QIP, the Exchange will determine whether a market maker qualifies for QIP rebates at the end of each month by looking back at each Member's (including BATS Options Market Makers) quoting statistics during that month. If at the end of the month a Market Maker meets the 70% criteria or a Member that is not registered as a BATS Options Market Maker meets the 80% criteria, the Exchange will provide the additional rebate for all executions subject to the QIP executed by that Market Maker or Member during that month. The Exchange will provide Members with a report on a daily basis with quoting statistics so such Members can determine whether or not they are meeting the QIP criteria. The Exchange is not proposing to impose any ADV requirements in order to qualify for the QIP at this time.

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.[12] Specifically, the Exchange believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,[13] 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 changes to Exchange execution fees and rebates proposed by this filing are intended to attract order flow to the Exchange by continuing to offer competitive pricing while also creating incentives to providing aggressively priced displayed liquidity. The proposed changes to Customer pricing, including the increase to the rebate provided for Customer orders and decrease to the fee to take liquidity from the Exchange are designed to incentivize firms to send additional Customer orders to the Exchange. While certain Members that currently reach the volume threshold and remove liquidity from the Exchange with Firm and Market Maker orders will pay higher fees due to the proposal, the increased revenue received by the Exchange will be used to fund programs that the Exchange believes will attract additional liquidity, including Customer liquidity, and thus improve the depth of liquidity available on the Exchange. Accordingly, the Exchange believes that the higher access fees for Firm and Market Maker orders will benefit Members' results in trading on the Exchange to the extent the pricing structure offered by the Exchange with respect to Customer orders, the continued operation of the NBBO Setter Program, and the expansion to the Quoting Incentive Program (QIP) incentivize liquidity providers to provide more aggressively priced liquidity.

Despite the increase in fees for Members that currently receive a discount when removing liquidity with Firm or Market Maker orders, the Exchange also believes that its proposed fee structure is fair and equitable as the Exchange's standard fees generally still remain lower than standard fees charged by other markets with similar fee structures, such as NYSE Arca and Nasdaq.

The Exchange believes that continuing to base its tiered fee structure and NBBO Setter Program based on overall TCV, rather than a static number of contracts irrespective of overall volume in the options industry, is a fair and equitable approach to pricing. Volume-based tiers such as the tiers in place on the Exchange have been widely adopted in the equities markets, and are equitable and not unfairly discriminatory because they are open to all members on an equal basis and provide rebates that are reasonably related to the value to an exchange's market quality associated with higher levels of market activity, such as higher levels of liquidity

[12] 15 U.S.C. 78f.

[13] 15 U.S.C. 78f(b)(4).

provision and introduction of higher volumes of orders into the price and volume discovery process. Accordingly, the Exchange believes that the proposal is not unfairly discriminatory because it is consistent with the overall goals of enhancing market quality.

Additionally, the Exchange believes that the proposed expansion of the Quoting Incentive Program, which is similar to a fee structure in place on at least one of the Exchange's competitors,[14] will further incentivize the provision of competitively priced, sustained liquidity that will create tighter spreads, benefitting both Members and public investors. The Exchange also believes that conditioning a Member's ability to receive the QIP's additional rebate on reaching one of the Exchange's quoting tiers is consistent with the Act for the reasons described above with respect to volume-based tiers. The Exchange also believes that providing a slightly lower threshold for meeting the QIP to registered BATS Options Market Makers appropriately incentivizes Members of BATS Options to register with the Exchange as Options Market Makers. While the Exchange does wish to allow participation in the QIP by all Members, the Exchange believes that registration by additional Members as Market Makers will help to continue to increase the breadth and depth of quotations available on the Exchange. The Exchange notes that in addition to the fact that the QIP will be available to all Members, the proposal is not unfairly discriminatory despite a slightly higher quotation requirement for non-Market Makers due to the fact that registration as a BATS Options Market Maker is equally available to all Members.

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.

[14] *See* Securities Exchange Act Release No. 61869 (April 7, 2010), 75 FR 19449 (April 14, 2010) (SR–ISE–2010–25) (notice of filing and immediate effectiveness of changes to fees and rebates including adoption of specific rebates for market makers qualifying for the Market Maker Plus program).

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 [15] and Rule 19b-4(f)(2) thereunder,[16] 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.

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–2011–043 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–2011–043. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro/shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–BATS–2011–043 and should be submitted on or before November 1, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–26103 Filed 10–7–11; 8:45 am]

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[15] 15 U.S.C. 78s(b)(3)(A)(ii).

[16] 17 CFR 240.19b–4(f)(2).

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65472; File No. SR–NYSEAmex–2011–72]

Self-Regulatory Organizations; NYSE Amex LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Fees Applicable to Qualified Contingent Cross Orders in the Options Fee Schedule

October 3, 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 26, 2011, NYSE Amex LLC (the ''Exchange'' or ''NYSE Amex'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. 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 NYSE Amex Options Fee Schedule (''Fee Schedule'') to establish fees relating to Qualified Contingent Cross

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

(''QCC'') orders that are entered and executed through the Exchange systems. The proposed change will be operative on September 26, 2011. The text of the proposed rule change is available at the Exchange, the Commission's Public Reference Room, and *http://www.nyse.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposal is to establish fees for executions of a new order type known as QCC.[3] The Exchange intends to charge Customer orders that comprise all or part of a QCC order a rate of $.00 per contract. This rate is consistent with the fees charged to Customer orders generally. All other participants[4] will be charged a rate of $.20 per contract for QCC orders in which they participate. The Exchange does not intend to allow QCC orders to be treated as Strategy Trades for billing purposes. Participants engaged in trades that would qualify for the fee caps on Strategy Executions can choose to either pay the proposed QCC fees or avail themselves of the Strategy Trade fee cap by not executing such orders utilizing the QCC order type.

Along with this change, the Exchange proposes to introduce an incremental service fee of $.05 or $.10 per contract for a QCC order executed on behalf of a Specialist, e-Specialist, Market Maker (both Directed and non-Directed), or Firm that has reached its respective fee cap for the month under endnotes 5 or 6 of the Fee Schedule.[5] When a capped participant trades with a non-Customer, the service fee will be $.05 per contract. When a capped participant trades with a Customer, the service fee will be $.10 per contract. Additionally, the incremental service fee of $.10 per contract will apply to all Firm Facilitation trades that would otherwise be charged a rate of $.00 per contract. All QCC trades will count towards the monthly fee caps and volume thresholds in endnotes 5 and 6 of the Fee Schedule.

QCC orders where a Customer trades against a Market Maker will not result in the collection of Marketing Charges.

Along with the proposed QCC fees, the Exchange intends to adopt a rebate of $.03 per contract for executed QCC orders. The rebate will be credited to the executing Floor Broker. The Exchange notes that the terms of a QCC order are negotiated and agreed to prior to being brought to an exchange for possible execution. In bringing a QCC order to the Exchange for execution, permit holders have two primary means of doing so. They can configure their systems to deliver the QCC order to the Exchange matching engines for validation and execution. Alternatively they can utilize the services of another ATP Holder acting as a Floor Broker. In turn, the Floor Broker who is in receipt of such an order can enter the order through an Exchange-provided system[6] to be delivered to the Exchange matching engine for validation and potential execution. In light of the fact that the Exchange does not offer a front-end for order entry, unlike some of the competing exchanges,[7] the Exchange believes it is necessary from a competitive standpoint to offer this rebate to the executing Floor Broker on a QCC order. The Exchange expects that the rebate offered to executing Floor Brokers will allow them to price their services at a level that will enable them to attract QCC order flow from participants who would otherwise utilize an existing front-end order entry mechanism offered by the Exchange's competitors instead of incurring the cost in time and money to develop their own internal systems to be able to deliver QCC orders directly to the Exchange systems. To the extent that Floor Brokers are able to attract these QCC orders, they will gain important information that will allow them to solicit the parties to the QCC orders for participation in other trades, which will in turn benefit all other Exchange participants through the additional liquidity and price discovery that may occur as a result. The Exchange notes that at least one other exchange offers a similar rebate.[8]

The proposed changes will be operative on September 26, 2011.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6(b)[9] of the Securities Exchange Act of 1934 (the ''Act''), in general, and Section 6(b)(4)[10] of the Act, in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among its members and other persons using its facilities.

The Exchange believes that adopting the proposed new fees for QCC orders where Customers pay $.00 and other participants pay $.20 per contract is reasonable, particularly since Customers have come to expect that they are able to trade for free. Also, Customers will likely have no way of knowing in advance whether or not their order might be executed as a QCC order or through some other means. Conversely, other parties to a QCC order will know in advance that they are being solicited to take part in a QCC order and can therefore factor in the expected charges in making their trading decision. Furthermore, the level of QCC fees for non-Customer participants is

[3] *See* Securities Exchange Act Release No. 65047 (August 5, 2011), 76 FR 49812 (August 11, 2011) (SR–NYSEAmex–2011–56). The QCC permits an NYSE Amex ATP Holder to effect a qualified contingent trade (''QCT'') in a Regulation NMS stock and cross the options leg of the trade on the Exchange immediately upon entry and without order exposure if the order is for at least 1,000 contracts, is part of a QCT, and is executed at a price at least equal to the national best bid and offer, as long as there are no Customer orders in the Exchange's Consolidated Book at the same price.

[4] This includes Specialists, e-Specialists, NYSE Amex Options Market Makers, Non-NYSE Amex Options Market Makers, Broker Dealers, Professional Customers, and Firms.

[5] Under endnote 5, Specialist, e-Specialist, and Market Maker (both Directed and non-Directed) fees are aggregated and capped at $350,000 per month plus an incremental service fee of $.01 per contract for all Specialist, e-Specialist and Market Maker volume executed in excess of 3,500,000 contracts per month. Under endnote 6, fees for Firm Proprietary manual trades are aggregated and capped at $100,000 per month for member firms plus an incremental service fee of $.01 per contract for all Firm Proprietary manual trading volume in excess of that cap.

[6] Floor Brokers are required by NYSE Amex Rule 955NY to have systematized orders prior to representing them in open outcry. Using the same Electronic Order Capture System, Floor Brokers will be able to enter QCC orders for validation by the Exchange matching engines and potential execution.

[7] The International Securities Exchange (''ISE'') offers PRECISE TRADE as a means for users to enter orders and Chicago Board Options Exchange (''CBOE'') has a similar front-end order entry system called PULSE. Such systems do not require users to develop their own internal front-end order entry systems and may provide savings to users in terms of development time and costs.

[8] See NASDAQ OMX PHLX fee schedule dated September 12, 2011, page 22 (describing a Floor Broker Subsidy that can range as high as $.09 per contract), available at *http://www.nasdaqtrader.com/content/marketregulation/membership/phlx/feesched.pdf.*

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4).

comparable to the existing fees such participants currently pay to participate in trades on the Exchange. For these reasons the Exchange believes that the proposed fees are reasonable.

The Exchange believes that the proposed new QCC order fees are not unfairly discriminatory because non-Customer participants generally are being charged the same rate. In addition, those participants who may benefit from a monthly fee cap and/or reduced or zero rates [11] for certain trades will be subject to service fees of either $.05 or $.10 per contract that will serve to ameliorate the per contract difference for a capped participant and a non-capped participant that is party to a QCC order.

The Exchange notes that the inclusion of QCC order fees and subsequent capping of such fees is consistent with what has been filed for and is effective on multiple exchanges, particularly with respect to the fee cap available to Firms.[12] Additionally, the Exchange notes that, in seeking approval for the Firm monthly fee cap, the Exchange stated that it:

> Believes that the proposed monthly fee cap, which applies only to manual firm proprietary trades, is not unfairly discriminatory to other market participants because its purpose is to attract large block order flow to the floor of the Exchange, where such orders can be better handled in comparison with electronic orders that are not negotiable. To the extent that this purpose is achieved, all of the Exchange's market participants should benefit from the improved market liquidity.[13]

Including QCC orders in the Firm monthly fee cap is not inconsistent with that statement for several reasons. First, the Exchange expects that most Firms will chose to utilize a Floor Broker to handle their QCC orders. As explained previously, entering a QCC order requires either modifying proprietary front-end order entry systems, utilizing a Floor Broker, or utilizing an exchange sponsored front-end order entry system.[14] Given the cost in both time and money associated with modifying proprietary front-end order entry systems and the fact that the Exchange does not offer an exchange sponsored front-end order entry system, it is the Exchange's expectation that the majority of QCC orders will be entered by a Floor Broker on behalf of Firms. Firms will utilize existing infrastructure, such as telephones, to communicate QCC orders to Floor Brokers for entry and execution in the same manner in which they communicate other orders to Floor Brokers for manual execution. In short, from a Firm's perspective, QCC orders will be handled by a Floor Broker just like their other orders that are subject to the Firm monthly fee cap.[15] By utilizing a Floor Broker, as opposed to an exchange-sponsored front-end order entry system available on other exchanges, Floor Brokers will gain important information that will allow them to solicit the parties to the QCC orders for participation in other trades, which will in turn benefit all other Exchange participants through the additional liquidity and price discovery that may occur as a result. For these reasons, the Exchange believes that the inclusion of QCC orders in the Firm monthly fee cap is not inconsistent with the statement made when the Firm monthly fee cap was implemented. Further, the adoption of these fees is expected to attract additional order flow to the Exchange and thereby benefit all market participants.

The Exchange also notes that even capped market participants will still pay at least $0.10 per contract for QCC executions, as opposed to $0.00 for open-outcry facilitation trades, so the proposed pricing will continue to provide a strong incentive to expose customer orders for possible price improvement, as is described further below.

The Exchange believes that adopting the service fee of $.05 or $.10 per contract for participants whose trading is subject to a fee cap and or reduced/zero rates is reasonable because it will allow those participants who reach their fee cap during a month to pay the service fee instead of the regular transaction fees and thus will be able to lower their monthly fees. The Exchange believes that charging a service fee is also reasonable because it will allow the Exchange to recoup the costs incurred in providing certain services, which include trade matching and processing, post-trade allocation, submission for clearing and customer service activities related to trading activity on the Exchange. The Exchange notes that charging a service fee to certain participants for trades is not new or novel and that the relative level of the service fee is consistent with that found on other exchanges like the ISE and NASDAQ OMX PHLX.[16]

The Exchange believes that charging a higher service fee of $.10 per contract when capped participants trade with a Customer is reasonable due to the nature of the order type. QCC orders will cross cleanly without exposure upon the entry of a qualifying QCC order. When a capped participant trades with a non-Customer, the total charge is either $.10 (when a capped participant, who is charged the $.05 services fee, trades with another capped participant, who is also charged the $.05 service fee) or $.25 (when a capped participant, who is charged the $.05 service fee, trades with a non-capped, non-Customer, who is charged $.20). By contrast, when a capped participant trades with a Customer, the total charge is $.10 (the capped participant is charged the $.10 service fee and the Customer is charged $.00). Therefore, the Exchange believes the higher service fee for capped participants trading with a Customer is warranted given the all-in (considering both sides of the trade) economic costs of executing a clean cross using QCC.

Additionally, the Exchange notes that Firms are still able to utilize Firm Facilitation trading procedures in attempting to facilitate their own Customer orders. Such Firm Facilitation trades are charged at the rate of $.00 per contract as an alternative to QCC. By charging capped Firms $.10 when they facilitate Customer orders using QCC, the Exchange is intentionally providing an economic incentive to encourage Firms to expose such orders in open outcry, instead of utilizing the clean cross afforded by a QCC order. The Exchange believes the proposed fee change will attract additional order flow to the Exchange and thereby will benefit all market participants.

The Exchange believes the proposal to adopt the service fee is equitable and not unfairly discriminatory because it would uniformly apply to participants who benefit from a monthly fee cap. The proposed fee is designed to give those capped participants that trade frequently on the Exchange a benefit by way of a lower transaction fee, while enabling the Exchange to recoup some of its costs in providing the services associated with validation, execution, submission for clearing, and customer service activities related to trading activity on the Exchange.

[11] *See supra* note 5.

[12] CBOE, ISE and NASDAQ OMX PHLX, all include QCC fees in the fee caps that they have adopted on behalf of Firms. *See* CBOE fee schedule dated September 1, 2011, page 5, footnote 11, available at *http://www.cboe.com/publish/feeschedule/CBOEFeeSchedule.pdf;* ISE fee schedule dated August 1, 2011, page 16, endnote 1, available at *http://www.ise.com/assets/documents/OptionsExchange/legal/fee/fee_schedule.pdf;* and NASDAQ OMX PHLX fee schedule, *supra* note 8, pages 8–9.

[13] *See* Securities Exchange Act Release No. 64656 (June 13, 2011), 76 FR 35493, 35494 (June 17, 2011) (SR–NYSEAmex–2011–36).

[14] *See supra* note 7.

[15] The Floor Broker's handling of orders will vary depending on whether the order is a solicitation, facilitation, or QCC order.

[16] *See* ISE and NASDAQ OMX PHLX fee schedules, *supra* notes 8 and 12.

The Exchange believes that the proposal to exclude QCC orders from the Marketing Charges program is reasonable given the nature of a QCC order. QCC orders by design are not subject to competitive bidding or offering, instead a qualifying QCC order is printed to the tape allowing for a clean cross. Therefore, it is the Exchange's expectation that inducements such as payment for order flow will not factor into attracting QCC orders since a market maker being solicited to be a party to such a trade will simply ask for the order to be sent to a venue that does not collect marketing charges for QCC orders. One such exchange, the CBOE, already explicitly excludes QCC orders from its payment for order flow program.[17] The Exchange believes therefore that it is reasonable to exclude QCC orders from the Marketing Charges program.

The Exchange believes the proposed $.03 per contract rebate for Floor Brokers who enter QCC orders that execute is reasonable because it will allow Floor Brokers the opportunity to compete for QCC orders that would otherwise be entered into front-end order entry systems of competing exchanges.[18] The proposed rebate is comparable to that found on NASDAQ OMX PHLX [19] in that it is being offered to Floor Brokers as an inducement that may allow them to competitively price their services offered to all participants. To the extent that the rebate is successful in attracting additional order flow to the Exchange, all participants should benefit. As such, the Exchange believes that the rebate is appropriate and reasonable.

The Exchange believes the proposal to adopt a $.03 per contract rebate is equitable and not unfairly discriminatory because it would uniformly apply to all QCC orders entered by a Floor Broker for validation by the system and potential execution. Any participant will be able to engage a rebate-receiving Floor Broker in a discussion surrounding the appropriate level of fees that they may be charged for entrusting the entry of the QCC order to the Floor Broker into the Exchange systems for validation and execution. The additional order flow attracted by this rebate should benefit all participants. For this reason, the Exchange believes the adoption of the proposed rebate is both equitable and not unfairly discriminatory.

For the reasons noted above, the Exchange believes that the proposed fees are fair, equitable and not unfairly discriminatory.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [20] of the Act and subparagraph (f)(2) of Rule 19b–4 [21] thereunder, because it establishes a due, fee, or other charge imposed by the NYSE Amex.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NYSEAmex–2011–72 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAmex–2011–72. 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, NW., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. The text of the proposed rule change is available on the Commission's Web site at *http://www.sec.gov.* Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEAmex–2011–72 and should be submitted on or before November 1, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–26102 Filed 10–7–11; 8:45 am]

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[17] *See* CBOE fee schedule, *supra* note 12, at page 4, footnote 6.

[18] *See supra* note 7.

[19] *See supra* note 8.

[20] 15 U.S.C. 78s(b)(3)(A).

[21] 17 CFR 240.19b–4(f)(2).

[22] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65477; File No. SR–FINRA–2011–028]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Withdrawal of Proposed Rule Change To Adopt Rules Regarding Supervision in the Consolidated FINRA Rulebook

October 4, 2011.

On June 10, 2011, Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange

Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'' or ''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to adopt rules regarding supervision in the consolidated FINRA rulebook. The proposed rule change was published for comment in the **Federal Register** on June 29, 2011.[3] The Commission received 12 comments on the proposal.[4] On July 26, 2011, FINRA extended the time period in which the Commission must approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to approve or disapprove the proposed rule change, to September 27, 2011.

On September 27, 2011, FINRA withdrew the proposed rule change (SR–FINRA–2011–028).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[5]

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–26101 Filed 10–7–11; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 64736 (June 26, 2011), 76 FR 38245 (June 29, 2011) (Notice of Filing of File No. SR–FINRA–2011–028) (''Notice'').

[4] The comment period ended on July 20, 2011; all comments are posted on the Commission's Web site, *http://www.sec.gov/rules/sro.shtml.*

[5] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65483 File No. SR–OCC–2011–13]

Self-Regulatory Organizations; Options Clearing Corporation; Notice of Filing of Proposed Rule Relating to Relative Performance Indexes

October 4, 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 21, 2011, The Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change. On October 4, 2011, OCC filed Amendment No. 1 to the proposed rule change. The proposed rule change as amended by Amendment No. 1 is described in Items I, II, and III below, which Items have been prepared primarily by OCC. The Commission is publishing this notice to solicit comments on the proposed rule change and Amendment No. 1 to the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change would remove any potential cloud on the jurisdictional status of relative performance indexes.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, OCC 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. OCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the proposed rule change is to remove any potential cloud on the jurisdictional status of relative performance indexes. NASDAQ OMX PHLX has proposed to trade options on indexes (''Alpha Index Options'') that measure the relative total returns of a stock or exchange-traded fund (''ETF'') against another stock or ETF, including where one of the reference ETFs measured by the index is a gold- or silver-based ETF.[3] Generally, a relative performance index should be considered to be an index of securities since the components of a relative performance index are ETFs or other securities. However, OCC would like to confirm the jurisdictional treatment of relative performance indexes in situations in which one of the reference securities of an underlying relative performance index is an ETF designed to measure the return of gold or silver. To accomplish this purpose, OCC is proposing to add an interpretation following Section 2 in Article XVII of OCC's By-Laws,[4] clarifying that OCC will clear and treat as securities any relative performance index, including in situations in which one of the reference securities of a relative performance index is an ETF designed to measure the return of gold or silver. The Commission and Commodity Futures Trading Commission (''CFTC'') have previously approved changes to OCC's By-Laws clarifying that options on the CBOE Gold ETF Volatility Index will be cleared and treated as securities.[5]

In its capacity as a ''derivatives clearing organization'' registered as such with the CFTC, OCC is filing this proposed rule change for prior approval by the CFTC pursuant to provisions of the Commodity Exchange Act (the ''CEA'') in order to foreclose any potential liability under the CEA based on an argument that the clearing by OCC of such options as securities options constitutes a violation of the CEA.

OCC believes that the proposed interpretation of OCC's By-Laws is consistent with the purposes and requirements of Section 17A of the Exchange Act because it is designed to promote the prompt and accurate clearance and settlement of transactions in securities options, to foster cooperation and coordination with persons engaged in the clearance and settlement of such transactions, to remove impediments to and perfect the mechanism of a national system for the prompt and accurate clearance and settlement of such transactions, and, in general, to protect investors and the public interest. It accomplishes this purpose by reducing the likelihood of a dispute as to the Commission's jurisdiction over relative performance indexes in situations where one of the reference securities of an underlying relative performance index is a gold- or silver-based ETF. The proposed rule change is not inconsistent with the By-Laws and Rules of OCC.

(B) Self-Regulatory Organization's Statement on Burden on Competition

OCC does not believe that the proposed rule change would impose any burden on competition.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The staff notes that on August 17, 2011, the Commission issued an Order granting approval this proposed rule change. *See* Securities Exchange Act Release No. 34–65149, 76 FR 52729 (August 23, 2011).

[4] The staff notes that OCC's is also adding a definition of ''relative performance index'' to Section 1, which will be defined as an index designed to measure the relative performance of a reference security or reference index in relation to another reference security or reference index.

[5] *See* Securities Exchange Act Release No. 34–62290, 75 FR 35861 (June 23, 2010); CFTC Order Exempting the Trading and Clearing of Certain Products Related to the CBOE Gold ETF Volatility Index and Similar Products, 75 FR 81977 (December 29, 2010).

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were not and are not intended to be solicited with respect to the proposed rule change and none have been received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the *Federal Register* or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commissions 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–OCC–2011–13 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–OCC–2011–13. 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 website viewing and printing in the Commission's Public Reference Section, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 pm. Copies of such filings will also be available for inspection and copying at the principal office of OCC and on OCC's Web site at *http://www.optionsclearing.com/components/docs/legal/rules_and_bylaws/sr_occ_11_13_a_1.pdf.*

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–OCC–2011–13 and should be submitted on or before November 1, 2011.

For the Commission by the Division of Trading and Markets, pursuant to delegated authority.[6]

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–26159 Filed 10–7–11; 8:45 am]

BILLING CODE 8011–01–P

[6] 17 CFR 200.30–3(a)(12).

SELECTIVE SERVICE SYSTEM

Form Submitted to the Office of Management and Budget for Extension of Clearance

AGENCY: Selective Service System.

ACTION: Notice.

The following form has been submitted to the Office of Management and Budget (OMB) for extension of clearance in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35):

SSS Form—402

Title: Uncompensated Registrar Appointment Form.

Need and/or Use: Is used to verify the official status of applicants for the position of Uncompensated Registrars and to establish authority for those appointed to perform as Selective Service System Registrars.

Respondents: United States citizens over the age of 18.

Frequency: One-time.

Burden: The reporting burden is three minutes or less per respondent.

Copies of the above identified form can be obtained upon written request to the Selective Service System, Reports Clearance Officer, 1515 Wilson Boulevard, Arlington, Virginia 22209–2425.

Written comments and recommendations for the proposed extension of clearance of the form should be sent within 30 days of the publication of this notice to the Selective Service System, Reports Clearance Officer, 1515 Wilson Boulevard, Arlington, Virginia 22209–2425.

A copy of the comments should be sent to the Office of Information and Regulatory Affairs, Attention: Desk Officer, Selective Service System, Office of Management and Budget, New Executive Office Building, Room 3235, Washington, DC 20503.

Date: September 26, 2011.

Lawrence G. Romo,

Director.

[FR Doc. 2011–25882 Filed 10–7–11; 8:45 am]

BILLING CODE 8015–01–M

DEPARTMENT OF STATE

[Public Notice: 7598]

Industry Advisory Panel: Notice of Open Meeting

The Industry Advisory Panel of the Bureau of Overseas Buildings Operations will meet on Tuesday, October 18, 2011 from 9:30 a.m. until 3:30 p.m. Eastern Daylight Time. The meeting is open to the public and will be held in the Loy Henderson Conference Room of the U.S. Department of State, located at 2201 C Street, NW., (entrance on 23rd Street), Washington, DC. For logistical and security reasons, it is imperative that everyone enter and exit using only the 23rd Street entrance.

The majority of the meeting will be devoted to an exchange of ideas between the Department's senior management and the panel members on design, construction, operations, and building maintenance. There will be reasonable time provided for members of the public to provide comment.

Entry to the building is controlled; to obtain pre-clearance, a member of the public planning to attend should provide, by October 7, his or her name, professional affiliation, date of birth, citizenship, and a valid government-issued ID number (*i.e.,* U.S. government ID, U.S. military ID, passport, or drivers license) via e-mail to: *IAPR@state.gov.* Requests for reasonable accommodation should be sent to the same e-mail address by October 7. Requests made

after that date will be considered, but may not be able to be fulfilled.

Personal data is requested pursuant to Public Law 99–399 (Omnibus Diplomatic Security and Antiterrorism Act of 1986), as amended; Public Law 107–56 (USA PATRIOT Act); and Executive Order 13356. The purpose of the collection is to validate the identity of individuals who enter Department facilities. The data will be entered into the Visitor Access Control System (VACS–D) database.

Please see the Privacy Impact Assessment for VACS–D at *http://www.state.gov/documents/organization/100305.pdf* for additional information.

Please contact Christy Foushee at *FousheeCT@state.gov* or (703) 875–4131 with any questions.

Dated: September 22, 2011.

Lydia Muniz,

Director, Acting, U.S. Department of State, Bureau of Overseas Buildings Operations.

[FR Doc. 2011–26173 Filed 10–5–11; 4:15 pm]

BILLING CODE 4710–24–P

DEPARTMENT OF STATE

[Public Notice: 7639]

Department of State Performance Review Board Members

In accordance with section 4314(c)(4) of 5 United States Code, the Department of State has appointed the following individuals to the Department of State Performance Review Board for Senior Executive Service members:

James L. Millette, Chairperson, Deputy Assistant Secretary, Bureau of Resource Management, Department of State;

Kelly Clements, Deputy Assistant Secretary, Bureau of Population, Refugees and Migration, Department of State;

Richard C. Visek, Deputy Legal Adviser, Office of the Legal Adviser, Department of State;

Marcia S. Bernicat, Ambassador, Department of State.

Dated: September 27, 2011.

Nancy J. Powell,

Director General of the Foreign Service and Director of Human Resources, Department of State.

[FR Doc. 2011–26231 Filed 10–7–11; 8:45 am]

BILLING CODE 4710–15–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2011–0111]

Agency Information Collection Activities: Notice of Request for Renewal of Two Previously Approved Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice and request for comments.

SUMMARY: The FHWA invites public comments about our intention to request the Office of Management and Budget's (OMB) approval to renew two information collections, which are summarized below under **SUPPLEMENTARY INFORMATION**. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by December 12, 2011.

ADDRESSES: You may submit comments identified by Docket ID Number FHWA–2011–0111 by any of the following methods:

Web Site: For access to the docket to read background documents or comments received go to the Federal eRulemaking Portal: Go to *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, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

Hand Delivery or Courier: U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title1: A Guide to Reporting Highway Statistics.

OMB Control Number: 2125–0032.

Abstract: A Guide to Reporting Highway Statistics provides for the collection of information by describing policies and procedures for assembling highway related data from the existing files of State agencies. The data includes motor-vehicle registration and fees, motor-fuel use and taxation, driver licensing, and highway taxation and finance. Federal, State, and local governments use the data for transportation policy discussions and decisions. Motor-fuel data are used in attributing receipts to the Highway Trust Fund and subsequently in the apportionment formula that are used to distribute Federal-Aid Highway Funds. The data are published annually in the FHWA's Highway Statistics. Information from Highway Statistics is used in the joint FHWA and Federal Transit Administration required biennial report to Congress, Status of the Nation's Highways, Bridges, and Transit: Conditions and Performance, which contrasts present status to future investment needs.

Respondents: State and local governments of the 50 States, the District of Columbia and the Commonwealth of Puerto Rico.

Estimated Average Burden Per Response: The estimated average reporting burden per response for the annual collection and processing of the data is 825 hours for each of the States (including local governments), the District of Columbia and the Commonwealth of Puerto Rico.

Estimated Total Annual Burden: The estimated total annual burden for all respondents is 42,900 hours.

FOR FURTHER INFORMATION CONTACT: Mr. Ralph Erickson, (202) 366–9235, Department of Transportation, Federal Highway Administration, Office of Policy, Office of Highway Policy Information, Highway Funding and Motor Fuels Division (HPPI–10), 1200 New Jersey Avenue, SE., Washington, DC 20590. Office hours are from 7 a.m. to 4:30 p.m., Monday through Friday, except Federal holidays.

Title 2: Highway Performance Monitoring System (HPMS). OMB Control Number: 2125–0028.

Abstract: The HPMS data that is collected is used for management decisions that affect transportation, including estimates of the Nation's future highway needs and assessments of highway system performance. The information is used by the FHWA to develop and implement legislation and by State and Federal transportation officials to adequately plan, design, and administers effective, safe, and efficient transportation systems. This data is essential to the FHWA and Congress in evaluating the effectiveness of the Federal-aid highway program. The HPMS also provides miles, lane-miles and travel components of the Federal-Aid Highway Fund apportionment formulae. The data that is required by the HPMS has recently been reassessed and streamlined by the FHWA.

Respondents: State governments of the 50 States, the District of Columbia and the Commonwealth of Puerto Rico.

Estimated Average Burden per Response: The estimated average burden

per response for the annual collection and processing of the HPMS data is 1,800 hours for each State, the District of Columbia and the Commonwealth of Puerto Rico.

Estimated Total Annual Burden: The estimated total annual burden for all respondents is 93,600 hours.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Rozycki, (202) 366–5059, Department of Transportation, Federal Highway Administration, Highway Systems Performance (HPPI–20), Office of Highway Policy Information, Office of Policy & Governmental Affairs, 1200 New Jersey Avenue, SE., Washington, DC 20590. Office hours are from 7:30 a.m. to 4 p.m., Monday through Friday, except Federal holidays.

Public Comments Invited

You are asked to comment on any aspect of these information collections, including: (1) Whether the proposed collections are necessary for the FHWA's performance; (2) the accuracy of the estimated burdens; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burdens could be minimized, including use of electronic technology, 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 these information collections.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. ch. 35, as amended; and 49 CFR 1.48.

Issued On: September 30, 2011.

Michael Howell,

Acting Chief, Management Programs and Analysis Division.

[FR Doc. 2011–26199 Filed 10–7–11; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2011–0113]

Agency Information Collection Activities: Notice of Request for Renewal of a Previously Approved Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Request for Renewal of a Previously Approved Information Collection.

SUMMARY: The FHWA invites public comments about our intention to request the Office of Management and Budget's (OMB) approval of a new information collection that is summarized below under **SUPPLEMENTARY INFORMATION**. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by December 12, 2011.

ADDRESSES: You may submit comments identified by DOT Docket ID Number 2011–0113 by any of the following methods:

Web Site: For access to the docket to read background documents or comments received, go to the *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, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

Hand Delivery or Courier: U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m. E.T., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mary Huie, 202–366–3039, Department of Transportation, Federal Highway Administration, Office of Infrastructure, 1200 New Jersey Ave., SE., E76–106, Washington, DC 20590. Office hours are from 8 a.m. to 4:30 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: Highways for LIFE Pilot Program.

Background: Section 1502 of SAFETEA–LU establishes the ''Highways for LIFE'' Pilot Program. The purpose of the Highways for LIFE pilot program is to advance longer-lasting highways using innovative technologies and practices to accomplish the fast construction of efficient and safe highways and bridges. ''Highways for LIFE'' is focused on accelerating the rate of adoption of proven technologies. The program will provide funding to States to accelerate technology adoption to construct, reconstruct, or rehabilitate Federal-aid highway projects that incorporate innovative technologies that will improve safety, reduce congestion due to construction, and improve quality. Those States interested in participating in the ''Highways for LIFE'' program will submit an application for project funding. The information to be provided on the application includes a description of the project, the innovative technologies to be used and a description of how these technologies will improve safety, reduce construction congestion, and improve quality. The collected information will be used by FHWA to evaluate and select projects for ''Highways for LIFE'' funding.

Respondents: The fifty State Departments of Transportation, the District of Columbia, and Puerto Rico.

Frequency: Annually.

Estimated Number of Respondents: 1,460 for file maintenance and 52 state highway agencies for statistical reports.

Estimated Average Burden per Response: 8 hours per respondent per application.

Total Annual Burden: It is expected that the respondents will complete approximately 30 applications for an estimated 240 total annual burden hours.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection of information is necessary for the U.S. DOT's performance, including whether the information will have practical utility; (2) the accuracy of the U.S. DOT's estimate of the burden of the proposed information collection; (3) ways to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, 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.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Issued on: September 30, 2011.

Michael Howell,

Acting Chief, Management Programs and Analysis Division.

[FR Doc. 2011–26201 Filed 10–7–11; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Safety Advisory 2011–02]

Following Procedures When Going Between Rolling Equipment

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of Safety Advisory.

SUMMARY: FRA is issuing Safety Advisory 2011–02 to remind railroads and their employees of the importance of following procedures when going

between rolling equipment. This safety advisory contains various recommendations to railroads to ensure that these issues are addressed by appropriate railroad operating policies and procedures, and to ensure that those policies and procedures are effectively implemented.

FOR FURTHER INFORMATION CONTACT: Ron Hynes, Director, Office of Safety Assurance and Compliance, Office of Railroad Safety, FRA, 1200 New Jersey Avenue, SE., Washington, DC 20590, telephone (202) 493–6404; or Joseph St. Peter, Trial Attorney, Office of Chief Counsel, FRA, 1200 New Jersey Avenue, SE., Washington, DC 20590, telephone (202) 493–6047.

SUPPLEMENTARY INFORMATION: The overall safety of railroad operations has improved in recent years. However, recent fatal events highlight the need for the railroad industry to refocus its attention on compliance with safety rules and procedures that apply to employees who, in the course of their work, place themselves between rolling equipment. The railroad industry has long recognized that employees whose responsibilities necessitate physically placing themselves between rolling equipment, as often occurs during switching operations, must take adequate safety precautions and be alert and aware of their surroundings at all times. Consequently, railroads developed rules and procedures designed to ensure the safety of employees when between rolling equipment.

In 1998, the industry recognized a troubling increase in the number of employee fatalities occurring during switching operations, including incidents of employees effectively being crushed between rolling equipment. At FRA's request, a voluntary group comprised of industry stakeholders was formed to examine and address that trend of increasing deaths. The group included representatives from the Association of American Railroads (AAR), the American Short Line and Regional Railroad Association (ASLRRA), the Brotherhood of Locomotive Engineers and Trainmen (BLET), the United Transportation Union (UTU), and FRA. The group was later named the Switching Operations Fatality Analysis (SOFA) Working Group. In October 1999, the Working Group issued a report titled ''Findings and Recommendations of the SOFA Working Group.'' The report can be found on FRA's Web site at *http://www.fra.dot.gov/Pages/1781.shtml.*[1] The report contains five major findings with an accompanying recommendation and discussion for each finding. The first of these five recommendations is directly applicable to situations where employees go between rolling equipment, or otherwise foul track or equipment. That recommendation reads as follows:

> Any crew member intending to foul track or equipment must notify the locomotive engineer before such action can take place. The locomotive engineer must then apply locomotive or train brakes, have the reverser centered, and then confirm this action with the individual on the ground. Additionally, any crew member that intends to adjust knuckles/drawbars, or apply or remove EOT device, must insure that the cut of cars to be coupled into is separated by no less than 50 feet. Also, the person on the ground must physically inspect the cut of cars not attached to the locomotive to insure that they are completely stopped and, if necessary, a sufficient number of hand brakes must be applied to insure the cut of cars will not move.

Many railroads have procedures similar to those described in this SOFA recommendation, and other railroads have adopted or modified their procedures to be utilized when going between rolling equipment to reflect this recommendation.

When the pre-SOFA, 9-year period (1992–2000) is compared with the post-SOFA, 9-year period (2001–2009), the industry realized a 60-percent reduction (15 vs. 6) in the number of employees killed when working between rolling equipment. Unfortunately, this positive trend has not continued. Within the last 10 weeks, the railroad industry has experienced three employee fatalities that have occurred when employees were between rolling equipment. In addition to these most recent fatalities, over the last 2 years, two additional employee fatalities have occurred when employees were between rolling equipment. This rise in employee fatalities as a result of being crushed between rolling equipment suggests a need to remind railroads and their employees of the critical importance of maintaining and abiding by railroad rules and procedures designed to ensure safety when going between rolling equipment.

The following is an overview of the circumstances surrounding these recent fatal incidents. Information regarding the three most recent incidents is based on FRA's preliminary investigation findings as the probable causes and or contributing factors of these incidents have not yet been established. Accordingly, nothing in this safety advisory is intended to attribute a definitive cause to these incidents, or place responsibility for the incidents on the acts or omissions of any person or entity.

Recent Incidents

- The most recent incident occurred on September 8, 2011. At approximately 5:15 a.m., a single helper locomotive had coupled to the rear of a standing 125-car train with the intent of assisting the train's movement up an ascending grade. At some point, the movement stopped and the conductor of the single helper locomotive detrained and separated his locomotive from the train he and his engineer had assisted. After the separation, the conductor of the single helper locomotive reattached the end of train device to the last car of the assisted train, and announced to the crew of that train that he had finished his tasks. He then began to walk back to his locomotive. Shortly thereafter, the slack on the assisted train adjusted and the conductor was crushed between the rear car of the assisted train and his locomotive. The deceased was 59 years old with 5 years of railroad experience.
- On August 15, 2011, at approximately 1:30 p.m., a three-person remote control locomotive (RCL) crew consisting of a foreman, a helper, and a trainee entered a track in a bowl yard from the east and coupled onto a cut of cars. The foreman and the trainee boarded the locomotive to provide point protection and the helper, using his remote control transmitter, began stretching the cars eastward to identify gaps created by uncoupled blocks of cars. As the gaps were revealed, the helper repeatedly entered the space between the blocks of cars and made adjustments to knuckles and/or drawbars. Using his remote control transmitter, he then shoved the cars attached to the locomotive westward to couple the cars before continuing the process. The last time the helper went into a gap to adjust the knuckles and/or drawbars, the cars attached to the locomotive moved west and crushed the helper between the cars being coupled. The deceased was 52 years old and had approximately 17 years of railroad experience.
- On July 25, 2011, at approximately 12:30 a.m., a two-person RCL operation had shoved into a classification track and coupled to the westernmost car on the track. The RCL conductor on the crew was creating gaps in the cuts of cars (by pulling west) to adjust couplers

[1] More recently, in March 2011, the SOFA Working Group issued a report titled ''Findings and Advisories of the SOFA Working Group,'' available online at: *http://www.fra.dot.gov/rrs/pages/fp_Findings%20and%20Advisories.shtml.*

and/or align drawbars with the intent of coupling the entire track of 28 cars and pulling it from the classification track. The conductor's helper was riding on the locomotive to provide point protection. The grade on the track was descending from east to west. During one such operation, when the conductor opened a gap, the cars standing to the east of him rolled westward into the cars attached to the locomotive, crushing the conductor. The deceased was 33 years old and had approximately 3½ years of railroad experience.

• On July 13, 2010, at approximately 1:30 a.m., a switching crew was performing a conventional flat, switching operation on a lead track. After separating a cut of cars, the conductor entered the space between the cars attached to his locomotive and those that he had just cut away from in order to make an adjustment to a coupler. He was crushed between the cars still attached to his locomotive and the cut of cars the crew had just cut away from. The deceased was 35 years old and had approximately 6 years of railroad experience.

• On May 10, 2009, at approximately 6:40 p.m., a remote control locomotive operator (RCO) was working in a bowl track, coupling railroad cars together for placement on a departure track. The RCO created gaps in the cuts of cars to adjust couplers and/or align drawbars, and then coupled the cars attached to the locomotive to the cars left standing. The RCO also replaced a knuckle on one of the cars he intended to couple. The RCO went in between the cars to adjust the knuckle he had just installed, and was crushed between equipment when the drawbars bypassed. The deceased employee was 33 years old and had approximately 8 years of railroad experience. The National Transportation Safety Board (NTSB) investigated this incident and cited the deceased employee's loss of situational awareness when he stepped between moving equipment in violation of the railroad's safety rules as a probable cause of the incident.

FRA understands that multiple factors typically contribute to fatal events. Three of the five cases outlined above involved remote control locomotive operations, and in all three cases, the fatally injured employee was in control of the movement at the time of the incident. The fact that RCLs were in use in three incidents does not appear to have any bearing on the events. In the 2010 conventional switching incident there appears to have been no radio transmissions made announcing that the employee on the ground was going between cuts of cars. In the most recent event, it appears there may not have been sufficient distance between the rolling equipment the employee went between.

Each of the above described events, however, demonstrate one consistency—the employees involved either did not have enough room or time to avoid the moving equipment, or were unaware that any equipment they were working with was in motion. These incidents suggest that existing railroad rules governing going between rolling equipment may not have been fully complied with, and also potentially indicate a loss of situational awareness by the employees involved, as well as inadequate management oversight of safety rules compliance by employees.[2]

Railroad operating employees work in an environment which is, by nature, often absent direct management oversight. As the above examples indicate, even slight lapses in rules compliance and situational awareness can lead to tragedy. Without a strong sense of personal responsibility for one's own safety, employees can become complacent and a danger to themselves or other crewmembers. A culture of performing each task safely and as instructed in training must be reinforced not only by management, but by senior, more experienced employees as well. Good workplace habits should be passed along, while questionable work practices should be identified and re-evaluated as newer employees are brought into the railroad workforce. At the same time, railroad management must positively reinforce the need for employees to perform their tasks safely and in accordance with established rules and procedures, and as operations change, management must review existing rules and procedures to ensure that the relevant safety risks of the operating environment are addressed, and that employees are appropriately trained. Moreover, railroad management must eliminate the pressures that it places on employees to expedite train and yard movements as such pressures can negatively impact an employee's ability and desire to perform their assigned task safely.

The discussion contained in this safety advisory is not intended to place blame on or assign responsibility to individuals or railroads, but to emphasize the fact that a robust culture of operating and safety rules compliance is everyone's job. Too often, it is not until after an incident has occurred that railroad management, labor, and regulators fully realize that dangerous work habits were formed and those routine behaviors have not been properly addressed. Support from railroad management and peer pressure from fellow employees encouraging individuals to perform each task in a safe manner via the proper procedures will help railroad employees maintain responsibility for their own safety.

Recommended Railroad and Railroad Employee Action: In light of the above discussion, and in an effort to maintain a heightened sense of safety vigilance among railroad employees who place themselves between pieces of rolling equipment, FRA recommends that railroads:

(1) Review current operating and safety rules that specifically address both remote control locomotive and conventional switching operations that require employees to go between rolling equipment, and determine whether those rules provide adequate protection to employees, or need to be updated or revised.

(2) Develop, implement, and monitor sound communication protocols that require employees on multi-person switch crews to notify their fellow crewmembers when the need arises to enter between two pieces of rolling equipment—regardless of whether the employee is the primary RCO or working on a conventional crew.

(3) Review the SOFA Safety Recommendation # 1, *Adjusting Knuckles, Adjusting Drawbars, and installing End of Train Devices,* reproduced above, and communicate its procedures implementing that recommendation to employees working in yards or other locations where the possibility of entering between rolling equipment exists.

(4) Convey to employees that their own personal safety is their responsibility and that railroad management supports and encourages those employees that make safety their number one priority, regardless of their immediate assignment.

(5) Convey to employees that they should encourage fellow employees to perform their tasks safely and in compliance with established railroad rules and procedures.

FRA encourages railroad industry members to take action that is consistent with the preceding recommendations, and to take other complimentary actions to help ensure the safety of the Nation's railroad employees. FRA may modify this Safety Advisory 2011–02, issue

[2] FRA published Safety Advisory 2010–03 (75 Fed. Reg. 63893 (Oct. 18, 2010)), titled ''Staying Alert and Situational Awareness,'' in response to railroad incidents where employees were killed. In addition to the recommendations made in this Safety Advisory 2011–02, FRA encourages railroads to review those recommendations previously made in Safety Advisory 2010–03 as well.

additional safety advisories, or take other appropriate actions necessary to ensure the highest level of safety on the Nation's railroads, including pursuing other corrective measures under its rail safety authority.

Issued in Washington, DC, on October 5, 2011.

Joseph C. Szabo,

Administrator.

[FR Doc. 2011–26283 Filed 10–7–11; 8:45 am]

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Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; 12-Month Finding on a Petition To List the Tehachapi Slender Salamander as Endangered or Threatened; Proposed Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[FWS–R8–ES–2008–0087]

Endangered and Threatened Wildlife and Plants; 12-Month Finding on a Petition To List the Tehachapi Slender Salamander as Endangered or Threatened

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of 12-month petition finding.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce a 12-month finding on a petition to list the Tehachapi slender salamander (*Batrachoseps stebbinsi*) as threatened or endangered, under the Endangered Species Act of 1973, as amended (Act). After review of all available scientific and commercial information, we find that listing the Tehachapi slender salamander is not warranted. However, we ask the public to submit to us any new information that becomes available concerning threats to the Tehachapi slender salamander or its habitat at any time.

DATES: The finding announced in this document was made on October 11, 2011.

ADDRESSES: This finding is available on the Internet at *http://www.regulations.gov* at Docket Number FWS–R8–ES–2008–0087 and at *http://www.fws.gov/ventura.* Supporting documentation we used in preparing this finding is available for public inspection, by appointment, during normal business hours at the U.S. Fish and Wildlife Service, Ventura Fish and Wildlife Office, 2493 Portola Road, Suite B, Ventura, CA 93003; telephone 805–644–1766; facsimile 805–644–3958. Please submit any new information, materials, or questions concerning this finding to the above address or via electronic mail (e-mail) at *tss@fws.gov.*

FOR FURTHER INFORMATION CONTACT: Michael McCrary, Listing and Recovery Program Coordinator, U.S. Fish and Wildlife Service, Ventura Fish and Wildlife Office (see **ADDRESSES**) by telephone at 805–644–7166; or by facsimile at 805–644–3958. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Background

Section 4(b)(3)(B) of the Endangered Species Act of 1973, as amended (Act) (16 U.S.C. 1531 *et seq.*), requires that, for any petition to revise the Federal Lists of Endangered and Threatened Species that contains substantial scientific or commercial information that listing the species may be warranted, we make a finding within 12 months of the date of receipt of the petition. In this finding, we will determine that the petitioned action is: (1) Not warranted, (2) warranted, or (3) warranted, but the immediate proposal of a regulation implementing the petitioned action is precluded by other pending proposals to determine whether species are threatened or endangered, and expeditious progress is being made to add or remove qualified species from the Federal Lists of Endangered and Threatened Species. Section 4(b)(3)(C) of the Act requires that we treat a petition for which the requested action is found to be warranted but precluded as though resubmitted on the date of such finding, that is, requiring a subsequent finding to be made within 12 months. We must publish these 12-month findings in the **Federal Register**.

Previous Federal Actions

On February 28, 2006, we received a petition, dated February 17, 2006, from Mr. Jeremy Nichols of Denver, Colorado, requesting that the Tehachapi slender salamander (*Batrachoseps stebbinsi*) be listed as threatened or endangered in accordance with section 4 of the Act. The petition clearly identified itself as such and contained the name, address, and signature of the petitioning private citizen, as required in 50 CFR 424.14(a).

In response to the petition, we sent a letter to the petitioner dated April 20, 2006, explaining that we would not be able to address the petition until fiscal year 2007. The reason for this delay was that responding to existing court orders and settlement agreements for other listing actions expended our listing funding. We also concluded in our April 20, 2006, letter that emergency listing of the Tehachapi slender salamander was not warranted. We were delayed in responding to the petition until funding became available.

On April 22, 2009, the Service issued its 90-day finding (74 FR 18336), concluding that the petition presented substantial scientific or commercial information to indicate that listing the Tehachapi slender salamander may be warranted. We also announced the initiation of a status review to determine if listing the species is warranted and solicited information to be provided in connection with the status review.

We contracted with Robert Hansen, a recognized scientific expert on the Tehachapi slender salamander, editor of the Herpetological Review, and author of peer-reviewed papers on the species (Hansen 1980, pp. 1–50; Hansen and Stafford 1994, pp. 252–255; Hansen and Wake 2005, pp. 693–695), to develop a technical report (Hansen 2009, pp. 1–30) addressing the species' range and distribution relative to current and foreseeable land uses to assess effects of habitat alteration on the salamander. This notice constitutes our 12-month finding on the February 28, 2006, petition to list the Tehachapi slender salamander as threatened or endangered.

Species Description

Like others in the Family Plethodontidae (the lungless salamanders), the Tehachapi slender salamander breathes through its smooth, thin skin. Species in the *Batrachoseps* genus tend to have elongated bodies and tails, and shorter limbs. Compared to other species of attenuate *Batrachoseps,* the Tehachapi slender salamander has a relatively broad head, long legs, large feet, long toes, a robust body, and a short tail. Both front and hind feet contain four toes and are more webbed than other *Batrachoseps* species. The dorsal color may be dark red, brick red, or light or dark brown with light-tan or black patches that often form a band-like pattern. The Tehachapi slender salamander is characterized by 19 intercostal grooves on each side of the body (Brame and Murray 1968, p. 19). The Tehachapi slender salamander is sexually dimorphic. The average size of adult females is 2.24 inches (in) (57 millimeters (mm), and adult males average 2.13 in (54 mm) snout-to-vent length. Brame and Murray (1968, p. 18) first described the species in 1968.

The Tehachapi slender salamander belongs in the genus *Batrachoseps,* one of 25 genera in the subfamily Bolitoglossinae (Jockusch *in litt.* 2009a, p. 2; Jockusch *in litt.* 2009b, p. 1). The subgenus *Batrachoseps* (under the genus *Batrachoseps*) consists of four groups or clades (a nontaxonomic rank based on genetic or morphological comparisons) comprising 16 species and a few undescribed taxa all of which are adapted to fossorial (subterranean) and semifossorial existences (Jockusch and Wake 2002, pp. 362, 380). The four groups are *attenuatus, nigriventris, pacificus,* and *relictus* (Jockusch *in litt.* 2009a, p. 1). The Tehachapi slender salamander belongs in the *nigriventris* group, along with the black-bellied

slender salamander (*B. nigriventris*), gregarious slender salamander (*B. gregarious*), and Kern Canyon slender salamander (*B. simatus*) (Jockusch *in litt.* 2009c, p. 1; Jockusch and Wake 2002, p. 363). Based on genetic studies, the Tehachapi slender salamander is considered to be closely related to the Kern Canyon slender salamander (Hansen and Stafford 1994, p. 252; Jockusch and Wake 2002, p. 364).

There are two known populations of Tehachapi slender salamander, the Caliente Canyon population and the Tehachapi Mountains population, both of which are described in detail below under the *Range and Distribution* section. We examined information suggesting that the two populations may represent separate species. We evaluated information discussed by Jockusch (1996, pp. 1–231) and Jockusch and Wake (2002, pp. 361–391), regarding the large amount of genetic and morphological differences between the two populations (Nichols 2006, p. 5). Hansen and Wake (2005, p. 694) also suggest that the two may eventually be classified as separate species based on genetic and morphological data. However, based on subsequent genetic research, Jockusch (*in litt.* 2009d, p. 1) concluded that considering the two populations separate species was not warranted at this time. Hansen (2009a, pers. comm.) believes there are not enough differences between the two populations to classify them as separate species or subspecies. Therefore, we conclude at this time that the two populations of Tehachapi slender salamanders are a single species.

Biology and Natural History

Western species of plethodontid salamanders, including the Tehachapi slender salamander, are completely terrestrial amphibians and do not need standing or flowing water for any stage of their life cycle (Zug *et al.* 2001, p. 383). Because their entire life cycle occurs on land, they are vulnerable to desiccation. Thus, the Tehachapi slender salamander, like other plethodontids, requires moist microhabitats. As such, its above-surface activity is greatly reduced outside of the rainy season (Feder 1983, pp. 295–296).

Peak periods of surface activity for the nocturnal Tehachapi slender salamander occur during the rainy season, typically February through March, but may occur earlier depending on the timing of late-fall/early-winter rains (Hansen and Wake 2005, p. 694; Hansen *in litt.* 2009a, p. 2). During wetter years, peak activity may extend to April or early May at higher elevations (Hansen and Wake 2005, p. 694). These salamanders retreat to underground refugia (up to 3 feet (ft) (0.9 meters (m)) below the surface) during the warmer months or during periods of freezing temperatures and are believed to aestivate during this time (Hansen and Wake 2005, p. 694; Hansen *in litt.* 2009b, p. 1; Hansen 2010 pers. comm.).

Specific information on the reproductive biology and behavior of the Tehachapi slender salamander is unknown. There is no reported information on the size and age at sexual maturity, nesting behavior, clutch size, or timing of egg hatching for the Tehachapi slender salamander (Hansen and Wake 2005, p. 694). However, Hansen and Wake (2005, p. 694) suggest that eggs are likely laid underground well below the talus and leaf litter material. The Tehachapi slender salamander cannot dig its own burrows, so it uses spaces dug in leaf litter or talus by other animals, or spaces that result from decaying vegetation (Hansen 2009b, pers. comm.; Hansen and Stafford 1994, p. 254). Jockusch and Mahoney (1997, p. 699) suggest that oviposition in Tehachapi slender salamanders occurs after the first rains in the fall or winter, and only once per season, based on their observations of oviposition occurring in November in the related black-bellied slender salamander.

Little is known about the behavior of *Batrachoseps* species, but feeding and reproduction are assumed to occur during brief periods of surface activity (Hansen *in litt.* 2009b, p. 1). The low metabolic rate of plethodontid salamanders enables them to sustain themselves on their energy reserves when surface conditions are not suitable for foraging. They are believed to be inactive (*i.e.,* do not forage) while underground (Feder 1983, pp. 304–306). The Tehachapi slender salamander has been observed to capture prey, consisting of small terrestrial invertebrates, with its projectile tongue (Hansen and Wake 2005, p. 694). Hansen and Stafford suggest that the diet of the Tehachapi slender salamander is likely to be similar to other related *Batrachoseps,* consisting of small spiders, mites, and insects (Hansen and Stafford 1994, p. 254). Predators of this species are not well known. Other salamander species are known to be preyed upon by birds, such as American crows (*Corvus brachyrhynchos*), common ravens (*Corvus corax*), and jays, as well as raccoons (*Procyon lotor*), skunks, opossums (*Didelphis virginiana*), and snakes (HumboldtHerps 2010, p. 2; Kuchta 2005, p. 266). The only documented predator of the Tehachapi slender salamander that we know of is a ring-necked snake (*Diadophis punctatus*) (Burkhardt *et al.* 2001, p. 245). We are not aware of any information about parasites or diseases affecting this species or information about symbiotic or mutualistic interactions with other organisms.

Habitat Characteristics

Tehachapi slender salamanders are restricted to seasonally mesic microhabitats on north-facing slopes in otherwise dry regions of the Tehachapi Mountains and the southern end of the Sierra Nevada Mountains (Hansen and Wake 2005, p. 694). Suitable habitat consists typically of shaded, north-facing slopes containing talus substrates or areas with considerable leaf litter or downed wood (Jockusch and Wake 2002, p. 362; Hansen and Wake 2005, p. 693; Hansen 2009, p. 2). These heavily shaded, north-facing slopes generally occur on the lower reaches of a hillside where sun exposure is the most limited (Hansen *in litt.* 2010b, p. 1). The species has most often been found to occur on slopes with limestone talus, scattered rocks, fissured rock outcrops, fallen logs, leaf litter under tree canopy cover where moisture and humidity are high compared to nearby sites with reduced canopy cover or greater slope exposure (Hansen and Wake 2005, p. 694; CaliforniaHerps 2008, p. 2; Hansen 2009, p. 2). The species was also recently found on an atypical, more exposed north-facing slope in a new location (Silver Creek) in the northeast corner of its range under large rocks; talus mixed with soil; logs; and in some cases, dead *Yucca* spp. plants (family Asparagaceae) (see Figure 1) (Sweet *in litt.* 2011, p. 1). Habitat that meets the requirements of the Tehachapi slender salamander in the two areas (Caliente Canyon and Tehachapi Mountains areas; see ''Range and Distribution'' section below) where the species occurs is sparse and patchily distributed. These patches of suitable habitat are dominated by *Aesculus californica* (California buckeye), *Platanus racemosa* (California sycamore), and *Quercus chrysolepis* (canyon live oak). Based on survey photographs (Sweet 2011, pp. 8–10), the atypical Silver Creek location in the northeast corner of the range also includes abundant junipers (*Juniperus californica*). The species has been documented to occur from 1,804 to 4,825 ft (550 to 1,471 m) in altitude throughout its range (Hansen 2009, p. 2; Sweet *in litt.* 2011, p. 1).

Movement patterns, individual dispersal, and home range size of the

Tehachapi slender salamander are unknown. However, genetic studies of related *Batrachoseps* species (Jockusch 1996, p. 80; Hansen and Wake 2005, p. 694) indicate that female movement is limited (Jockusch and Wake 2002, p. 381). Jockusch (1996, p. 80) observed genetic differences over short geographic distances (ranging from 1.6 to 25 miles (mi) or 2.5 to 40 kilometers (km)) within a population of a closely related species, the black-bellied slender salamander, indicating that the females had not moved between populations for millions of years. No quantitative studies on movement patterns, individual dispersal, and home range size have been completed for species of *Batrachoseps* except for the California slender salamander (*Batrachoseps attenuatus*). Anderson (1960, p. 369) observed that the California slender salamander movements were limited to approximately 5 ft (2 m), and Maiorana (1978, p. 1020) observed that individuals of the same species stay within a 6.6-ft (2-m) area, on average. Based on the limited data on the California slender salamander, we infer that individual Tehachapi slender salamanders are likely to stay within an area of a few meters during their lifetime (Hansen *in litt.* 2009b, p.1; Hansen *in litt.* 2009c, p. 1).

Range and Distribution

The Tehachapi slender salamander is endemic to Kern County, California (Stebbins 2003, p. 185; Hansen and Wake 2005, p. 693). The general range of the species in the Tehachapi Mountains extends from the Piute Mountains in the north to Fort Tejon State Historic Park (SHP) in the south.

Since the publication of our 90-day finding (74 FR 18336; April 26, 2009), we have obtained additional data regarding the distribution of the Tehachapi slender salamander. In this finding, we have updated the description of the distribution of the Tehachapi slender salamander presented in the 90-day finding to reflect the best available scientific information. As stated above, we relied extensively on Hansen's technical report on the Tehachapi slender salamander in the preparation of this review because it provides the most comprehensive information on confirmed species occurrences throughout the species' range. An occurrence refers to a small patch of habitat (rather than a specific point location), where one or more individuals of the species was observed and verified. Hansen's 2009 report incorporates his past work, information gathered from the September 2008 habitat assessment, all vouchered museum specimen occurrences, and confirmed reports of occurrences from Jockusch and Wake (2002), other species experts, and the California Natural Diversity Database (CNDDB 2007). This report also documents current land uses and land ownership at sites where this species has been reported, assesses habitat quality, and reviews potential threats to the species based on its distribution and natural history. We also report new locations not included in any of the above that were recently found by Christopher Evelyn and Dr. Sam Sweet (University of California, Santa Barbara) in the northeastern portion of the species' range (Sweet 2011, pp. 8–10; Sweet *in litt.* 2011, p. 1).

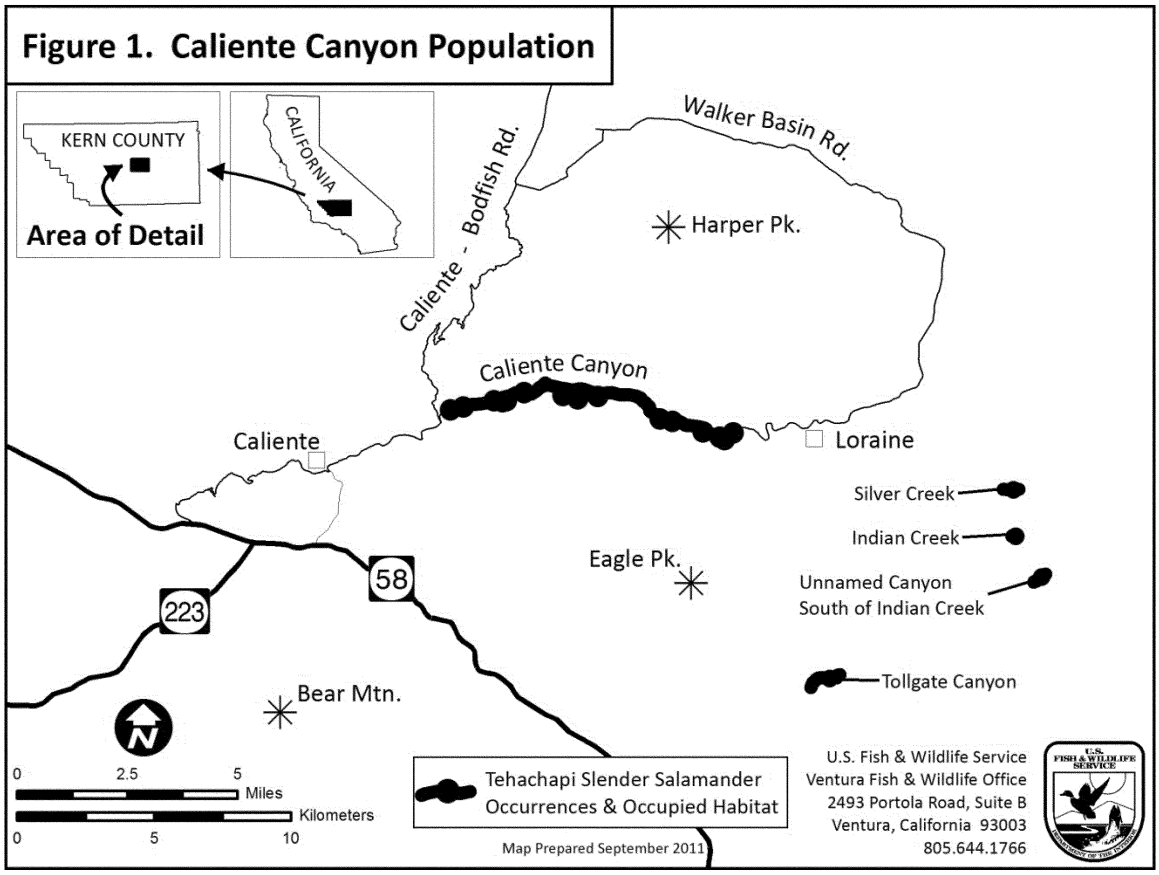
The current known range of the Tehachapi slender salamander consists of two disjunct areas that are separated by approximately 13 mi (21 km) of dry, rugged, mountainous terrain. We consider these two disjunct areas as separate populations, the Caliente Canyon and Tehachapi Mountains populations. The Caliente Canyon population is located northeast of State Highway 58 and west of the Piute Mountains, and lies in the southern foothills of the Sierra Nevada Mountains, south of Kern Canyon. The Tehachapi Mountains population is located southwest of State Highway 58 and extends to Fort Tejon State Historic Park (SHP) (Hansen and Stafford 1994, p. 255). This population lies in the Tehachapi Mountains and the San Emigdio/Mount Pinos area of Kern County, on both sides of Interstate Highway 5. Until recently, the species was known from 21 occurrences (from northeast to southwest), 14 in Caliente Canyon, 6 in the Tehachapi Mountains (including 5 on Tejon Ranch and 1 on Fort Tejon SHP), and 1 near Highway 58 (Tehachapi Pass location, see Figure 1 below) (Hansen 2009, pp. 8–10; ICF Jones and Stokes 2009, p. 4.4–156 and Figure 4.4–8). The 21 previously known occurrence records span a period from 1957 through 2007; most recorded occurrences are on private land. In addition to the 21 previously known occurrences, Christopher Evelyn and Dr. Sam Sweet found 4 new locations in the northeastern portion of the species' range (Sweet 2011, pp. 1–13; Sweet *in litt.* 2011, p. 1), bringing the total known occurrences to 25, including one that is extirpated.

We have defined the ranges of the two populations of the Tehachapi slender salamander as the canyons with known occurrences. Based on the presence of at least one known occurrence, we infer that the habitat up- and downcanyon from the occurrence is likely to be suitable and occupied. By using the best available aerial photographs, we determined the boundaries of each occupied segment based on the up- and downcanyon extent of vegetation that could support the species. We have not calculated the actual acreage of each canyon segment because we cannot determine the actual width of the suitable habitat, but in many cases it probably only extends about 50–100 ft (15–30 m) upslope from the canyon bottom. Instead, each occupied segment includes the approximate linear extent of contiguous suitable habitat within each canyon that has documented occurrences.

The known range of the Caliente Canyon population is based on 18 occurrences (including 4 newly discovered occurrences) and consists of 5 canyon segments totaling approximately 9 linear mi (14.5 km) (Figure 1), including: Caliente Canyon (14 occurrences, 7 linear mi (11.3-km)), Tollgate Canyon (1 occurrence, 0.8 linear mi (1.3 km)), Indian Creek (1 occurrence, 0.5 linear mi (0.8 km)), an unnamed canyon south of Indian Creek (1 occurrence, 0.4 linear mi (0.6 km)), and Silver Creek (1 occurrence, 0.3 linear mi (0.5 km)).

Tehahcapi slender salamanders were first discovered in Caliente Canyon in 1967 (Brame and Murray 1968, p. 18), and Hansen included Caliente Canyon is his 2008 habitat assessment (Hansen 2009, pp. 1–30). However, Hansen's 2009 report does not include any information on the four new occurrences outside Caliente Canyon, which were discovered in 2011. The 14 occurrences in Caliente Canyon closely follow Caliente Creek between the junction of Bealville Road and California Bodfish Road (10 mi (16 km) west of Loraine) and the unincorporated community of Loraine (see Figure 1). Caliente Canyon runs roughly from east to west and has a number of seasonally moist areas on the steep north-facing slopes bordering Caliente Canyon Road. Tehachapi slender salamander habitat in Caliente Canyon is patchily distributed and discontinuous because slope aspect throughout the canyon varies as a result of the natural bends in the canyon and the occurrence of side canyons. Twelve of the 14 occurrences (approximately 85 percent) in Caliente Canyon occur on private land and 2 (approximately 15 percent) occur on Bureau of Land Management (BLM) land (Hansen 2009, p. 3). Suitable habitat for the species may also occur on north-facing slopes of unnamed side canyons that stem from Caliente Canyon (Hansen 2008a, b, pers. comm.; Sweet *in litt.* 2009, p. 2).

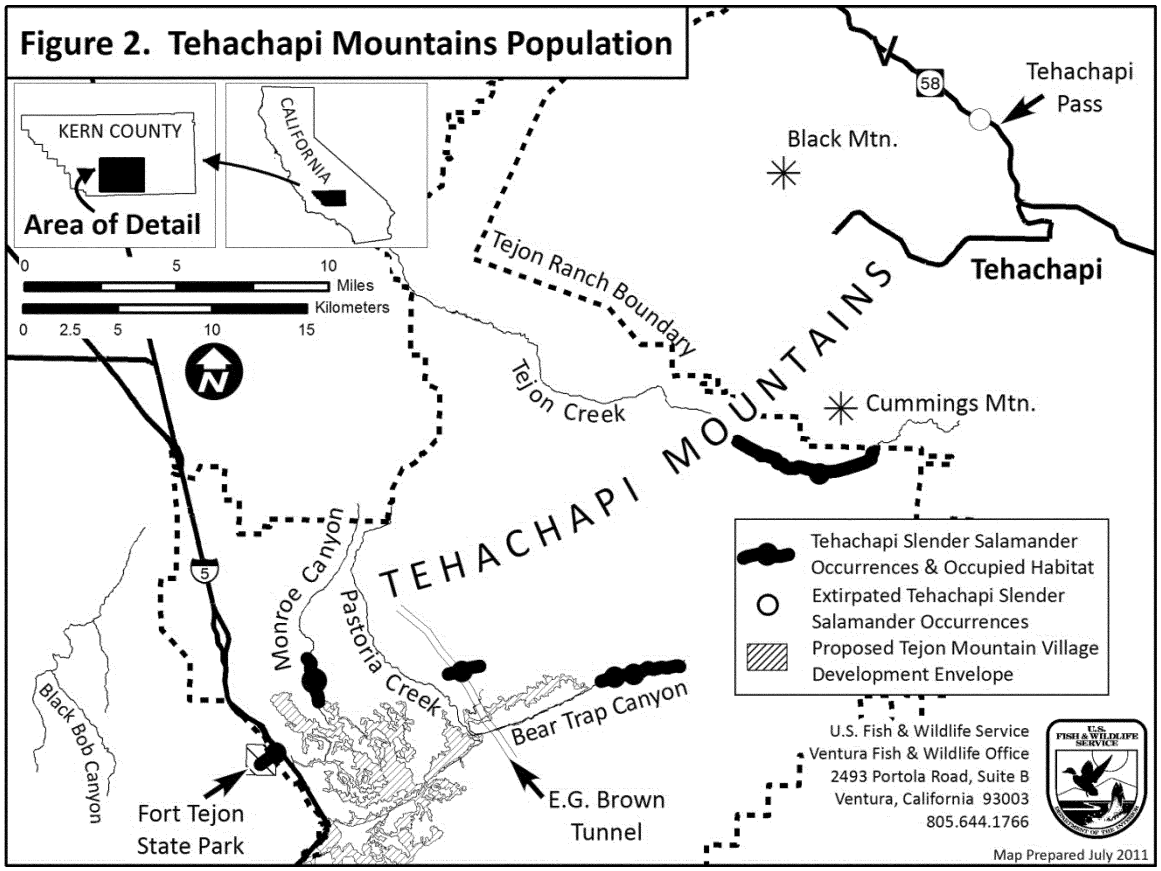
Information is limited for the four newly discovered occurrences of the Caliente Canyon population at this time. The new occurrences range from about 5.75 to 7 mi (9.3 to 11.3 km) south and southeast of the the easternmost occurrence in Caliente Canyon (Figure 1). Based on photos of the new areas taken when the species was first found there (Sweet 2011, pp. 1–13), the habitat in the vicinity of the occurrences in Tollgate Canyon, Indian Creek, and the unnamed canyon south of Indian Creek is typical of Tehachapi slender salamanders—steep, shaded, tree-covered, north-facing slopes, with talus and fallen logs. Although the Silver Creek occurrence is also on a north-facing slope, it is atypical for the species in that it is more exposed than other occurrences, with *Juniperus california* and *Pinus* spp. (pines) predominating instead of *Quercus chrysolepis* and *Aesculus californica.* Three of the four new occurrences for the Caliente Canyon population occur on private land and one occurs on BLM land.



The Tehachapi slender salamander was reported along the Tehachapi Pass, 8 mi (13 km) southwest of Caliente Canyon in 1957, but has not been reported in that area since (Hansen 2009, p. 9). At the Tehachapi Pass location (see Figure 2), the species was observed on the north side of Black Mountain, between State Highway 58 and the Southern Pacific rail line (Hansen 2009, pp. 3, 21). We have no information to indicate whether surveys have been conducted for this species in this area since 1957. Because we do not have current information indicating that the species still occupies this area, whether that habitat still remains, or which population this occurrence belongs to, we do not discuss this historical occurrence further in this review.

The known range of the Tehachapi Mountains population, which is based on six occurrences (Dudek 2008, p. 5–14; Hansen 2009, pp. 9–10), consists of five canyon segments totaling approximately 10.2 linear mi (16.4 km). Four of the five occupied canyons (five of the known occurrences) within this region are on the privately owned Tejon Ranch (see Figure 2), and span from Tejon Canyon in the northeast, to Monroe Canyon 17.5 linear mi (28.2 km) to the southwest. The occupied canyons on Tejon Ranch are in Bear Trap Canyon (two occurrences; approximately 2.7 linear mi (4.3 km)); the Tejon Creek drainage of Tejon Canyon (one occurrence; approximately 5 linear mi (8 km)); an unnamed canyon near the Edmond G. Brown Tunnel between Bear Trap Canyon and Geghus Ridge (one occurrence; approximately 0.5 linear mi (0.8 km)); and the recently discovered occupied location (Dudek 2008, p. 5–14) at Monroe Canyon (one occurrence; approximately 1.5 linear mi (2.3 km). Hansen (2009, p. 4) described the occupied habitat on Tejon Ranch (Bear Trap Canyon specifically) as having moist, loamy soil on north-facing talus slopes with canyon live oak, *Quercus kelloggii* (black oak), *Q. wislizenii* (interior live oak), *Calocedrus decurrens* (incense cedar) and *Aesculus californica* (California buckeye).

The one confirmed occurrence in the Fort Tejon SHP area (approximately 0.5 linear mi (0.8 km)) is located on the west side of Interstate Highway 5, approximately 3 mi (4.8 km) northwest of the unincorporated community of Lebec, California (Hansen 2009, p. 10; CNDDB 1997).



A few reports of Tehachapi slender salamanders have not been confirmed or have been determined to be other species of slender salamander. In 1973, Richman reported the presence of Tehachapi slender salamander in Tulare County (Richman 1973, p. 97). Richman stated that two adult specimens fitting the description of the Tehachapi slender salamander were found under a *Pinus jeffreyi* (Jeffrey pine) log on an east-facing slope in the Sequoia National Forest, Tulare County, California. In a 1980 report to the State of California Resources Agency, Hansen (1980, p. 38) disagreed with Richman's claim that the range of the Tehachapi slender salamander extended to Tulare County. Based on his own collections at the site described by Richman, Hansen (1980, p. 38) stated that the specimens are definitively not *Batrachoseps stebbinsi,* and later found that what Richman described was the first sighting of the Kern Plateau salamander (*B. robustus*) (AmphibiaWeb 2009, p. 4; Hansen and Wake 2005, p. 695; Wake *et al.* 2002, p. 1016). BLM also reported the species occurring in Tulare County (BLM 2009, p. 1); however, this report could not be confirmed (Verner *in litt.* 2008, p. 1). The U.S. Forest Service reported that there are no known occurrences of the species within the lands of the National Forest System (U.S. Forest Service 2009, p. 2). Based on this information, we currently do not believe that the range of the Tehachapi slender salamander extends beyond Kern County.

Potential Suitable Habitat

Although we do not include any potentially suitable habitat outside the canyons that are known to be occupied for the reasons described below, researchers have speculated that suitable habitat occurs in other canyons and that other canyons may be occupied. During his 2008 habitat assessment, Hansen (pers. comm. 2008b; 2009, pp. 5–6) identified additional areas of suitable habitat along Caliente Creek Road between the junction of Bodfish Road and the community of Loraine, and in the southwest reaches of the Fort Tejon SHP in Johnson Canyon, near the border with Los Padres National Forest. Hansen's report identified five general areas containing mesic north-facing slopes as potential habitat for the Tehachapi slender salamander, including: (1) Along Indian Creek Road, southeast of Loraine in Caliente Canyon; (2) drainages in Cummings and Bear Valleys; (3) canyons on Tejon Ranch connected to Clear, Sycamore, Cedar, Chanac, Tunis, and El Paso Creeks; (4) areas in Johnson Canyon within Fort Tejon SHP near the border with Los Padres National Forest; and (5) the northern slopes of the San Emigdio Mountains (*e.g.,* Black Bob Canyon) (Hansen 2009, pp. 5–6). Hansen (2009) did not provide a quantitative estimate of potential habitat. Subsequent to Hansen's 2009 report, Indian Creek has been found to be occupied by the salamander (Sweet *in litt.,* p. 1).

In addition to Hansen's work, Dr. Sweet identified suitable habitat in several tributary canyons extending south of Caliente Canyon (Sweet *in litt.* 2009, pp. 1–2). Within this estimated 30-square-mile (7,770-ha) area, Sweet (*in litt.* 2009, pp. 1–2) described the presence of steep, north-facing slopes containing patches of oak trees, springs and seepages, and areas containing talus. In his 2009 letter, Sweet (*in litt.* 2009, p. 2) stated that he had seen the Tehachapi slender salamander in this area and suggested that they may be widespread in these tributary canyons stemming from Caliente Creek. However, at that time, Sweet was unable to provide the Service with specific occurrence information. Subsequently, Christopher Evelyn and Dr. Sweet verified that at least a few of these canyons are occupied (Sweet 2011, pp. 1–13).

Although other canyons may have some habitat characteristics similar to those that are known to be occupied, we are not speculating here as to either their suitability for Tehachapi slender salamanders or the likelihood that they may be occupied. Although not studied in detail, the species' habitat requirements appear to be highly specific (*e.g.,* specific soil type; narrow range of soil moisture and temperature; substrate type and density; over- and understory structure; presence of appropriate refugia) and habitat that may have the general appearance of being suitable (*e.g.,* north-facing slope with an overstory) may be lacking one or more essential components. Also, the species has seldom been found when these areas of apparently suitable habitat have been searched. For example, on April 5, 2009, as a followup to the 2009 report, Hansen (2009), with assistance from Service biologists, conducted a survey for Tehachapi slender salamanders in San Emigdio Canyon (within the privately owned Wind Wolves Preserve located on the south side of Interstate Highway 5 and northwest of Fort Tejon) and in Johnson Canyon of Fort Tejon SHP. Although these areas included north-facing slopes that visually appeared similar to habitat at known occurrences, no Tehachapi slender salamanders were found. Also, during an extensive study on Tejon Ranch, only one individual Tehachapi slender salamander was found in the 77 drainages surveyed (Dudek 2008, p. 6–5). The one individual that was found in Monroe Canyon is a new occurrence of the species.

The lack of success in finding salamanders in potentially suitable habitat may simply be a function of the species not being at the surface on the day the search was conducted. However, it is also likely that the habitat was not actually occupied because it only had the most general habitat requirements but was missing some important feature required by the species. Therefore, we believe that it is overly speculative to assume that suitable habitat can be readily identified and that habitat that appears to be suitable is in fact occupied.

Population Sizes and Trends

The populations of occupied canyons have not been determined, and we are not aware of any information on actual population trends. The best available information indicates that the number of occurrences has remained relatively stable (Hansen 2009, pp. 3–5, 11, 12). One occurrence (Tehachapi Pass) has been extirpated as a result of road construction, and five new occurrences (Monroe Canyon, Tollhouse Canyon, Indian Creek, an unnamed canyon south of Indian Creek, and Silver Creek) have been found.

Current Status

The Tehachapi slender salamander has been listed as threatened by the State of California since June 1971 (CDFG 2009, p. 7). The species has a global heritage ranking of G2, meaning that the species is classified by NatureServe as globally imperiled (NatureServe 2009, p. 1; Hansen 2009, p. 2). The Tehachapi slender salamander is considered sensitive by BLM (2006, p. 2) and the U.S. Forest Service (2005, p. 78).

Summary of Information Pertaining to the Five Factors

Section 4 of the Act (16 U.S.C. 1533) and implementing regulations at 50 CFR part 424 set forth procedures for adding species to the Federal List of Endangered and Threatened Wildlife. An ''endangered species'' is any species in danger of extinction throughout all or a significant portion of its range. A ''threatened species'' is any species which is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. Under section 4(a)(1) of the ESA, a species may be determined to be endangered or threatened based on any of the following five factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

In considering what factors might constitute threats, we must look beyond the exposure of the species to the factor to determine whether the species responds to the factor in a way that causes actual impacts to the species. If there is exposure and the species responds negatively, the factor may be a threat and we then attempt to determine how significant a threat it is. If the threat is significant, it may drive or contribute to the risk of extinction of the species such that the species warrants listing as endangered or threatened as those terms are defined by the Act.

In making our 12-month finding, we considered and evaluated all scientific and commercial information in our files, including information received during the public comment period that ended June 22, 2009.

Factor A: The Present or Threatened Destruction, Modification, or Curtailment of the Species' Habitat or Range

Under Factor A, we consider whether the Tehachapi slender salamander is threatened by the present or threatened destruction, modification, or curtailment of its habitat or range by growth and development of human communities, road construction, mining, domestic livestock grazing, and flood control projects (Nichols 2006, p. 6). We will evaluate each of these threats for both the Caliente Canyon population and Tehachapi Mountains population of the Tehachapi slender salamander.

Like other plethodontids, Tehachapi slender salamanders require moisture to maintain the permeability of their skin for gas exchange for respiration (Feder 1983, p. 295). This physiological requirement limits the time during which they are active at the soil's surface to relatively brief, rainy periods between the late fall and early spring (Hansen 2009, p. 2; Hansen and Wake 2005, p. 694). These salamanders forage and breed during periods of surface activity (Feder 1983, p. 296). During the remainder of the year, they retreat into talus or rocky substrates, or deep under fallen logs or leaf litter, which provide refuge from the climatic extremes of the Tehachapi and Sierra Nevada Mountains (Hansen 2009, p. 2).

Given its physiology and life history, this species may be negatively affected by disturbances that remove or reduce surface and soil moisture, relative humidity, or suitable rocky and leafy substrates. Disturbances that reportedly impact Tehachapi slender salamanders through habitat removal and degradation include residential and commercial development, livestock grazing, road construction, mining, and flood control projects (Hansen and Wake 2005, p. 693; Hansen and Stafford 1994, pp. 254–255; Jennings 1996, pp. 928–929). Construction associated with residential and commercial development, new roads, and mines can remove habitat and can also cause erosion that washes away the substrates of talus, woody debris, and leaf litter that the Tehachapi slender salamander uses as refugia. The removal and degradation of habitat can also cause habitat fragmentation, which would require individuals to travel longer distances between suitable habitat patches during brief periods of suitable climate to find mates. In addition, these activities, along with flood control

projects, may alter the hydrology of the mesic environment upon which the species depends (Jennings 1996, pp. 928–929; Hansen and Wake 2005, p. 693; CNDDB 2007). Our evaluation of the extent and magnitude of potential effects caused by these activities is based on existing and expected land uses within the species' range.

Caliente Canyon Population

The main land use within the range of the Caliente Canyon population of the Tehachapi slender salamander is livestock grazing (mainly cattle). Seventeen of the 18 confirmed occurrences of the Caliente Canyon population of the Tehachapi slender salamander are on lands used primarily for livestock grazing. The remaining occurrence is on a 34-ac (13.8-ha) parcel with a private residence located at the base of a north-facing slope. In terms of land ownership, 15 occurrences are on private land, and 3 occurrences are on BLM land.

In 2008, Hansen conducted a habitat assessment of the 14 occurrences in Caliente Canyon (Hansen 2009, pp. 1–30) (Figure 1), which was prior to the discovery of the other 4 occurrences that make up the Caliente Canyon population. In his 2009 report, Hansen (pp. 11–12) noted moderate but localized impacts at 4 of the 14 occurrences in Caliente Canyon from one or more of the following: Cattle grazing, disturbance associated with a residence on a private parcel, or erosion from a nearby road (Hansen *in litt.* 2010a, pp. 1–3). The other 10 occurrences show minor to low levels of disturbance from cattle grazing (Hansen *in litt.* 2010a, pp. 1–5; Hansen 2009, p. 11). Hansen did point out that there was plenty of suitable habitat in good to fair condition at all 14 occurrences that would adequately function for the species (Hansen *in litt.* 2010a, pp. 3–7; Hansen 2010 pers. comm.), and that overall, the habitat in the canyon had remained relatively stable since his first visit in 1979 (Hansen 2009, p. 3).

Livestock grazing could potentially impact Tehachapi slender salamander habitat through trampling and erosion. The degree of cattle-related degradation is directly related to the concentration of cattle in a given area (Hansen *in litt.* 2010a, p. 3). Heavy trampling, particularly during moist conditions, could crush Tehachapi slender salamander burrows and individual salamanders during their surface activity, and could degrade habitat by displacing and removing talus, logs, and rocks that serve as critical components of cover and habitat for the species (Hansen 2010, 2008b, pers. comm.; Kuritsubo 2010 pers. comm.). Habitat cover consisting of talus, leaf litter, and woody debris can be displaced by cattle and further removed by wind and water erosion, potentially making the area less hospitable for the species to burrow and retain moisture for skin respiration. However, impacts from cattle within the range of the Caliente Canyon population of the Tehachapi slender salamander are typically localized, and are generally low to moderate in degree (Hansen *in litt.* 2010a, pp. 1–7). In addition, Tehachapi slender salamander occurrences in Caliente Canyon have persisted for decades in areas grazed by cattle (Hansen 2009, pp. 3, 11). The same is likely true for the four newly discovered occurrences of the Caliente Canyon population.

Although livestock grazing (mainly cattle) occurs throughout Caliente Canyon, Hansen (2009) found a moderate and localized level of habitat degradation from livestock grazing in the vicinity of only 3 of the 14 occurrences in the canyon, but also noted that sufficient habitat in good-to-fair condition remained in these three areas to support the species. One of the three occurrences that show a moderate level of habitat degradation is on BLM land that has been designated as a BLM grazing allotment. BLM manages the allotment in Caliente Canyon for 74 animal unit months (AUMs) (*i.e.,* 6 cows graze throughout the allotment year-round or 74 cows graze in the allotment for 1 month per year) on 470 ac (190 ha) within the Canyon (Kuritsubo *in litt.* 2009b, p. 1). Although the other occurrence in Caliente Canyon on BLM land is also within the grazing allotment, it is considered to be in good condition (Hansen 2009, p. 11). The third occurrence affected by grazing is on private land (Hansen 2009, p. 11). The limited impact of cattle grazing on Tehachapi slender salamander habitat in Caliente Canyon and elsewhere may be because they are free ranging. Cattle tend to graze the grass to a certain height and move on, unless their movement is restricted to a corral or a fenced area. According to Hansen (*in litt.* 2010a, p. 3; 2010 pers. comm.), cattle throughout the range of the species are free ranging, thus trampling and removal of vegetation to the point of exposing bare ground to such an extent that it reduces, fragments, or otherwise makes the habitat unsuitable for the Tehachapi slender salamander is not evident for any of the occurrences throughout the Caliente Canyon population's range.

The fourth occurrence in Caliente Canyon (of the four with visible disturbance) is located on private land near a residence. The area immediately surrounding the point where the species had originally been found showed moderate to high localized disturbance; however, Hansen (*in litt.* 2010a, pp. 1–7; Hansen 2009, p. 11) indicated that sufficient undisturbed habitat remained in the area to support the species.

All of the confirmed occurrences in Caliente Canyon are adjacent to a two-lane, paved road. The impacts of roads on the Tehachapi slender salamander are varied. Road construction, such as construction of State Highway 58 (the section between the unincorporated communities of Keene and Monolith was constructed during the 1960s), Interstate Highway 5 (the section between Lebec and Fort Tejon was completed in 1964), and Caliente Creek Road (date of construction unknown), likely removed Tehachapi slender salamander habitat and likely caused some habitat fragmentation (Cismowski *in litt.* 2010, p. 1; Hansen and Wake 2005, p. 693; Hansen 2009b pers. comm.). Further, road run-off from precipitation may contribute to erosion of the talus, leaf litter, and small rocks that comprise salamander habitat. Hansen noted that erosion was occurring, possibly from run-off from the roads, in the vicinity of 2 of the 14 occurrences in Caliente Canyon (Hansen 2009, p. 11). Erosion at one of the two occurrences is associated with the main paved road through the canyon, while the other is from a narrow, unpaved road (see below). The impact of erosion in the vicinity of these two occurrences was moderate and localized, with sufficient remaining habitat nearby to continue to support the species (Hansen *in litt.* 2010a, p. 3). We are not aware of any new roads planned for construction within the range of this population.

Mining has occurred in the Caliente Creek region of Kern County since the late 1800s (SRK Consulting 2002, p. 6). The Zenda Gold Mine project is located on private land about 1 mi (1.6 km) from one of the occurrences of the Tehachapi slender salamander in Caliente Canyon (Hansen 2009, p. 11). Kern County issued a conditional use permit in 1990 to Equinox, the mine owner at the time, but the permit has since expired and has not been renewed (Kuritsubo 2009b pers. comm.). Although the Zenda Gold Mine is located on private land and is sufficiently distant not to be a threat to any occurrences, Equinox's mining claim also extends onto BLM land in the vicinity of one or more occurrences. Mining companies often hold claims for lands that they may not own that extend beyond what they are currently mining (Kuritsubo 2009c pers. comm.). For example, these areas may be included to

provide access to the actual mine site. Although Equinox's claim extends onto BLM land, they have not conducted any activity on the claim (Falcon *in litt.* 2010, p. 1; SRK 2002, pp. 6–7). Although the claim is still in effect,the county permit for the mine has expired, and there are no mine plans filed with BLM or Kern County under the State Mining and Reclamation Action of 1975 (SMARA) (Falcon *in litt.* 2010, p. 1; Kuritsubo 2009a pers. comm.). Based on the best information available to us, there are no active mines within the range of this population.

One of the two occurrences where erosion has occurred is downslope from Last Chance Canyon Road, a narrow, unpaved road leading to the Zenda gold mine. Hansen (2009, p.11) notes in his 2009 report that construction of this unpaved road eliminated some Tehachapi slender salamander habitat and is causing erosion of the remaining habitat in this area. Regardless of how much the Last Chance Canyon Road is traveled, its mere presence may degrade Tehachapi slender salamander habitat through erosion from wind and runoff from seasonal precipitation. Even so, Hansen (*in litt.* 2010a, p. 1) describes the impacts to the habitat in the general vicinity of the occurrence as moderate and localized, but also noted that sufficient habitat in good-to-fair condition remained to support the species. There are no new mining roads planned within the range of the Caliente Canyon population.

The habitat at the four new occurences of the Caliente Canyon population has not been surveyed, and therefore the habitat assessment below is based on topographic maps, aerial photos, and survey photo records of each location (Sweet 2011, pp. 2–5 and 8–10). The habitat at the Tollgate Canyon occurrence appears to be in good condition, and although grazing likely occurs in the general area, there are no signs of disturbance from grazing. An unpaved road is near the occurrence, but there are many acres of contiguous salamander habitat surrounding the occurrence. There are no paved roads, buildings, mines, or other forms of activity in the area. The habitat at the unnamed canyon south of Indian Creek occurrence appears to be in good condition. This occurrence is on BLM land that is not part of a grazing allotment, and there are no signs of disturbance from grazing. There are no paved or unpaved roads, buildings, mines, or other forms of activity in the area. The habitat at the Indian Creek location appears to be in fair to good condition because grazing is more readily apparent near this occurrence than the two above occurrences. There is also an unpaved road in the vicinity of the occurrence. However, there are no paved roads, buildings, mines, or other forms of activity in the area. The habitat at the Silver Creek occurrence appears to be in fair to good condition because grazing occurs in the area. There is also a building and an unpaved road near this occurrence, but there are many acres of contiguous salamander habitat surrounding the occurrence.

In summary, grazing occurs on much of the private land and the BLM lands that are part of allotments in the range of the Caliente Canyon population of the Tehachapi slender salamander. Of the 14 occurrences in Caliente Canyon, 4 have experienced a moderate level of localized habitat disturbance. Of these four, one occurrence is moderately affected by cattle grazing; one on BLM land is moderately affected by cattle grazing and erosion from an adjacent paved road; one is moderately affected by grazing and erosion from an adjacent narrow, unpaved mine road; and one is moderately affected by a residence. Habitat with little or no disturbance is present in the same areas as these four occurrences. The other 10 occurrences show a minor-to-low level of disturbance from cattle grazing (Hansen *in litt.* 2010a, pp. 1–4; Hansen 2009, p. 11). The only activity in the areas where the 4 new occurrences are located is cattle grazing, with the exception of a single building near one of the occurrences. One of the newly discovered occurrences appears to be in good condition, with little sign of grazing. Another, which is on BLM land that is not part of an allotment, appears to be in good condition. We classify the other two occurrences as being in fair to good condition because there are signs of cattle grazing in their immediate vicinity. There are no flood control projects occurring or planned within areas of known Tehachapi slender salamander occurrences in Caliente Canyon.

Based on the best information we have, there are no planned or proposed land use changes within the range of the Caliente Canyon population of the Tehachapi slender salamander. BLM's land use management plans are updated every 15 to 20 years. Although the BLM land containing three confirmed occurrences may be disposed of (meaning relinquished or sold) based on the current plan, we have no information to indicate that the land will be sold or developed, or that the current grazing practices will change within the next 15 to 20 years (Kuritsubo *in litt.* 2008, p. 1; Kuritsubo 2009b pers. comm.). No new residential or commercial development projects planned on parcels with occupied Tehachapi slender salamander habitat are expected in the foreseeable future (Kern County *in litt.* 2009, p. 9). No permit requests have been submitted to Kern County to restart mining activity in the foreseeable future. Therefore, the Caliente Canyon population of the Tehachapi slender salamander and its habitat are not threatened with destruction or curtailment now and are not likely to be threatened with destruction or curtailment in the future.

Tehachapi Mountains Population

For the reasons discussed above (see ''Potential Suitable Habitat'' section), we define the range of the Tehachapi Mountains population as consisting of five occupied canyon segments totaling 10.2 linear mi (16.4 km), which includes six known occurrences. Four of the canyon segments (five of the occurrences) are on the privately owned Tejon Ranch, and one is on Fort Tejon SHP. The main land uses that are presently occurring within the range of the Tehachapi Mountains population of the Tehachapi slender salamander are ranching, farming, and recreation (Hansen 2009, p. 12; ICF Jones and Stokes 2009, p. 1–4). Currently, specific land uses on the 270,365-ac (109,413-ha) Tejon Ranch include: farming and irrigation systems; livestock grazing and range management activities; film production (which may involve temporary construction and use of explosives); repair, maintenance, and use of roads; maintenance and construction of utilities; and fence construction and maintenance (Dudek 2008, pp. 2–5 through 2–8). There is an existing 2-in (5-cm) water pipeline that overlaps with one confirmed occurrence near Pastoria Creek (Miller *in litt.* 2010b, p. 2). Because this pipeline is already in place, and it does not carry any dangerous substance, we do not find the presence of this pipeline to threaten the Tehachapi slender salamander or its habitat. The closest farming and irrigation activities are approximately 1,000 ft (305 m) from the occupied portion of any canyon, and are, therefore, far enough away not to negatively affect slopes known to be occupied by Tehachapi slender salamanders (Miller *in litt.* 2010b, p. 4).

Possible impacts from cattle grazing are as discussed for the Caliente Canyon population of the Tehachapi slender salamander. There are approximately 14,500 head of cattle (Dudek 2008, p. 2–5) grazing on 255,000 ac (103,195 ha) (Miller *in litt.* 2010b, p. 5) of Tejon Ranch. Cattle grazing on Tejon Ranch are managed by seasonal rotation,

following the availability of green pasture (Miller *in litt.* 2010a, p. 1). While Tejon Ranch's livestock managers continually assess the availability of feed, cattle are allowed to ''drift'' through gates to different pastures where feed is available (Miller *in litt.* 2010a, p. 1). This approach provides for active management of free-range cattle grazing and avoids depletion of vegetation and significant damage of the habitat.

In his 2000 Tehachapi slender salamander survey, Hansen documented that grazing, and to a limited extent logging, were evident in occupied Tehachapi slender salamander habitat (Hansen 2009, p. 12). Specifically, Hansen noted that grazing and logging activities were evident along Bear Trap Canyon in the area known to be occupied (Hansen 2009, p. 5). From 1989 through 1994, Tejon Ranch had a short-term timber harvesting operation targeting hardwoods for fuel on 367 ac (148.5 ha) in an area that includes Bear Trap Canyon (Vance *in litt.* 2009a, pp. 2, 8). To the best of our knowledge, no commercial logging activities are currently in operation and none are proposed on Tejon Ranch (Brauer *in litt.* 2009, p.1; Vance *in litt.* 2009a, p. 1). Hansen reported that the habitat at all of the then known four occurrences on Tejon Ranch was in good condition, despite the presence of grazing (Hansen 2009, p. 12). The fifth, and most recently discovered occurrence in Monroe Canyon, is reported to be in habitat of good condition, with no evidence of disturbance by cattle (Miller *in litt.* 2010b, p. 4).

Wild turkeys (*Meleagris gallopavo*) and pigs (*Sus scrofa*) were introduced on Tejon Ranch in 1989 and 1990, respectively (Miller *in litt.* 2010b, p. 5; Dudek 2008, p. 3–4). There are approximately 1,200 turkeys and 5,000 pigs with free range on 255,000 ac (103,195 ha) on Tejon Ranch (Miller *in litt.* 2010b, pp. 4–5). Similar to livestock grazing, wild pigs and turkeys could degrade and fragment Tehachapi slender salamander habitat by removing talus and leaf litter, thus damaging the soil cover while foraging (Dudek 2008, pp. 5–26, 6–6). Pigs are known to be particularly destructive because of their rooting and tilling behavior (Hansen 2009, p. 4; Dudek 2008, p. 3–4). Although turkeys and pigs overlap with the Tehachapi population of the Tehachapi slender salamander and have the potential to destroy habitat through scraping and rooting, we have no information to indicate that the Tehachapi slender salamander is being threatened by these nonnative species; and no damage from turkeys or pigs has been reported in occupied habitat. In fact, Tehachapi slender salamander habitat on the ranch is reported to be in good habitat condition (Miller *in litt.* 2010b, p. 5; Hansen *in litt.* 2010a, p. 3).

Activities involving ground disturbance associated with construction include film production; repair, maintenance, and use of roads; maintenance and construction of utilities; and fence construction and maintenance. All of these activities could result in the removal of habitat cover (talus, leaf litter, and vegetation), digging, and removal of soil. Such actions may result in habitat degradation, fragmentation, and the injury or mortality of the Tehachapi slender salamander. All of these activities occur on a sporadic and limited basis. We have no evidence that they occur in areas of known Tehachapi slender salamander occurrences.

Overall, current ranch-wide activities on Tejon Ranch have not removed or destroyed the Tehachapi slender salamander's habitat within the range of the Tehachapi Mountain population. Cattle ranching has been practiced since the late 1800s (Tejon Ranch 2011, p. 1), and the presence of cattle has not modified the habitat in any noticeable manner (Hansen 2009, p. 12). Fuel management (vegetation thinning and clearing) does not appear to have any visible effect on habitat. Wild turkeys and pigs cause localized habitat degradation, but apparently no degradation has been documented in this area. Finally, with the exception of one existing water pipeline, farming, irrigation, road repair and construction activities do not occur within occupied habitat.

Tejon Ranch plans to construct a residential and commercial development on their property called Tejon Mountain Village (TMV). The TMV development envelope consists of 7,860 ac (3,181 ha), within which a development footprint of up to 5,533 ac (2,239 ha) is proposed (Letterly *in litt* 2010, p. 1). Although Tejon Ranch does not plan to exceed the 5,533-ac (2,239-ha) footprint, the exact location for construction could be anywhere within the 7,860-ac (3,181-ha) development envelope.

The TMV development would include a total of 3,624 dwelling units, 464,920 square feet (43,192 square meters) of commercial development, two golf courses, an equestrian center, up to 750 hotel rooms, and up to 350,000 square feet (32,516 square meters) of support uses (*e.g.,* hotel lobby support services, food and beverage service, golf clubhouses, equestrian facilities, private recreation facilities) (Dudek 2008, p. 2–11) that would be constructed over approximately 30 years. The TMV development envelope has been designed to completely avoid all occupied habitat (*i.e.,* occupied canyon segments that make up the range of the species) and all known occurrences of the Tehachapi slender salamander. Potentially, the closest development to occupied habitat (*i.e.,* the distance to the boundary of the development envelope) is about 0.5 mi (0.8 km) at Monroe Canyon; all other occupied habitat is a minimum 1 mi (1.6 ha) from any potential development. Therefore, because the species is confined to the identified canyon segments based on the biology of the species, and those canyon segments are outside of the proposed development envelope, we do not expect that construction of the TMV project will result in the loss of any occupied habitat.

The proposed TMV development is expected to reduce the area grazed on the ranch by approximately 2 percent (5,000 ac (2,023 ha) of the 255,000 ac (103,195 ha)), leaving approximately 250,000 ac (101,171.4 ha) available to cattle (Miller *in litt.* 2010b, p. 5). The number of cattle grazing on the ranch would be commensurate with the reduction in area available for grazing, and the reduction in available feed (Miller *in litt.* 2010b, p. 5). As a result, we do not anticipate grazing impacts to increase as a result of the proposed TMV development.

Tejon Ranch has submitted a habitat conservation plan (HCP) to the Service, in support of an application for an incidental take permit (ITP), that addresses 27 species, including the Tehachapi slender salamander, that potentially may be affected by the TMV project and current ranch-wide uses, such as grazing, proposed to be covered under the ITP. The HCP covers approximately 141,886 ac (57,419 ha) of the 270,365-ac (109,413-ha) ranch (Dudek 2008, p. 1–1). In addition to an HCP, a draft Environmental Impact Statement (EIS) on the HCP/ITP has been circulated for public comment in accordance with the National Environmental Policy Act (NEPA). A Final Environmental Impact Report (EIR) that focuses on the TMV project was certified by Kern County in 2009 to comply with the California Environmental Quality Act (CEQA).

Dudek, the consultants preparing the HCP for Tejon Ranch, developed a habitat suitability model to estimate impacts to each of the species addressed in the plan. Based on the model, Dudek estimates up to 3,797 ac (1,537 ha) of suitable habitat for the Tehachapi slender salamander may exist within the

141,886-ac (57,419-ha) HCP boundary (Dudek 2008, p. 5–14; ICF Jones and Stokes 2008, p. 3.1–15). However, both Tejon Ranch and Dudek point out that the habitat suitability model is constrained by broad assumptions and limited information on the species' habitat characteristics; thus, the model likely overestimates the presence of suitable habitat (Dudek 2008, pp. 5–14 and D–31). We concur with Dudek's assessment of the model, and also believe it greatly overestimates the amount of suitable habitat; therefore, the model should be considered a worst-case approach for determining the amount of potentially affected habitat.

As we discussed in the ''Potential Suitable Habitat'' section above, the species' habitat requirements are highly specific, and the Dudek model overgeneralizes suitable habitat. For example, we understand that the species is mostly found on north-facing slopes; however, the model includes east-facing (90 degree) and west-facing (270 degree) slopes (Dudek 2008, p. D–31). Further, information was not available for the model to account for the presence of talus or leaf litter that the species uses for refuge. The model also assumes uniform distribution of habitat, whereas in reality, the species and its habitat are patchily distributed in the landscape. As a result, suitable habitat identified in the model includes areas with unsuitable and inhospitable substrates for the species, and thus the model overgeneralizes and overestimates the amount of Tehachapi slender salamander habitat. For these reasons, we have based our analysis mainly on threats to the known occupied canyons. However, we also recognize the possibility that other suitable habitat exists beyond these canyons and that some of these areas could potentially be occupied, and, therefore, we have also considered the results of the Dudek suitability model as a worst-case approach to assessing the impacts of the TMV project.

Although the TMV development envelope avoids all habitat segments we consider to be occupied and all known occurrences within the Tehachapi Mountains population (*i.e.,* the discrete range of this portion of the species), the habitat suitability model for the Tehachapi slender salamander estimates that 108 ac (44 ha) (16 percent) of the 760 ac (308 ha) of potentially suitable habitat within the proposed TMV development envelope would be removed (ICF Jones and Stokes 2008, p. 4.1–31). The EIR for the proposed TMV project states that short-term and long-term impacts from construction, which would result in the loss of 16 percent of potentially suitable habitat in the project area without the proposed mitigation measures sited in the EIR (ICF Jones and Stokes 2009, pp. 4.4–102 and 4.4–156), could be significant to the Tehachapi slender salamander. However, we believe the EIR's conclusion overstates potential impacts to the Tehachapi slender salamander.. Our reasons are based on the following:

(1) The EIR for the proposed TMV project uses data from the Dudek habitat suitability model for the Tehachapi slender salamander to estimate potential impacts to the species, which as previously discussed, overestimates the amount of suitable habitat for the species on the ranch and likewise, overestimates the number of acres of suitable habitat potentially removed as a result of the project;

(2) the EIR analysis of impacts is based on the estimated number of acres of potentially suitable habitat within the boundaries of the proposed TMV development envelope, but the loss of 108 ac (44 ha) actually represents only 2.8 percent of the potentially suitable habitat within the HCP boundary on the ranch;

(3) we have no indication that the 108 ac (44 ha) is occupied by the species; and

(4) the development envelope does not overlap with occupied habitat or known occurrences of the species.

Although known occupied habitat will not be lost as a result of the proposed development, development will result in the fragmentation of potential modeled habitat in some canyons, and development will occur between some canyons. Although no salamanders were found in the canyons within the development envelope during surveys, (Dudek 2008, p. 6–5), if in fact these canyons are actually occupied (based on a worst-case scenario considering best available information currently identifies this area as unoccupied), salamander movement up- and down-canyon could be restricted in some areas. However, we do not believe salamanders are capable of moving from canyon to canyon because of the dry and rugged terrain that occurs between canyons. Therefore, we do not believe that the proposed development will result in any further isolation of occupied habitat and the effects of fragmentation would be limited to the loss of potential suitable habitat in some of the canyons that occur within the development envelope and would only constitute an impact to the species if those canyons were occupied.

A component of the TMV proposed project includes fuel management (vegetation thinning and clearing) to reduce threats of fire outbreaks and damage. Outside of the development areas, fuel management on 141,886 ac (57,419 ha) of the 270,365-ac (109,413-ha) ranch will consist primarily of cattle grazing, which is used to maintain vegetation at a certain height rather than denude areas to bare ground or involve the removal of shrubs, branches, or trees. In addition to the existing grazing program, fuel management activities in open space areas will include maintenance of the existing fuel break network (*e.g.,* dirt/gravel roads), coordination with State or local agencies for mowing or other fire protection measures along fire prone areas (*e.g.,* highways), and irrigation or vegetation clearing/mowing within 120 ft (36.6 m) surrounding existing structures (*e.g.,* hunting cabins and ranch structures). Within the TMV development envelope, fuel management zones in open space may extend 200 ft (61 m) from new structures and fuel management will be limited to thinning and nonirrigation treatment.

Fuel management may remove some vegetation cover that maintains soil moisture in the mesic microenvironments that provide suitable habitat for the Tehachapi slender salamander; however, it is not expected to affect any of the known occupied habitat or occurrences. Tejon Ranch proposes to develop a fuel management plan, as described in the HCP and Ranch-wide Land Use Agreement, which, if the HCP is approved, will be subject to Service review and approval to ensure consistency with the conservation measures described in the HCP (Dudek 2008, pp. 2–5, 2–6; Agreement 2008, pp. 4, 20). Even without the fuel management plan, fuel management activities are not expected to threaten the existence of the Tehachapi slender salamander now or in the foreseeable future because no occupied habitat is within 200 ft (61 m) of the TMV development.

If the TMV project is realized, new roads would be constructed to gain access to residential, commercial, and recreational areas. However, no new roads are planned near occupied habitat or known occurrences (ICF Jones and Stokes 2009, Figure 3–14). The TMV project does propose to implement road improvements, including an existing ranch road in Bear Trap Canyon, which is one of the canyons occupied by the salamander. This road may approach the very west end of occupied habitat in the canyon, but it is located entirely on the flat, dry terrain below the occupied

north-facing slope and veers entirely out of the canyon at that point. Any improvements to the existing road are expected to be limited because the road will be used only as an Emergency Access Road (ICF Jones and Stokes 2009, Figures 4.4–8 and 3–14; Marshall *in litt.* 2009, p. 1), and any potential impact to the salamander would be at the very west end of occupied habitat. This information is also consistent with the proposed development envelope being situated away from known Tehachapi slender salamander occurrences. Although new roads or road improvements will not affect occupied habitat, they may cross potentially suitable habitat (modeled habitat) and may result in additional fragmentation of potentially suitable habitat.

Although there will be no direct impacts to the known range of the Tehachapi Mountains population (which is based on six occurrences and consists of five canyon segments totaling approximately 10.2 linear mi (16.4 km) of known occupied habitat) from the proposed development of the TMV project, the EIR lists the following potential indirect effects from construction as significant: Construction dust; increased human activity from construction workers; construction-related noise, vibration, and lighting; vehicle collisions, chemical releases, and hydrological modifications (ICF Jones and Stokes 2009, p. 4.4–156); and increased foot traffic and trail usage.

Given that this species is primarily nocturnal and spends most of the year up to 3 ft (0.9 m) underground (*i.e.,* during dry conditions), and given that impacts from construction dust would be limited to above-ground surfaces, it is unlikely to have a negative effect on the fossorial habitat of the species. Impacts from increased human activity, noise, vibrations, lighting, and vehicle collisions are not likely to have an effect on the species' population because they would be primarily limited to the development envelope (Hansen 2010 pers. comm.), which is at a minimum 0.5 mi (0.8 km) removed from any occupied Tehachapi slender salamander habitat and about 0.7 mi (1.1 km) from any known occurrence.

It is possible that chemical releases from a construction activity could affect habitat, depending on the location and time of year (*e.g.,* during the rainy season a release could be washed over a larger area, compared to a release in the dry season); however, chemical releases associated with construction are expected to be restricted to the development envelope and therefore, away from areas of occupied habitat. Even if under unusual circumstances, a chemical release was to move past the development envelope, the closest area to occupied habitat is about 0.5 mi (0.8 km), and we do not believe that any construction-related chemical release would be of sufficient quantity to extend that far.

Stormwater runoff resulting from residential and commercial development can increase water flows due to an increase in impervious surfaces and degrade water quality. Although new roads would be limited to the development envelope, and therefore at a sufficient distance from known occurrences as to not have direct effects on individual salamanders, we do not have information to accurately estimate the frequency and intensity of impacts from runoff that could potentially affect Tehachapi slender salamanders. According to the EIR, hydrological modifications from the TMV development involving stormwater runoff, siltation, and erosion are expected to be only minor (*e.g.,* less than 5 percent) (ICF Jones and Stokes 2009, p. 4.8–32; Letterly *in litt.* 2011, p. 1).

Stormwater runoff from residential and commercial communities can degrade water quality. However, water quality is not expected to experience a noticeable change from existing levels of potential pollutants, including phosphorous, nitrates, ammonia, copper, lead, and zinc (ICF Jones and Stokes 2009, p. 4.8–26; Letterly *in litt.* 2011, p. 1). Therefore, degradation of water quality from stormwater runoff is not expected to have a measurable impact on the Tehachapi slender salamander and its habitat.

In addition to the indirect effects identified in the TMV EIR, potential indirect effects to the Tehachapi slender salamander from increased human presence on TMV include edge effects, changes in microclimate, and increased predation. Terrestrial salamanders are impacted by edge effects. Microclimate conditions within forest edges of habitat often exhibit higher air and soil temperatures, lower soil moisture, and lower humidity compared to interior forested areas (Moseley *et al.* 2009, p. 426). Due to the physiological nature of terrestrial salamanders, they are sensitive to these types of microclimate alterations, particularly to temperature and moisture changes (Moseley *et al.* 2009, p. 426). Generally, more salamanders are observed with increasing distance from some edge types, which is attributed to reduced moisture and microhabitat quality (Moseley *et al.* 2009, p. 426). However, edge effects from the proposed TMV development are expected to be at a sufficient distance from known occurrences as to not substantially impact the species. In addition, the Tehachapi slender salamander's semifossorial behavior further limits the negative impacts from edge effects, as the salamanders emerge to the surface during the rainy season.

Increased human residential, commercial, and recreational use of the area will likely increase the number of potential predators (*i.e.,* dogs, cats, crows, and raccoons) in developed areas. Domestic cats are known to kill amphibians although the proportion of amphibians killed by cats compared to other species is very small (Woods *et al.* 2003, p. 1). Coyotes (*Canis latrans*) also occur in Kern County (see Ralls and White 1995, Cypher and Spencer 1998, Nature Alley 2010) and the Tejon Ranch (ICF Jones and Stokes 2009, p. 4.4–432), and the abundance of cats and raccoons has been found to be much lower where coyotes occur (Crooks and Soulé 1999, p. 563). Crooks and Soulé (1999, p. 565) also found that a large number of owners restrict their cats' outdoor activity when coyotes were present. In addition, the salamander's exposure to predation is very limited due to its short activity period above ground, thus we do not believe that the increased presence of predators would rise to the level of threatening the Tehachapi slender salamander now or in the foreseeable future.

Foot traffic, increased use of trails, and creation of new trails would also likely increase in the vicinity of residential development. Increased use of existing trails can result in erosion and new trails can eliminate habitat and cause erosion. The Tehachapi slender salamander habitat that would most likely be affected would be in Monroe Canyon, which is the closest to the development envelope (minimum of 0.5 mi (0.8 km)). However, foot traffic in this area and any area of potential suitable habitat would most likely be along existing dirt roads and the flatter terrain below or above the steep, talus-covered slopes occupied by the species.

The fifth occupied canyon (one occurrence) of the Tehachapi Mountains population of the Tehachapi slender salamander is Johnson Canyon on Fort Tejon SHP on the west side of the Interstate Highway 5, adjacent to a service road near the entrance to the Park (Hansen 2009, p. 28; CDPR 1989, p. 175). The habitat at this occurrence on Fort Tejon SHP shows minimal, if any, impacts. Fort Tejon SHP provides for passive recreational activities including hiking, picnicking, camping, wildlife viewing, and educational

programs; no livestock grazing is allowed. A narrow, paved road lies at the base of the occupied slope but does not cross any habitat, and there are no plans to widen or change this road. As such, we do not believe that impacts from the road (if any) threaten the existence of the species in the area. No future land use changes on Fort Tejon SHP are planned that would affect the Tehachapi slender salamander (Bylin *in litt.* 2009, p. 1).

In summary, based on the best scientific and commercial information available, we conclude that current ranch-wide activities do not pose a threat to the Tehachapi Mountains population of the Tehachapi slender salamander and its habitat, nor do we anticipate such activities will pose a threat in the future. We also conclude that the proposed TMV development will avoid known occurrences of the species and all occupied habitat (*i.e.,* occupied canyon segments that make up the range of the species) on Tejon Ranch (see ''Tehachapi Mountains Population'' section under Factor A) and is not likely to cause any significant indirect impacts to the Tehachapi Mountains slender salamander or its habitat now or in the future.

Summary of Factor A

Livestock grazing occurs throughout the species' range (with the exception of Fort Tejon SHP), and depending on the intensity, grazing has the potential to degrade Tehachapi slender salamander habitat through trampling, soil scraping, and compaction, which can cause surface soil erosion and desiccation. However, habitat degradation in the range of the salamander is notable at only a few occurrences in Caliente Canyon. Road construction can destroy Tehachapi slender salamander habitat, but no new road construction is planned for either Caliente Canyon or the other occupied canyons that make up the Caliente Canyon population, and roads planned for the TMV project avoid occupied habitat. Erosion from existing roads through Caliente Canyon may be having a localized effect in a few areas in the occupied portion of the canyon, but the overall impact on the range of the Caliente Canyon population is at most minimal. There has been no mining activity within the Caliente Canyon area for almost 20 years, and there are no plans for mining to start again in the foreseeable future.

The one new residential and commercial development planned within the range of the species is proposed on Tejon Ranch. Tejon Ranch's proposed TMV development would remove 108 ac (44 ha) of potentially suitable habitat based on a habitat suitability model. However, the 108 ac (44 ha) are not known to be occupied by the species, and TMV is designed to avoid all occupied habitat and all known occurrences on Tejon Ranch. Indirect effects from development (*e.g.,* construction-associated impacts (lighting, noise, vibrations), increased human presence, predators, soil erosion, runoff, and edge effects) are not expected to rise to a point that would threaten the Tehachapi Mountains population of the species. We are also not aware of any existing or planned flood control projects within the range of the species. For these reasons, we conclude that cattle grazing, roads, mining, flood control projects, and commercial and residential development do not constitute a substantial threat to the Tehachapi slender salamander throughout its range now and are not likely to pose a substantial threat in the future. Therefore, we conclude that the Tehachapi slender salamander is not threatened or endangered throughout all of its range by the present or threatened destruction, modification, or curtailment of its habitat or range.

Factor B: Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

We do not have any information that overutilization for commercial, recreational, scientific, or educational purposes is a threat to the Tehachapi slender salamander. Therefore, we have no information to suggest that the Tehachapi slender salamander is threatened or endangered throughout all of its range now, or within the future, by overutilization for commercial, recreational, scientific, or educational purposes.

Factor C: Disease or Predation

Little is known about predators of the Tehachapi slender salamander. The only known predator of the species is the ring-necked snake; although turkeys and pigs, present on Tejon Ranch, are known to consume amphibians. However, we have no evidence that turkeys and pigs are threatening Tehachapi slender salamanders on Tejon Ranch, and there is no evidence that they are affecting the salamanders' habitat; therefore, we do not consider them a threat to the species.

Potential indirect effects from residential and commercial development within or near Tehachapi slender salamander habitat could include an increase in human and introduced predator presence. This could potentially be the case for the Tehachapi Mountains population of the Tehachapi slender salamander, as indirect, long-term potential effects from the TMV project would include an increase in human and introduced predator presence on the Tejon Ranch. For example, there may be an increase in passive outdoor recreation by adults and children, and their pets (*e.g.,* cats). The increase in human presence may also increase the population of native amphibian predators, including raccoons (*Procyon lotor*) and various species of corvids (such as crows and jays). However, coyotes may also be more abundant near development, and as discussed previously, the abundance of cats and raccoons has been found to be much lower where coyotes occur (Crooks and Soulé 1999, p. 563). The species' nocturnal and subfossorial behavior may also reduce potential impacts from predation by corvids.

There are no reports of the Tehachapi slender salamander being infected with any disease. However, related species have been found to suffer from Chytridiomycosis, a skin infection. Chytridiomycosis is described as an epidermal infection of amphibians caused by the chytrid fungus (*Batrachochytrium dendrobatidis*). Chytridiomycosis has been implicated in mass mortalities, population declines, and extinctions of some amphibian species, but species appear to vary in their susceptibility to the disease (Blaustein *et al.* 2005, p. 1460; Ouellet *et al.* 2005, p. 1431). The chytrid fungus requires moisture for survival, and is most likely transmitted to amphibians by contact with infected water or other amphibians (Johnson and Speare 2003, p. 922). Chytridiomycosis was thought to be restricted to species using aquatic habitat and surface water; however, Cummer *et al.* (2005, p. 248) reported the first case of the chytrid fungus infecting a strictly terrestrial salamander. The infected Jemez Mountains salamander (*Plethodon neomexicanus*), a completely terrestrial species endemic to the Jemez Mountains of New Mexico, suggests that the chytrid fungus can survive in terrestrial habitats (Cummer *et al.* 2005, p. 248). The authors note the origin of the pathogen is unknown, but hypothesize the Jemez Mountains salamander may have been directly or indirectly infected by a sympatric aquatic amphibian carrying the pathogen (Cummer *et al.* 2005, p. 248). Further, these findings suggest that more amphibians are at risk of contracting the chytrid fungus than was previously believed.

Indirect effects from livestock activities may include the risk of aquatic disease transmission, such as chytrid,

from earthen stock ponds that create areas of standing surface water. Earthen stock tanks are often utilized by tiger salamanders (*Ambystoma tigrinum*) (Davidson *et al.* 2003, pp. 601–607), western toads (*Bufo boreas),* Pacific treefrogs (*Hyla regilla),* and introduced bullfrogs (*Rana catesbeiana*), which are known to be vectors for disease (*i.e.,* they can carry and spread disease). It is possible that these species use adjacent upland areas and may transmit disease to the Tehachapi slender salamander in areas where they co-occur (Hansen *in litt.* 2011, p. 1). However, we do not have enough information to draw conclusions on the extent or role western toads, Pacific tree frogs, and bullfrogs may play in disease transmission. Although some small-scale habitat modification is possible, livestock are managed to maintain a grassy habitat under the tree canopies, and the connection between earthen stock tanks for livestock and aquatic disease transmission is unclear. Therefore, we conclude that disease transmission from livestock is not a current threat to the salamander, nor do we believe it will be in the future.

A recent study from the University of California, Berkeley, has shown that the chytrid fungus has infected the California slender salamander, Oregon slender salamander (*Batrachoseps wrighti*), Gabilan Mountains slender salamander (*B. gavilanensis*), and relictual slender salamander (*B. relictus*), all related species sharing the same genus as the Tehachapi slender salamander (Weinstein *in litt.* 2008b, p. 1). Weinstein's study confirms that Chytridiomycosis causes California slender salamander mortality in the lab; however, individuals may fair better in the field because the population has remained stable, despite the presence of the pathogen in the wild population for a minimum of 35 years (Weinstein *in litt.* 2008a, p. 1; Weinstein 2009, p. 1). Results showed that infected salamanders maintained in a dry environment in the lab were able to recover, whereas salamanders in a wet lab environment had high mortality rates (Weinstein, In press, p. 2). These findings not only confirm that the chytrid fungus can infect terrestrial species in the subgenus *Batrachoseps,* but also the possibility that salamanders may recover from the disease in dry environments.

We do not know whether the Tehachapi slender salamander has been, or will be, exposed to the chytrid fungus or that exposure would lead to transmission throughout its range. The likelihood of the Tehachapi slender salamander contracting the pathogen is lower than if it were closely associated with aquatic environments because this species is not associated with bodies of water, occurs in a characteristically dry environment, has limited chances of coming into contact with other amphibians due to its brief above-ground activity during intermittent periods during the year, and has limited dispersal abilities. To the best of our knowledge, no studies have been done to detect the pathogen in the Tehachapi slender salamander, or in the yellow-blotched salamander (also referred to as the yellow-blotched ensatina (*Ensatina eschscholtzii croceator*)) that co-occurs with both populations of the Tehachapi slender salamander (Jockusch *in litt.* 2009d, pp. 1–2; Germano 2006, pp. 123–125; Hansen and Wake 2005, p. 694).

The black-bellied slender salamander, which is a close relative of the Tehachapi slender salamander and co-occurs with the Tehachapi Mountains population, is vulnerable to the chytrid fungus (Jockusch *in litt.* 2009d, p. 1). Some of the black-bellied slender salamanders collected in San Luis Obispo County in the 1990s exhibited symptoms of Chytridiomycosis (Jockusch *in litt.* 2009d, pp. 1–2). Weinstein later confirmed that those specimens indeed carried *Batrachochytrium dendrobatidis* (Jockusch *in litt.* 2009d, p. 1). However, the infected black-bellied slender salamanders were collected in San Luis Obispo County, which is 110 mi (177 km) from the closest confirmed occurrence of the Tehachapi Mountains population of the Tehachapi slender salamander in Kern County. It is unlikely that infected black-bellied slender salamanders in San Luis Obispo County could infect individuals in Kern County due to the distance and the species' limited dispersal abilities. We do not have any evidence of infected black-bellied slender salamanders in Kern County that co-occur with the Tehachapi slender salamander.

Summary of Factor C

We have no evidence that predation is an impact to the Tehachapi slender salamander. Although there is potential for an increase in human and introduced predator presence within the vicinity of occupied salamander habitat that could result in indirect impacts to the salamander, we anticipate that the presence of coyotes and the species' nocturnal and subfossorial behavior will likely reduce potential impacts. We do not have any information to indicate that the chytrid fungus is present in either the Caliente Canyon or the Tehachapi Mountains population of the Tehachapi slender salamander or in co-occurring populations of other species that may carry this fungus. The chytrid fungus is known to have infected a closely related species, the black-bellied slender salamander. However, the infected black-bellied slender salamanders were 110 mi (177 km) from the closest confirmed occurrence of the Tehachapi slender salamander within the Tehachapi Mountains population. Although we do have information that the disease has infected other terrestrial and aquatic salamanders, we do not have any evidence that the disease is present in either the Tehachapi Mountains population or the Caliente Canyon population of the Tehachapi slender salamander, nor is there evidence that this or any other disease currently places this species at risk of extinction. In addition, we do not have any information in our files to suggest that this, or any other disease, will become a threat to either population of the Tehachapi slender salamander in the future. Therefore, we conclude that the Tehachapi slender salamander is not threatened or endangered throughout all of its range now, or in the future, by disease or predation.

Factor D: Inadequacy of Existing Regulatory Mechanisms

In determining whether the inadequacy of existing regulatory mechanisms constitutes a threat to the Tehachapi slender salamander, we focused our analysis on existing Federal and State laws and regulations that apply to the species and its habitats, and that could potentially address any possible significant threats identified under the other Factors. If a threat is minor, listing may not be warranted even if existing regulatory mechanisms provide little or no protection to counter the threat. Regulatory mechanisms may preclude the need for listing if such mechanisms are judged to adequately address the threat(s) to the species such that listing is not warranted. Conversely, threats on the landscape are exacerbated when not addressed by existing regulatory mechanisms, or when the existing mechanisms are inadequate (or not adequately implemented or enforced).

Federal Protections

National Environmental Policy Act

The National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), as amended (NEPA), requires that all activities undertaken, authorized, or funded by Federal agencies be analyzed for potential impacts to the human environment prior to implementation. Under NEPA, all Federal agencies are

required to formally document and publicly disclose the environmental impacts of their actions and management decisions. Documentation for NEPA is provided in an environmental impact statement, an environmental assessment, or a categorical exclusion, and may be subject to administrative or judicial appeal. NEPA does not require that adverse impacts be mitigated. NEPA is required for projects with a Federal nexus (*i.e.,* projects that require a Federal permit, receive Federal funding, or are implemented by a Federal agency). Actions with no Federal nexus are not required to comply with this law. For actions with a Federal nexus, NEPA would apply regardless of the location of the action within the range of the species. Our review finds that there are no significant threats to the species on lands with a Federal nexus for any of the four other Factors.

Clean Air Act

The Clean Air Act of 1970 (42 U.S.C. 7401 *et seq.*) directs the Environmental Protection Agency (EPA) to develop and enforce regulations to protect the general public from exposure to airborne contaminants that are known to be hazardous to human health. In 2007, the U.S. Supreme Court ruled that gases that cause global warming are pollutants under the Clean Air Act, and that the EPA has the authority to regulate carbon dioxide and other heat-trapping gases (*Massachusetts et al.* v. *EPA* 2007 [Case No. 05–1120]).

The EPA published a regulation to require reporting of greenhouse gas emissions from fossil fuel suppliers and industrial gas suppliers, direct greenhouse gas emitters, and manufacturers of heavy-duty and off-road vehicles and engines (74 FR 56260; October 30, 2009). The rule, effective December 29, 2009, does not require control of greenhouse gases; rather it requires only that sources above certain threshold levels monitor and report emissions. On December 7, 2009, the EPA found under section 202(a) of the Clean Air Act that the current and projected concentrations of six greenhouse gases in the atmosphere threaten public health and welfare. EPA's finding itself does not impose requirements on any industry or other entities, but is a prerequisite for any future regulations developed by the EPA. At this time, it is not known what regulatory mechanisms will be developed in the future as an outgrowth of EPA's finding or how effective they would be in addressing climate change. Therefore, the Clean Air Act and its existing implementing regulations do not currently address climate change effects on wildlife, plants, and ecosystems. However, our status review did not reveal information that indicates that climate change is a significant threat to the Tehachapi slender salamander now or within the foreseeable future (see Factor E).

Federal Land Policy and Management Act

As noted earlier, three occurrences of the Caliente Canyon population of Tehachapi slender salamander are on BLM land, while there are no occurrences of the Tehachapi Mountains population on Federal land. Although strongly oriented toward multiple use, the Federal Land Policy and Management Act of 1976, which is BLM's organic act, requires that public lands be managed in a manner that will protect the quality of scientific, scenic, historical, ecological, environmental, air and atmospheric, water resource, and archeological values; that, where appropriate, will preserve and protect certain public lands in their natural condition; that will provide food and habitat for fish and wildlife and domestic animals; and that will provide for outdoor recreation, human occupancy and use. Typically, land management plans are renewed every 15 to 20 years (Kuritsubo *in litt.* 2010a, p. 1). This law does not require specific protection for the Tehachapi slender salamander against potential threats that may occur on BLM land, such as impacts from grazing. One of the three occurrences on BLM land shows some moderate, localized habitat degradation from cattle trampling, as discussed under Factor A. However, our status review did not reveal information that indicates that livestock grazing is a significant threat to the Tehachapi slender salamander throughout its range (see Factor A).

Sensitive Species Designation by the Bureau of Land Management

As noted earlier, the Tehachapi slender salamander is classified by BLM as a sensitive species. As stated in BLM's Manual, Section 6840, BLM Sensitive Species are managed to promote their conservation and to minimize the likelihood and need for listing under the Act (Kuritsubo *in litt.* 2009a, p. 1). BLM's Bakersfield, California Field Office implements BLM's National and State policy directives (California BLM Manual supplement 6840.2) by evaluating projects for potential Tehachapi slender salamander habitat prior to implementing or authorizing activities that may affect the species (Kuritsubo *in litt.* 2009a, pp. 1–2). If potential habitat is present, then BLM designs the project or places stipulations on the authorization such that impacts to salamander habitat are avoided and/or minimized (Kuritsubo *in litt.* 2007, p. 1). BLM has screened and surveyed for Tehachapi slender salamander habitat for several projects on their lands that fall within the range of the species as part of NEPA compliance.

Two of the three Tehachapi slender salamander occurrences located on BLM land are within an existing grazing allotment (Kuritsubo *in litt.* 2010b, p. 1); the third location on BLM land is in an area that is not leased for grazing (BLM 2011, p. 1). BLM is required by Federal grazing regulations (43 CFR 4100) to periodically (approximately every 5 to 10 years) evaluate all grazing allotments. If grazing is determined to have adverse impacts to Tehachapi slender salamander habitat, BLM regulations require that BLM take action to modify the grazing management to ensure that the negative impact is addressed (Kuritsubo 2009b, pers. comm.). As described in Factor A, we did not find that cattle grazing and trampling are significant threats to the Caliente Canyon population of the Tehachapi slender salamander or its habitat. BLM's land use management plan for this area is in the process of being updated, and is still in draft. All alternatives in the draft plan include measures to provide habitat for sensitive species, including the Tehachapi slender salamander (Kuritsubo *in litt.* 2010a, p. 1). There are no plans for the allotment to change within the next 15 to 20 years (Kuritsubo *in litt.* 2010a, p. 1; Kuritsubo *in litt.* 2009b, p. 1; Kuritsubo 2009b, 2010, pers. comm.).

BLM's organic act and designation of the Tehachapi slender salamander as a sensitive species provide some protection for the species where it occurs on BLM land. However, the benefits to the species are limited because BLM land within the range of the salamander is limited to the Caliente Canyon population and makes up only a small portion (3 of 24 occupied occurrences, or 12.5 percent) of the species' entire range.

State Protections in California

California Endangered Species Act

The Tehachapi slender salamander is listed as threatened under CESA (CDFG 2009, p. 7). CESA provides protections for the Tehachapi slender salamander both through the prohibition against take of State-listed species without authorization (*i.e.,* 2081 incidental take permit) and the requirement that any

take authorized under the statute must be fully mitigated (14 CCR § 783.4). Under CESA, private landowners who wish to implement projects that would result in take of State-listed species must obtain a 2081 permit. Similar to section 10(a)(1)(B) of the Federal Endangered Species Act, 2081 permit applicants must develop an HCP that explains how the impacts of taking Tehachapi slender salamanders would be fully mitigated. HCPs developed to support a 2081 permit request would include conservation measures, often in the form of habitat conservation, to address the loss of Tehachapi slender salamanders. In our experience working with the CDFG in reviewing HCPs on private land in support of incidental take permit applications under CESA and the Federal Endangered Species Act, such plans require measures to avoid, minimize, or mitigate the impacts of the taking, including mortality resulting from habitat removal.

CESA offers protections for the Tehachapi slender salamander on private and State-owned land, comprising the majority of lands that are known to be occupied by the species (*i.e.,* 21 of the 24 occupied occurrences or 87.5 percent). CESA does not necessarily constrain activities on the small portion (12.5 percent) of occupied Tehachapi slender salamander habitat on Federal lands within the Caliente Canyon population. However, as noted above, regulations are in place that provide some protection to Tehachapi slender salamander habitat on BLM land.

California Environmental Quality Act

Another State law that may address threats to the Tehachapi slender salamander is the California Environmental Quality Act (CEQA). CEQA requires review of any project that is undertaken, funded, or permitted by the State or a local governmental agency. If significant effects are identified, the lead agency has the option of requiring mitigation through changes in the project or to decide that overriding considerations make mitigation infeasible (CEQA section 21002). In the latter case, projects may be approved that cause significant environmental impacts, including impacts to listed species and their habitat. Protection of listed species through CEQA is, therefore, dependent upon the discretion of the lead agency involved.

Tejon Ranch's proposed TMV project has undergone CEQA review. The TMV Final Environmental Impact Report (EIR) found that construction activities could result in significant impacts to the Tehachapi Mountain population of the Tehachapi slender salamander without the implementation of specific species and habitat avoidance and mitigation measures (ICF Jones and Stokes 2009, pp. 4.4–102, 4.4–156) (see discussion under Factor A). However, based on our own analysis (described in Factor A) we do not concur with the EIR's conclusions regarding significant impacts to the species, and find that the project design avoids direct impacts, and any indirect impacts that may occur would not likely rise to a level that would threaten the species.

CEQA applies to the entire range of the species. As of the date of this finding, we are not aware of any other projects proposed or planned within the range of the Caliente Canyon population that would require CEQA analysis.

Summary of Factor D

Twenty of the known occupied occurrences of the Tehachapi slender salamander occur on privately owned land, three occur on BLM land and one occurs on State land. Almost all of the private land and two of the three areas on BLM lands (the third area is not part of a BLM allotment) are primarily used for grazing. We did not find that grazing poses a significant threat to the Tehachapi slender salamander or its habitat and thus do not consider existing regulatory mechanisms, including CEQA, CESA, NEPA, FLPMA, and BLM's classification of the Tehachapi slender salamander as a sensitive species, inadequate to address the impacts of grazing on the species and its habitat. If such threats were to emerge in the future due to a change in grazing intensity, then CEQA and CESA would apply on private land and require authorization for take of Tehachapi slender salamander. Additionally, NEPA, FLPMA, and BLM regulations and policies would apply on Federal land and require that potential impacts from grazing or any other development be identified and measures implemented to avoid or minimize such impacts.

The TMV project within Tejon Ranch is the one planned residential and commercial development proposed within the vicinity of known occurrences (5 out of 24 occupied occurrences or approximately 20.8 percent) in the foreseeable future (Kern County *in litt.* 2009, pp. 1–9). The TMV project has been designed to avoid all known occurrences and occupied habitat of the Tehachapi slender salamander and to minimize any indirect effects on the species and its habitat.

In summary, we conclude that the threats to the Tehachapi slender salamander and its habitat on Federal, State, and private lands from grazing and other existing uses, and on private lands from proposed development are low. Existing Federal regulatory mechanisms provide protection for the species on the small portion of Tehachapi slender salamander habitat on BLM lands, and existing State laws provide protection on State and private lands from these threats. We did not find the current limitations of implementing the Clean Air Act to be a significant threat to the Tehachapi slender salamander. We did not find any threats to the Tehachapi slender salamander associated with Factors B or C that would warrant protection through a regulatory mechanism. Climate change and stochastic events pose potentially minor threats to the species (see Factor E); however, the current limitations of regulatory mechanisms addressing these potential threats do not pose a significant threat to the species now or in the foreseeable future. Therefore, we conclude that the species is not threatened now or in the future throughout its range by the inadequacy of existing regulatory mechanisms.

Factor E: Other Natural or Manmade Factors Affecting the Continued Existence of the Species

Under Factor E, we consider whether climate change and stochastic events threaten the Tehachapi slender salamander. Stochastic events are rare, chance events such as epidemics; prolonged drought; and large, severe wildfires.

Climate Change

The term ''climate'' refers to an area's long-term average weather patterns, or more specifically as the mean and variation of surface variables such as temperature, precipitation, and wind, whereas ''climate change'' refers to any change in climate over time, whether due to natural variability or human activity (Intergovernmental Panel on Climate Change (IPCC) 2007, pp. 6, 871). Although changes in climate occur continuously over geological time, changes are now occurring at an accelerated rate. For example, at continental, regional, and ocean-basin scales, recent observed changes in long-term trends include: a substantial increase in precipitation in eastern parts of North America and South America, northern Europe, and northern and central Asia; declines in precipitation in the Mediterranean, southern Africa, and parts of southern Asia; and an increase in intense tropical cyclone activity in

the North Atlantic since about 1970 (IPCC 2007, p. 30). Examples of observed changes in the physical environment include an increase in global average sea level and declines in mountain glaciers and average snow cover in both the northern and southern hemispheres (IPCC 2007, p. 30).

The IPCC used Atmosphere-Ocean General Circulation Models and various greenhouse gas emissions scenarios to make projections of climate change globally and for broad regions through the 21st century (Meehl *et al.* 2007, p. 753; Randall *et al.* 2007, pp. 596–599). Highlights of these projections include: (1) It is virtually certain there will be warmer and more frequent hot days and nights over most of the earth's land areas; (2) it is very likely there will be increased frequency of warm spells and heat waves over most land areas, and the frequency of heavy precipitation events will increase over most areas; and (3) it is likely that increases will occur in the incidence of extreme high sea level (excludes tsunamis), intense tropical cyclone activity, and the area affected by droughts in various regions of the world (Solomon *et al.* 2007, p. 8). More recent analyses using a different global model and comparing other emissions scenarios resulted in similar projections of global temperature change (Prinn *et al.* 2011, pp. 527, 529).

As is the case with all models, there is uncertainty associated with projections due to assumptions used, data available, and features of the models. Despite this, however, under all models and emissions scenarios the overall surface air temperature trajectory is one of increased warming in comparison to current conditions (Meehl *et al.* 2007, p. 762; Prinn *et al.* 2011, p. 527). Climate models and associated assumptions, data, and analytical techniques continue to be refined, and thus projections are refined as more information becomes available (*e.g.,* Rahmstorf 2010 entire). For instance, observed actual emissions of greenhouses gases, which are a key influence on climate change, are tracking at the mid- to higher levels of the various scenarios used for making projections, and some expected changes in conditions (*e.g.,* melting of Arctic sea ice) are occurring more rapidly than initially projected (Raupach *et al.* 2007, Figure 1, p. 10289; Comiso *et al.* 2008, p. 1; Pielke *et al.* 2008, entire; LeQuere *et al.* 2009, Figure 1a, p. 2; Manning *et al.* 2010, Figure 1, p. 377; Polyak *et al.* 2010, p. 1797). In short, the best scientific and commercial data available indicates that increases in average global surface air temperature and several other changes are occurring and likely will continue for many decades and in some cases for centuries (*e.g.* Solomon *et al.* 2007, pp. 822–829; Church 2010, p. 411).

Changes in climate can have a variety of direct and indirect impacts on species, and can exacerbate the effects of other threats. For instance, climate-associated environmental changes to the landscape, such as decreased stream flows, increased water temperatures, reduced snowpacks, and increased fire frequency, or other changes occurring individually or in combination, may affect species and their habitats. The vulnerability of a species to climate change impacts is a function of the species' sensitivity to those changes, its exposure to those changes, and its adaptive capacity (IPCC 2007, p. 883). As described above, in evaluating the status of a species the Service uses the best scientific and commercial data available, and this includes consideration of direct and indirect effects of climate change. As is the case with all other stressors we assess, if the status of a species is expected to be affected that does not necessarily mean it is a threatened or endangered species as defined under the Act.

We recognize that temperatures in southern California where the Tehachapi slender salamander occurs are likely to increase, which could potentially negatively affect the Tehachapi slender salamander. As discussed in the ''Biology and Natural History'' section, the Tehachapi slender salamander's surface activity, during which the species forages and likely finds mates, is limited to periods with high surface moisture and above freezing temperatures. Increased average surface temperatures could cause soils used by Tehachapi slender salamanders to become drier earlier in the year or for longer periods, which may further limit the amount of time they can remain at the surface. If the period when surface moisture is sufficient for activity becomes too short, then the habitat may no longer be suitable for the species.

It is especially difficult with currently available models to make meaningful predictions of climate change for specific, local areas such as the small portion of California where the Tehachapi slender salamander occurs (Parmesan and Matthews 2005, p. 354). However, a climate change stress report for the Tehachapi Mountains (TNC 2009) projects varying levels of drought stress by the end of the 21st Century. The following examples demonstrate possible changes in precipitation and temperature from averaging 15 global climate models (TNC 2009, no page numbers):

(1) The two most likely possibilities of precipitation change are a 40 percent projection that the area will see little (−1 to +1 in (−2.5 to 2.5 cm)) change in precipitation, and a 53 percent projection that the area will receive between 1 and 5 in (2.5 and 12.7 cm)) less precipitation.

(2) The two most likely possibilities of temperature change are a 53 percent projection that the temperature of the area will increase by greater than 10 degrees Fahrenheit (5.6 degrees Celcius), and a 27 percent projection that the temperature of the area will increase by 8 to 10 degrees Fahrenheit (4.4 to 5.6 degrees Celsuis).

On the other hand, Kelly and Goulden (2008, p. 11824) predict that the amount and duration of precipitation may increase for California (in general), and, if this occurs, surface moisture could be maintained despite the warmer temperatures that are predicted. In addition, warming may reduce the degree and duration of extreme cold at higher elevations. Under these conditions, the duration of surface activity for the Tehachapi slender salamander may remain the same.

Climate change can affect plants and animals in a number of ways, including changes in distribution, population size, behavior, and even changes in physiological and physical characteristics (Parmesan and Mathews 2005, p. 373). A number of published studies predict that temperature and precipitation trends may change in the near future, and some describe how biotic communities may respond to such changes (Parmesan and Mathews 2005, pp. 333–374; IPCC 2007a, pp. 1–21; IPCC 2007b, pp. 1–22; Kelly and Goulden 2008, pp. 11823–11826; Miller *et al.* 2008, pp. 1–17; Loarie *et al.* 2008, pp. 1–10; Jetz *et al.* 2007, pp. 1211–1216). During a 30-year study in Southern California's Santa Rosa Mountains, Kelly and Goulden (2008, pp. 11823–11824) observed a geographic shift in plant distributions to higher elevations that was uniform across elevation gradients and that corresponded with an observed increase in surface temperatures and variability in precipitation over the same timeframe. Similarly, a study in California's Cascade and Sierra Nevada Ranges found that plant species tended to move towards higher elevations in response to increasing temperatures regardless of the presence of suitable habitat to the north or south (Loarie *et al.* 2008, p. 3).

Based on the research on plant communities in montane habitats by Kelly and Goulden (2008, pp. 11823–11824) and Loarie *et al.* (2008, p. 3),

populations of Tehachapi slender salamanders may respond to climate change by attempting to shift to higher elevations to follow the shifting vegetation patterns. However, we cannot predict the consequences of any potential shift because there is likely a complex suite of indirect effects for any shift in distribution. For example, the mesic microclimates that define suitable Tehachapi slender salamander habitat are dependent on a combination of vegetation cover (providing shade), slope, and aspect (affecting the amount of sun exposure on a hillside). The more a hillside is exposed to sun, the more it experiences heat and evapotranspiration (and thus, desiccation). For example, steeper north-facing slopes experience less time in the sun than gradual south-facing slopes. In addition, the upper slopes of north-facing hillsides are exposed to sun for longer periods than north-facing canyon bottoms.

Populations of Tehachapi slender salamanders may be limited to shifting their range up-canyon to north-facing slopes at higher elevations. The ability of a population to shift up-canyon would depend on the availability of contiguous (or closely spaced) habitat patches that would provide a movement corridor. We do not expect that the species would be able to shift to different canyons at higher altitudes because of the limited dispersal ability of individuals and the presence of rugged and unsuitable habitat that occurs between most canyons. Also, shifting farther up the slopes that are currently occupied could be limited because the upper reaches of a hillside would be more exposed to sunlight, and thus to increased evapotranspiration and dry surface cover, which are considered unsuitable for Tehachapi slender salamander.

It is possible that some of the Tehachapi slender salamander's range could be reduced (*i.e.,* suitable habitat that is contiguous with the known occurrences could disappear from the lower elevations or from more mesic habitat patches), especially if both temperature increases and precipitation declines. Depending on the degree of temperature rise and precipitation decline, some loss of habitat and reduction in range is likely; however, potential loss of habitat or a range reduction could be compensated for in those areas where up-canyon shifts in distribution are possible.

Overall, the limited range of the Tehachapi slender salamander makes it vulnerable to potential climate change impacts such as habitat alteration (Jetz *et al.* 2007, pp. 1211–1216; Parmesan and Mathews 2005, p. 373) or fragmentation. Habitat fragmentation resulting from warmer, drier conditions could make it difficult for Tehachapi slender salamanders to travel between habitat patches. If temperatures potentially increase and precipitation decreases in the forseeable future (as discussed above), one can expect changes in vegetation such as a shift in vegetation to higher elevations or a reduction of suitable habitat and possibly a reduction in the range of the species. Vegetation changes within the range of the Tehachapi slender salamander will likely be most prevalent in more open, montane habitat that is not representative of the vegetation on the lower, most heavily shaded portions of north-facing slopes where the salamander occurs (TNC 2009, p. 4). Thus, these lower, north-facing slopes may not be altered or fragmented to the degree that the open, montane habitat could be, resulting in the salamander's habitat (*i.e.,* the current known occurrences and the contiguous suitable habitat that makes up the range of the species) remaining relatively stable and acting as refugia for the salamander.

In summary, available climate models predict average temperatures in the Tehachapi Mountains are likely to increase in the future, although there is less certainty as to whether precipitation will remain the same or decrease. However, there is a great deal of uncertainty as to how these changes may affect the Tehachapi slender salamander. How the Tehachapi slender salamander may react to these changes will be the result of a complex array of factors including the degree of temperature increase, the decline in precipitation, if any; the degree to which the specific habitat requirements of the salamander (such as the timing and duration of soil moisture, and under- and overstory composition) will be affected; changes and shifts in plant diversity and abundance; and the ability and opportunity of salamander populations to shift over time.

It is possible that the range of some populations may be reduced, while others are able to shift up-canyon to higher slopes. It may also be that the vegetation on the cooler, lower portions of the north-facing slopes occupied by the salamander may not be subject to the same changes predicted for more open, warmer, and drier slopes. Because of these uncertainties, any prediction about the potential impact of climate change on the Tehachapi slender salamander will be highly speculative. However, with those uncertainties in mind, we believe that, although some loss of habitat in the more exposed portions of the canyons currently occupied by the salamander will occur because of climate change, habitat will remain in the lower, most-shaded portions to support the salamander and in some cases the salamander may be able to shift within the canyon in response to climate change.

In addition to the uncertainties discussed above, habitat loss due to potential future human encroachment could exacerbate the potential effects of climate change by both reducing the availability of suitable habitat the species can move to and increasing the distance between habitat patches (Jetz *et al.* 2007, pp. 1211–1216; Parmesan and Mathews 2005, p. 373). As described under Factor A above and based on the best information currently available, TMV is the one development with County approval near Tehachapi slender salamander occurrences, and this project is not expected to impact the salamander's occurrences nor the adjacent contiguous suitable habitat that makes up the range of the Tehachapi Mountains population of the species. We do not anticipate significant impacts to the species across its range as a result of cumulative effects from human encroachment and climate change due to a combination of the ecology of the species (*e.g.,* its ability to retreat to underground refugia, minimal surface time during the moist periods of the year, generation time) and because the TMV development is designed to avoid all known occurrences and occupied habitat (see ''Climate Change'' discussion above under Factor E, ''Tehachapi Mountains Population'' discussion under Factor A, and the *Biology and Natural History* section).

Stochastic Events

Under Factor E, we also consider whether three risks, represented by demographic, genetic, and environmental stochastic events, are substantive enough to threaten the continued existence of the Tehachapi slender salamander.

In basic terms, demographic stochasticity is defined by chance changes in the population growth rate for the species (Gilpin and Soulé 1986, p. 27). Population growth rates are influenced by individual birth and death rates (Gilpin and Soulé 1986, p. 27), immigration and emigration rates, as well as changes in population sex ratios. Natural variation in the survival and reproductive success of individuals and chance disequilibrium of sex ratios may act in concert to contribute to demographic stochasticity (Gilpin and Soulé 1986, p. 27).

Genetic stochasticity is caused by changes in gene frequencies due to genetic drift, and diminished genetic diversity, and effects due to inbreeding (*i.e.,* inbreeding depression) (Lande 1995, p. 786). Inbreeding can have individual or population-level consequences either by increasing the phenotypic expression (the outward appearance, or observable structure, function, or behavior of a living organism) of recessive, deleterious alleles or by reducing the overall fitness of individuals in the population (Shaffer 1981, p. 131).

Environmental stochasticity is defined as the susceptibility of small, isolated populations of wildlife species to natural levels of environmental variability and related ''catastrophic'' events (*e.g.,* disease epidemics, prolonged drought, wildfire) (Young 1994, pp. 410–412; Mangel and Tier 1994, p. 612; Dunham *et al.* 1999, p. 9). Each risk will be analyzed specifically for the Tehachapi slender salamander.

As a whole, the Tehachapi slender salamander is considered a naturally rare species, due to its restricted and endemic geographic distribution and specific habitat requirements and is likely vulnerable to the threat of genetic stochasticity. The two populations of the Tehachapi slender salamander have relatively small geographic ranges and limited dispersal abilities, and we do believe that any contact between the two populations is unlikely because of the distance and type of terrain between them. This conclusion is supported by the substantial genetic differences between the two populations (Jockusch *in litt.* 2009e, p. 1).

As with all species of *Batrachoseps,* Tehachapi slender salamanders are sedentary and individuals travel no more than about 10 ft (3 m) (Hansen *in litt.* 2009b, p. 1). For example, a study reported that the California slender salamander stayed within a 5-ft (1.5-m) area over 2 years of observations (Yanev 1980, p. 533). Analyses of the fossil record of currently threatened species suggest that species with these characteristics are at a higher risk of extinction than are mobile, widely distributed species (Jablonksi 1986, pp. 129–133; Manne *et al.* 1999, p. 260; Dynesius and Jansson 2000, p. 9116; Payne and Finnegan 2007, pp. 10506–10511). However, other than the one occurrence near the Tehachapi Pass (see Figure 2), and the area along the Tejon Pass (*i.e.,* the Interstate Highway 5 corridor), there is no evidence that the species distribution has significantly changed over the past 200 years (Hansen *in litt.* 2011, p. 1). The four occurrences of Tehachapi slender salamander discovered in 2009 are all located within the general range of the Caliente Canyon population; though distributed over a a wider area than previously thought (Sweet *in litt.* 2011, p. 1). Occupied habitat in Caliente Canyon is more patchily distributed than in any of the other occupied canyons, with a few gaps between habitat of more than a mile. These gaps are beyond the limited dispersal ability of individuals, and movement up and down canyon across large gaps may only occur under extreme circumstances (such as a major flood).

Habitat in the other occupied canyons is more contiguous, and movement up and down canyon is likely to occur. The average distance between occupied canyons for both the Caliente Canyon and Tehachapi Mountains populations is about 4 mi (6.4 m), indicating that genetic exchange between canyons is unlikely. However, although the species may be vulnerable to genetic stochasticity, we have no evidence of a genetic bottleneck or inbreeding depression. We do not have information to indicate that these have occurred.

The vulnerability of the species to demographic stochasticity may be indicated by skewed sex ratios or a small or reduced number of offspring. However, there are no data that would indicate such a threat to the species exists.

Stochastic (chance) events such as epidemics, severe drought, or large, severe fires can threaten the persistence of species with restricted ranges because a single event can occur within all or a large portion of their range. Species that are relatively sedentary are probably less able than mobile animals to recolonize parts of their range where they have been extirpated. The Tehachapi slender salamander's characteristics of being rare, patchily distributed, and sedentary could further increase the species' risks of extinction from stochastic events (Hansen and Wake 2005, p. 694). In the absence of information identifying threats to the species and linking those threats to the rarity of the species, the Service does not consider rarity alone to be a threat. However, we need to consider potential threats (*e.g.,* fire, drought) that might be exacerbated by rarity, as discussed below.

Epidemics and large, severe fires are two kinds of stochastic events that could negatively affect populations of the Tehachapi slender salamander. The only lethal disease we are aware of that could behave as an epidemic in populations of this salamander is chytridiomycosis (see Factor C), but we have no information of this species contracting the disease or whether it would be lethal in wild populations of the Tehachapi slender salamander (see Factor C). Further, we do not know of any other salamander species, or other amphibians, that co-occurs with either population that has been affected by the fungus in Kern County that could pass along the infection through physical contact.

The State of California has experienced cycles of drought for many years. For example, between 1928 and 1987 the U.S. Geological Survey (USGS) reported five severe droughts across California, including the longest drought in the State's history from 1929 to 1934 (USGS 2004, p. 2). The Tehachapi slender salamander has persisted through these periods of severe drought. During periods of severe drought, Tehachapi slender salamanders likely remain in a state of aestivation below ground. Plethodontids are known for their low metabolism and ability to survive long periods without feeding (Feder 1983, pp. 304–305). Therefore, based on their metabolism and demonstrated ability to persist during periods of severe drought in the past, we do not believe that severe drought will threaten the species in the foreseeable future.

The Tehachapi slender salamander could be at some risk from large, severe wildfires in the foreseeable future. Studies suggest that forests in California will experience longer fire seasons and more frequent, extensive, and severe fires by the end of this century (Lenihan *et al.* 2003, p. A–13; Miller *et al.* 2008, pp. 1–15). An increase in fire frequency and extent will likely lead to an increase in fire impacts, including soil erosion, sediment runoff, and habitat fragmentation (Miller *et al.* 2008, p. 13). Therefore, fire could have a negative impact on the species in the future if the frequency and intensity of forest fires increases as predicted.

The impacts of forest fires on the Tehachapi slender salamander are not well understood. Fire outbreaks would likely occur during the dry season when salamanders are aestivating below ground where they are afforded some level of protection. However, the vegetation canopy that helps retain surface moisture and the leaf litter and downed logs that are important components of the salamander's habitat would be affected. As discussed in the Climate Change section above, there is also a great deal of uncertainty about future climate change within the range of the species and in turn, over the future of fire. However, the Tehachapi slender salamander has persisted in Caliente Canyon (and surrounding

occupied canyon areas) and the Tehachapi Mountains, which are prone to forest fires, for thousands of years. Therefore, we conclude that forest fires are a concern, but do not rise to the level of a significant threat to the Caliente Canyon and Tehachapi Mountains populations of the Tehachapi slender salamander.

Summary of Factor E

Because of the rarity and limited dispersal ability of the species, genetic stochasticity is a concern. However, we do not have any evidence of genetic bottlenecks or inbreeding depression to indicate that genetic stochasticity is a significant threat. Nor do we have any information to indicate that demographic stochasticity or a disease outbreak is likely to be a significant threat in the future. Environmental stochasticity, particularly wildfire, is a concern; however, we do not believe that this rises to a level that threatens the persistence of the species over the long-term.

Changes in climate can have a variety of direct and indirect impacts on species such as the Tehachapi slender salamander, and can exacerbate the effects of other threats. However, there is a great deal of uncertainty as to how climate change may affect the Tehachapi slender salamander, and any prediction about the potential impact of climate change on the Tehachapi slender salamander will be highly speculative. However, with those uncertainties in mind, we believe that, although some loss of habitat in the more exposed portions of the canyons currently occupied by the salamander will occur because of climate change, habitat will remain in the lower, most-shaded portions to support the salamander and in some cases the salamander may be able to shift within the canyons in response to climate change.

A species may also be affected by more than one threat in combination. Within the preceding review of the five listing factors, we have identified several threats that could have interrelated impacts on the Tehachapi slender salamander. For example, potential suitable habitat may be lost or altered as a result of a combination of development (Factor A) and effects of climate change (Factor E). Likewise, predation (Factor C) in combination with a stochastic event (Factor E), such as a forest fire could result in a major loss of individuals in one or more populations. However, as we discuss above, regardless of its source, we do not believe that the threats discussed above, either individually or in combination, are of sufficient imminence, intensity or magnitude to affect the status of the Tehachapi slender salamander.

We conclude that the best available information concerning Factor E indicates that the Tehachapi slender salamander is not threatened individually or cumulatively by the effects of climate change or demographic, genetic, or environmental stochasticity. Therefore, we conclude that the Tehachapi slender salamander is not threatened or endangered throughout all of its range now or in the future by other natural or manmade factors.

Finding

We have assessed the best scientific and commercial information available regarding threats faced by the Tehachapi slender salamander. We have reviewed the petition, scientific literature, information available in our files, and all information submitted to us following our 90-day petition finding (74 FR 18336; April 22, 2009). We also consulted with recognized Tehachapi slender salamander experts, Federal land managers, and local governments, and arranged for a recognized Tehachapi slender salamander expert to assess potential threats to the habitat and range of the species relative to current and planned land uses and occurrences of the species.

Potential threats include development, road construction, mining, domestic livestock grazing, introduced species, and flood control projects. Based on the best available information, we find that the evidence supports a finding that listing the Tehachapi slender salamander is not warranted.

While only two Tehachapi slender salamander populations are known, information in our files does not indicate whether these populations are in decline, stable, or increasing; however, the Caliente Canyon population is now known to be made up of five populations, rather than the previously known single population (Sweet *in litt.* p. 1). The best available information indicates that this species is naturally rare. While rare species may face threats from normal population fluctuations due to predation, disease, changing food supply, and stochastic (random) events, our evaluation of the best available information indicates that these potential threats do not threaten the continued existence of the Tehachapi slender salamander.

The range of the salamander within the Caliente Canyon area is primarily on land used for grazing, an activity for which data shows only minor to moderate signs of degradation from livestock use. Some localized habitat at 3 of the 18 occurrences (approximately 16.7 percent) show signs of moderate impact from cattle trampling; however, habitat in good to fair condition that would support the species remains at the 3 occurrences. There are no proposed projects associated with residential or commercial development, road construction, or mining anywhere near known occurrences within Caliente Canyon.

The primary land use within the range of the Tehachapi Mountains population is also livestock grazing, and we do not have any information that indicates that use by cattle has resulted in significant habitat degradation of any of the five canyons known to be occupied by this population. Tejon Ranch is planning a large-scale residential and commercial development project, TMV. However, the TMV development envelope is designed to avoid known salamander occurrences and all occupied habitat within the species range for the Tehachapi Mountains population. In a worst-case scenario, 2.8 percent of the potentially suitable habitat for the species on the Tejon Ranch will be lost to development. Indirect impacts from the TMV project are expected to be restricted to the immediate vicinity of development well away from all occupied habitat and known occurrences of the species. Therefore, we believe that the development is not a significant threat to the species.

We do not have any indication that flood control projects occur or are planned to occur within either the Caliente Canyon or Tehachapi Mountains area.

The impact of climate change is a concern for the species, and although there is uncertainty, we believe that some loss of habitat in the more exposed portions of the canyons that are currently occupied by the salamander will occur because of climate change. However, we also believe that habitat will remain in the lower, most-shaded portions of canyons to support the salamander and in some cases the salamander may be able to shift within the canyon in response to climate change. Because of the rarity and limited dispersal ability of the species, genetic stochasticity is also a concern. However, we do not have any evidence of genetic bottlenecks or inbreeding depression to indicate that genetic stochasticity is a significant threat.

There are regulatory mechanisms in place, such as CESA, CEQA, and BLM's special status designation for the

species, that provide adequate protections from threats for both populations of the species.

In summary, the main activity in the range of the Tehachapi slender salamander at the present time is cattle grazing, which is likely to remain the only activity within the range of the Caliente Canyon population. We have determined that the impacts of grazing are limited to a few areas in Caliente Canyon, and sufficient habitat to support the species remains in these areas; few impacts from grazing have been observed in the canyons known to be occupied by the Tehachapi Mountains population. Therefore, we have determined that cattle grazing is not a significant impact to the species now or in the foreseeable future. Second, we have determined the proposed residential and commercial development on Tejon Ranch will not have a significant impact on the species because the footprint of the development has been designed to avoid all known occurrences of the salamander and does not overlap with any habitat that is likely occupied. Third, we have determined that indirect impacts from the proposed development will not be significant because they are not likely to extend far enough from the proposed development footprint to affect known occurences or occupied habitat and because the salamander is above ground for only a few months of the year and remains under talus and fallen logs when it is at the surface. Fourth, although climate change is a concern, we have determined that the impacts of climate change will not be significant because there is some uncertainty as to how the climate in the area where the species occurs will change and that sufficient habitat will remain to support the species. Finally, we have determined that the cumulative impacts of all of the five factors on the species will not be significant because, based on the best available information, the interrelated current and anticipated impacts of development, road construction, mining, domestic livestock grazing, introduced species, flood control projects, climate change, and stochastic events do not threaten the Tehachapi slender salamander. Considering all of the identified impacts in combination, sufficient habitat will remain to support the species.

Therefore, on the basis of the best scientific and commercial information available, we find that the species is not at risk of extinction across its range now or in the foreseeable future and as a result find that listing the species range-wide as threatened or endangered under the Act is not warranted at this time.

Distinct Vertebrate Population Segments

After assessing whether the species is threatened or endangered throughout its range, we next consider whether a Distinct Vertebrate Population Segment (DPS) or whether any significant portion of the Tehachapi slender salamander's range is in danger of extinction or likely to become so within the foreseeable future.

Distinct Population Segment

As previously noted, we have determined that there are two separate populations of the Tehachapi slender salamander. Under section 4(a)(1) of the Act, we must evaluate five threat factors to determine whether a species should be listed as endangered or threatened. Section 3(16) of the Act defines ''species'' to include ''any subspecies of fish or wildlife or plants, and any distinct population segment (DPS) of any species of vertebrate fish or wildlife which interbreeds when mature'' (16 U.S.C. 1532(16)). To interpret and implement the DPS portion of the definition of a species under the Act and Congressional guidance, the Service and the National Marine Fisheries Service published an interagency *Policy Regarding the Recognition of Distinct Vertebrate Population Segments under the Act* (DPS Policy) on February 7, 1996 (61 FR 4722). The DPS Policy allows for more refined application of the Act that better reflects the conservation needs of the taxon being considered and avoids the inclusion of entities that may not warrant protection under the Act.

Under our DPS Policy, we consider three elements in a decision regarding the status of a possible DPS as endangered or threatened under the Act. We apply them similarly for additions to the List of Threatened and Endangered Wildlife and Plants (List), reclassification, and removal from the List. They are: (1) discreteness of the population segment in relation to the remainder of the taxon; (2) the significance of the population segment to the taxon to which it belongs; and (3) the population segment's conservation status in relation to the Act's standards for listing (whether the population segment is, when treated as if it were a species, endangered or threatened).

Analysis for Discreteness

Under the DPS policy, a population segment of a vertebrate taxon is considered to be discrete if it meets one of the following conditions:

(1) It is markedly separated from other populations of the same taxon as a consequence of physical, physiological, ecological, or behavioral factors. Quantitative measures of genetic or morphological discontinuity may provide evidence of this separation.

(2) It is delimited by international governmental boundaries within which differences in control of exploitation, management of habitat, conservation status, or regulatory mechanisms exist that are significant in light of section 4(a)(1)(D) of the Act. We note that the standard set forth in the DPS policy is that a DPS be ''markedly separated'' from other populations—thus, while absolute separation is not required, there must be sufficient separation such that ''large numbers'' of individuals are not migrating between populations.

Markedly Separated From Other Populations of the Taxon

The Caliente Canyon and Tehachapi Mountains populations of the Tehachapi slender salamander both meet the discreteness element of the DPS policy. The general region where the Tehachapi slender salamander occurs consists of semi-arid terrain containing localized areas of mesic habitat favorable to salamanders (Hansen *in litt.* 2009a, p. 13). The Caliente Canyon group of occurrences is isolated from the Tehachapi Mountains occurrences by a minimum of 13 mi (21 km) of rugged terrain, much of which is dry, unsuitable habitat (Hansen *in litt.* 2009a, p. 11). There is no evidence of movement between the Caliente Canyon and Tehachapi Mountains populations due to the sedentary nature of the species, and the distance and rugged terrain between them (Hansen *in litt.* 2009a, p. 11). In addition, genetic studies show that the Caliente Canyon and Tehachapi Mountains populations have been isolated from each other for over a million years (Hansen *in litt.* 2009a, p. 11; Hansen 2009b pers. comm.; Jockusch 1996, p. 91; Jockusch *in litt.* 2009f, p. 2).

Further, we have no evidence of breeding and gene flow between the Caliente Canyon population and the Tehachapi Mountains population. Genetic exchange between these populations is prevented by the distance and lack of suitable movement corridors between them (Hansen 2009a, pers. comm.). Hansen suggests that interbreeding of Tehachapi slender salamanders between occupied canyons within the two populations rarely occurs due to a number of factors, including: patchy distribution of Tehachapi slender salamanders, distance between occupied habitat, lack of suitable habitat corridors between occupied canyons, and the sedentary

characteristics of the salamanders (Hansen 2009b pers. comm.).

In addition to the distance and the physical and genetic isolation between the two populations, there are reported differences in morphology (appearance) and habitat between the Caliente Canyon population and the population found in the Tehachapi Mountains (Jockusch and Wake 2002, p. 383; Hansen and Wake 2005, p. 694). As stated in the DPS policy, ''Quantitative measures of genetic or morphological discontinuity may provide evidence of this separation.'' For example, Tehachapi slender salamanders in Caliente Canyon tend to have more noticeable brick-red/copper coloration, and tend to be larger with proportionately larger tails than salamanders living in the Tehachapi Mountains (Hansen 2009b pers. comm.; Hansen *in litt.* 2009d, p. 1). Tehachapi slender salamanders in the Caliente Canyon area occur at much lower elevations (1,804 ft (550 m)) than those in the Tehachapi Mountains (3,100 ft (945 m)) (Hansen 2009, p. 1; Sweet *in litt.* 2011, p. 1). Tehachapi slender salamanders in Caliente Canyon are more often found under rocks and talus. On the other hand, salamanders in the Tehachapi Mountains are more often found under leaves, woody debris, and talus (Hansen and Wake 2005, p. 694). Based on the physical separation of the two populations and the evidence that they do not interbreed, including differences in genetics and morphology, we find that the Caliente Canyon and Tehachapi Mountains populations are discrete.

International Border Issues

A population segment of a vertebrate species may be considered discrete if it is delimited by international governmental boundaries across which differences in control of exploitation, management of habitat, conservation status, or regulatory mechanisms exist that are significant in light of section 4(a)(1)(D) of the Act. Given that the range of the species as a whole lies entirely within the United States borders, international border issues do not apply in this situation.

In summary, available information on the Tehachapi slender salamander indicates that the Caliente Canyon population and Tehachapi Mountains population are markedly separated from one another by distance, gene flow, and to a lesser degree, morphology and habitat use and, therefore, meet the criteria for being discrete. If a population segment is considered discrete pursuant to one or more of the conditions described in our DPS policy, its biological and ecological significance will be considered in light of Congressional guidance.

Analysis of Significance

If a population segment is considered discrete under one or more of the conditions described in our DPS policy, its biological and ecological significance will be considered in light of Congressional guidance that the authority to list DPSs be used ''sparingly'' while encouraging the conservation of genetic diversity. In making this determination, we consider available scientific evidence of the discrete population segment's importance to the taxon to which it belongs. Since precise circumstances are likely to vary considerably from case to case, the DPS policy does not describe all the classes of information that might be used in determining the biological and ecological importance of a discrete population. However, the DPS policy does provide four possible reasons why a discrete population may be significant. As specified in the DPS policy (61 FR 4722), this consideration of the population segment's significance may include, but is not limited to, the following:

(1) Persistence of the discrete population segment in an ecological setting unusual or unique to the taxon;

(2) Evidence that loss of the discrete population segment would result in a significant gap in the range of a taxon;

(3) Evidence that the discrete population segment represents the only surviving natural occurrence of a taxon that may be more abundant elsewhere as an introduced population outside its historic range; or

(4) Evidence that the discrete population segment differs markedly from other populations of the species in its genetic characteristics.

A population segment needs to satisfy only one of these criteria to be considered significant. Furthermore, the list of criteria is not exhaustive; other criteria may be used as appropriate.

Ecological Setting

The Caliente Canyon and Tehachapi Mountains populations are 13 mi (21 km) apart, and we would not generally expect that ecological differences would occur in that short distance, and the habitat of the two populations is similar. However, as discussed previously, the range of the Caliente Canyon population is as much as 1,300 ft (396 m) lower in elevation than that of the Tehachapi Mountains population. This elevational difference exposes the two populations to different climatic conditions. For example, the lower Caliente Canyon populations experience higher temperatures for a longer period of time than any of the Tehachapi Mountains populations, and snowfall occurs less often and remains on the ground for shorter periods of time at the lower elevations. These differences are likely to result in differences in the length and timing of surface activity between the two populations. There are also minor differences in either the material available on the surface or the surface material selected by the two populations, with the Caliente Canyon population most often found under rocks and talus, while the Tehachapi Mountains population is more often found under leaves, woody debris, and talus (Hansen and Wake 2005, p. 694). Although differences exist in the ecological setting of the two populations, we do not find these differences to be great enough to be considered unusual or unique for the taxon.

Gap in the Range

Because the species consists of only two, discrete populations that constitute 47 percent and 53 percent, respectively, of the species known range, the loss of either the Caliente Canyon population to the north or the Tehachapi Mountains population to the south would create a substantial gap in the range of the species.

Whether the Population Represents the Only Surviving Natural Occurrence of the Taxon

Both populations of the Tehachapi slender salamander are in entirely natural settings, and there are no populations that have been introduced outside the range of the species and there are no captive populations. Consequently, this factor is not applicable to our determination regarding significance.

Marked Differences in Genetic Characteristics

As discussed previously, a high level of divergence (greater than 5 percent) in mtDNA exists between the Caliente Canyon and Tehachapi Mountains populations (Jockusch *in litt.* 2009e, p. 1; Jockusch *in litt.* 2009f, pp. 1–2). However, mtDNA represents only five females of the two populations (Jockusch *in litt.* 2009e, p. 1). Jockusch's (*in litt.* 2009d, p. 1) preliminary findings on nuclear DNA (based on only two individuals), which represents both sexes, found less divergence than with mtDNA. Although this research indicates that there may be genetic differences between the two populations, because of the small

sample size, the available information is too inconclusive and limited for us to find that the two populations are markedly genetically different from each other.

Conclusion of Distinct Population Segment Review

We find that, because there are only two populations of the species, the loss of either would result in a significant gap in the overall range of the species. However, we do not find that either population represents the only surviving natural occurrence or that either population is markedly genetically different. Therefore, because each population meets one of the considerations for significance in our DPS policy, we find that both the Caliente Canyon and Tehachapi Mountains populations are significant under the policy.

The Caliente Canyon and the Tehachapi Mountains populations of the Tehachapi slender salamander are both discrete and significant. The two populations have been physically separated by distance and barriers such as dry, unsuitable habitat for over a million years, and there is no evidence of gene flow between the two. The two populations are each significant because loss of either one would result in a substantial gap in the range of the species. For these reasons, we find that the Caliente Canyon population and the Tehachapi Mountains population each constitute a distinct population segment of the Tehachapi slender salamander.

Summary of Information Pertaining to the Five Factors

Section 4 of the Act (16 U.S.C. 1533) and implementing regulations at 50 CFR part 424 set forth procedures for adding species to the Federal List of Endangered and Threatened Wildlife. An ''endangered species'' is any species in danger of extinction throughout all or a significant portion of its range. A ''threatened species'' is any species which is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. In making this finding, we summarize below information regarding the status and threats to the two DPS's of the Tehachapi slender salamander in relation to the five factors in section 4(a)(1) of the Act. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1) of the Act. In making our 12-month finding, we considered and evaluated all scientific and commercial information in our files, including information received during the public comment period that ended June 22, 2009.

Factor A: The Present or Threatened Destruction, Modification, or Curtailment of the Species' Habitat or Range

Because the Factor A analysis for the entire range of the species specifically discussed these threats for the Caliente Canyon population, the same analysis applies for the Caliente Canyon DPS. Likewise, the analysis of threats under Factor A for the Tehachapi Mountains population, equally applies to the Tehachapi Mountains DPS. The threats are briefly summarized below for each DPS. Please refer to the Factor A analysis for the entire range of the species for details.

Summary of Factor A of the Caliente Canyon DPS

Overall, 4 out of 18 occurrences showed relatively localized signs of moderate disturbance from cattle grazing, residential use, or erosion from a nearby road. Disturbance specifically associated with cattle trampling was seen at 3 out of 18 occurrences (approximately 16.7 percent). However, sufficient habitat in good-to-fair condition to support the species remains at all 4 locations, while all of the habitat at the other 14 occurrences is in good to fair condition. No new road construction is planned within the range of the Caliente Canyon population; however, erosion associated with an existing road in Caliente Canyon is affecting habitat in a few localized areas. Mining activity within the Caliente Canyon area is not occurring, and there are no confirmed plans for mining to start again in the foreseeable future. In addition, there are no plans for new residential or commercial development within the Caliente Canyon DPS of the species. We are also not aware of any flood control projects within the range of the DPS or any planned flood control projects. For these reasons, we conclude that cattle grazing, roads, mining, flood control projects, and commercial and residential development do not constitute a substantial threat to the Caliente Canyon DPS of the Tehachapi slender salamander. Therefore, we conclude that this DPS is not threatened or endangered throughout all of its range within the future by the present or threatened destruction, modification, or curtailment of its habitat or range.

Summary of Factor A of the Tehachapi Mountains DPS

Four of the five canyons (five of the six known occurrences) occupied by the Tehachapi Mountains DPS are found on Tejon Ranch. Current land use on Tejon Ranch in the area where occupied canyons and potential habitat for the Tehachapi slender salamander are located includes cattle grazing, farming, and recreation. We know that cattle grazing and rooting from pigs and turkeys can affect the habitat of Tehachapi slender salamander through trampling and erosion. However, habitat at all known occurrences on Tejon Ranch is in good condition, despite the presence of cattle, turkeys, and pigs (Hansen *in litt.* 2010a, p. 3; Miller *in litt.* 2010b, p. 4). Therefore, we have no evidence that indicates that cattle grazing or rooting from pigs and turkeys are threats to the Tehachapi Mountains DPS on Tejon Ranch.

None of the four occupied canyons fall within the 7,860-ac (3,181-ha) proposed TMV development envelope, and all occupied habitat and occurrences are will be at least 0.5 mi (0.8 km) away from any development. Although Tejon Ranch's planned TMV project may remove 108 ac (44 ha) of potentially suitable habitat, the TMV project is designed to avoid all occupied habitat and all known occurrences of the Tehachapi slender salamander within the project development area and footprint. Because the TMV development is designed to avoid direct impacts to the DPS, and indirect effects from the development (including increased presence of humans, pets, and predators) are not considered to be a significant threat to the species, the proposed residential and commercial development is not considered a threat to the Tehachapi Mountains DPS.

There are no known flood control projects or mining projects occurring or planned to occur within the range of this DPS. In addition, there are no known threats of habitat removal or degradation for the species on Fort Tejon SHP. Therefore, we conclude that this DPS is not threatened or endangered throughout all of its range within the future by the present or threatened destruction, modification, or curtailment of its habitat or range.

Factor B: Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

We are not aware of any information that indicates overutilization for commercial, recreational, scientific, or educational purposes is a threat to the Caliente Canyon DPS or the Tehachapi

Mountains DPS of the Tehachapi slender salamander. Therefore, we conclude that neither DPS is threatened or endangered throughout all of its range within the future by overutilization for commercial, recreational, scientific, or educational purposes.

Factor C: Disease or Predation

As discussed under Factor C for the species as a whole, we do not know whether the Tehachapi slender salamander has been, or will be, exposed to a deadly pathogen, such as the chytrid fungus. However, related terrestrial species of salamanders have been found to suffer from Chytridiomycosis, including the California and black-bellied slender salamanders. As previously discussed, Weinstein's study showed that Chytridiomycosis causes mortality of a fully terrestrial salamander species in a moist lab environment; however, individuals were able to recover in a dry lab environment. Her study suggests that individuals of terrestrial slender salamander species may fair better in the field (Weinstein *in litt.* 2008a, p. 1; Weinstein 2009, p. 1).

We do not have any information to indicate that the chytrid fungus is present in the Caliente Canyon DPS of the Tehachapi slender salamander or any other species with which it co-occurs. The black-bellied slender salamander, which has been infected by chytrid in San Luis Obispo County (110 mi or 177 km away), only co-occurs with the Tehachapi Mountain DPS of the Tehachapi slender salamander. Other amphibian species that could co-occur with the Tehachapi slender salamander that have been known to carry chytrid include the Pacific tree frog, western toad, and bullfrog; however, the disease has not been detected in these species in the range of the Tehachapi slender salamander in Kern County. Based on the limited information available, it appears that the Tehachapi Mountains DPS runs a slightly higher risk of contracting chytrid from a co-occurring species than the Caliente Canyon DPS. However, based on our current understanding of the transmission and the ability of fully terrestrial slender salamander species to recover from the effects of chytrid, we do not believe that this risk rises to the level of threatening the continued existence of either DPS.

As discussed in Factor C for the species as a whole, potential indirect effects from residential or commercial development within or near Tehachapi slender salamander habitat could include an increase in human and predator presence. This could potentially be the case for the Tehachapi Mountains DPS of the Tehachapi slender salamander, as indirect, long-term potential effects from the TMV project would include an increase in human and predator presence at Tejon Ranch. An increased presence of humans, domestic animals, and predators will be primarily concentrated within the TMV development envelope, although it is possible for predators to disperse to areas of occupied Tehachapi slender salamander habitat. We do not have any evidence to indicate that these indirect effects will rise to a level that would threaten the existence of the Tehachapi slender salamander.

We do not have any evidence that predation threatens the persistence of either the Caliente Canyon or Tehachapi Mountains DPS. Pigs and turkeys are present within the Tehachapi Mountains DPS and are known to prey on amphibians; however, currently available information does not indicate that they are affecting Tehachapi slender salamanders. Therefore, we conclude that the Caliente Canyon and Tehachapi Mountains DPSs of the Tehachapi slender salamander are not threatened or endangered throughout all of their range within the future by disease or predation.

Factor D: Inadequacy of Existing Regulatory Mechanisms

To the extent that we identify possibly significant threats in the other Factors, we consider under this factor whether those threats are adequately addressed by existing regulatory mechanisms. Thus, if a threat is minor, listing may not be warranted even if existing regulatory mechanisms provide little or no protection to counter the threat. Please refer to the Factor D discussion in the species section for a description of the relevant regulatory mechanisms that may provide some protections for one or both DPSs.

Federal Protections

NEPA is required for projects within the Caliente Canyon and Tehachapi Mountains DPSs if there is a Federal nexus (*i.e.,* projects that require a Federal permit, receive Federal funding, or are implemented by a Federal agency). Although NEPA requires analysis and disclosure of impacts to the human environment, including biological resources such as the Tehachapi slender salamander, it stops short of requiring that protection measures be implemented.

EPA policies to implement the Clean Air Act in addressing climate change caused by greenhouse gas emissions are still evolving. Our status review did not reveal substantial information that indicates that climate change poses a significant threat to the Tehachapi slender salamander throughout its range including both the Caliente Canyon and Tehachapi Mountains DPSs (see Factor E).

BLM's organic act and designation of the Tehachapi slender salamander as a sensitive species provide some protection for the species where it occurs on BLM land. Although we find that BLM's policies protect Tehachapi slender salamander habitat, the benefits to the species are limited because only a small portion of the Tehachapi slender salamander's range within the Caliente Canyon DPS occurs on BLM land (approximately 16.7 percent), and there is no BLM land within the range of the Tehachapi Mountains DPS.

State Protections

CESA provides protection to the species on privately owned and State-owned land (*i.e.,* 21 of the 24 occupied occurrences or 87.5 percent), but not necessarily on the small portion (12.5 percent) of occupied habitat on Federal lands within the Caliente Canyon population.

CEQA applies to both the Caliente Canyon and Tehachapi Mountains DPSs; however, as of the date of this finding, there are no projects proposed or planned within the range of the Caliente Canyon DPS that would require CEQA. The EIR associated with Tejon Ranch's proposed TMV project addresses occurrences of the Tehachapi slender salamander within the Tehachapi Mountains DPS. The Final EIR serves to confirm a project design that avoids all known occurrences and occupied habitat of the Tehachapi slender salamander on Tejon Ranch.

There are no other development projects proposed within the Tehachapi Mountains DPS; therefore, threats of habitat removal and degradation from commercial and residential development (see Factor A) do not rise to a level that would threaten the DPS at this time or within the future.

Summary of Factor D

As discussed in Factors A, B, C, and E, we did not find a specific factor that threatens the continued survival of the Tehachapi slender salamander within the Caliente Canyon or the Tehachapi Mountains DPSs. Therefore, we find that neither DPS is threatened by the inadequacy of existing regulatory mechanisms throughout its range now, or within the future.

Factor E: Other Natural or Manmade Factors Affecting the Continued Existence of the Species

As discussed in the analysis of threats under Factor E for the Tehachapi slender salamander across its entire range, the petitioner stated the Tehachapi slender salamander is threatened by climate change caused by anthropogenic emissions of greenhouse gases, and by stochastic events due to its small, narrowly distributed populations (Nichols 2006, p. 8).

Climate Change

The possible effects to the populations within the Caliente Canyon and Tehachapi Mountains areas, as discussed in Factor E for the species, are identical for each DPS. Please refer to the Factor E discussion for the species for further details. Based on a review of available information, we believe that some loss of habitat in the more open, exposed parts of occupied canyons will occur as a result of climate change. However, we also believe that habitat will remain in the lower, most-shaded portions of canyons to support the salamander and in some cases the salamander may be able to shift within the canyon in response to climate change. Therefore, we find that neither the Caliente Canyon nor Tehachapi Mountains DPS of the Tehachapi slender salamander is threatened by climate change throughout its range, now or within the future.

Stochastic Events

Under this factor we explore whether three risks, represented by demographic, genetic, and environmental stochastic events, are substantive to threaten the continued existence of the Tehachapi slender salamander within the Caliente Canyon and the Tehachapi Mountains DPSs. Because of the rarity and limited dispersal ability of the species, genetic stochasticity is a concern. However, we do not have any evidence of genetic bottlenecks or inbreeding depression to indicate that genetic stochasticity is a significant threat. Nor do we have any information to indicate that demographic stochasticity or a disease outbreak is likely to be a significant threat in the foreseeable future. Environmental stochasticity (particularly wildfire) is a concern; however, we do not believe that this rises to a level that threatens the persistence of the species over the long-term.

A species may also be affected by more than one threat in combination. Within the preceding review of the five listing factors, we have identified several threats that could have interrelated impacts on the Tehachapi slender salamander. For example, potential suitable habitat may be lost or altered as a result of a combination of development (Factor A) and effects of climate change (Factor E). Likewise, predation (Factor C) in combination with a stochastic event (Factor E), such as a forest fire could result in a major loss of individuals in one or more populations. However, as we discuss above, regardless of its source, we do not believe that the threats discussed above, either individually or in combination, are of sufficient imminence, intensity or magnitude to affect the status of either the Caliente Canyon or Tehachapi Mountains DPS of the Tehachapi slender salamander.

Therefore, we conclude that neither the Caliente Canyon nor the Tehachapi Mountains DPS is threatened or endangered throughout its range within the future by other natural or manmade factors.

Finding for Distinct Population Segments

As previously mentioned for the finding for the species as a whole, we have carefully assessed the best scientific and commercial information available regarding threats faced by the Caliente Canyon DPS and the Tehachapi Mountains DPS of the Tehachapi slender salamander. We have reviewed the petition, scientific literature, information available in our files, and all information submitted to us following our 90-day petition finding (74 FR 18336; April 22, 2009). We also consulted with recognized Tehachapi slender salamander experts, Federal land managers, and local government, and arranged for a recognized Tehachapi slender salamander expert to assess potential threats to the habitat and range of the species relative to current and planned land uses and species occurrences.

Potential threats include development, road construction, mining, domestic livestock grazing, introduced species, and flood control projects. Based on the best available information, we find that there is little evidence to support a finding that listing either DPS is warranted based on these identified threats.

While the available information suggests that the number of individuals in each DPS appears to be few and that they are narrowly distributed, we do not have any trend data to indicate that the number of individuals within each DPS is in decline, stable, or increasing.

The range of the Caliente Canyon DPS is primarily on land used for grazing and showed generally low signs of degradation from livestock trampling and erosion, with only 3 of 18 occurrences exhibiting moderate degradation in some portions of their habitat. There are no proposed projects associated with residential or commercial development or mining anywhere near known occurrences within Caliente Canyon.

The primary land use within the range of the Tehachapi Mountains DPS is also livestock grazing, but we do not have any information that indicates that grazing has resulted in significant habitat degradation. Tejon Ranch is planning a large-scale residential and commercial development project, TMV. The TMV development envelope avoids all known occurrences and adjacent contiguous habitat, and occurs at a sufficient distance from the species' dispersal range. Because the DPS' confirmed occurrences are discretely distributed and isolated, the proposed development is not expected to affect movement patterns or breeding. The approved EIR estimates that 108 ac (44 ha) of potentially suitable habitat within the TMV development envelope would be lost due to construction. The loss of 108 ac (44 ha) is likely an overestimation of the amount of suitable habitat that exists, due to the constraints of modeling projections, but even using this 108 ac (44 ha) value as a worst-case assumption, only 2.8 percent of the potentially suitable habitat on the Tejon Ranch would be lost to development.

Indirect effects from development—including increased human presence, runoff and erosion, and predators—are not expected to pose a significant threat to the Tehachapi Mountains DPS. Depending on the nature of the potential impact, the source of the impact is either far enough removed from any known occurrence or occupied habitat so as not to constitute a threat, or there is some other factor, such as the species' nocturnal and subfossorial behavior, that greatly reduces the potential threat. Therefore, impacts from development are not expected to threaten the Tehachapi Mountains DPS. We do not have any indication that flood control projects occur or are planned to occur within either the Caliente Canyon or Tehachapi Mountains DPSs.

The impact of climate change is a concern for the species, and while there is uncertainty, we believe that some loss of occupied habitat will occur because of climate change in the more exposed portions of the canyons salamander. However, we also believe that habitat will remain in the lower, most-shaded portions of canyons to support the salamander, and in some cases the

salamander may be able to shift within the canyon in response to climate change. Because of the rarity and limited dispersal ability of the species, genetic stochasticity is also a concern. However, we do not have any evidence of genetic bottlenecks or inbreeding depression to indicate that genetic stochasticity is a significant threat.

There are regulatory mechanisms in place, such as CESA, CEQA, and BLM's special status designation for the species, that provide adequate protections for both DPSs of the species given the types and minor degree of potential threats faced by the species. Therefore, we find that listing the Caliente Canyon DPS or the Tehachapi Mountains DPS as threatened or endangered under the Act is not warranted at this time.

And finally, we determined that both of the DPSs are not affected cumulatively by all of the five factors. Therefore, based on our conclusions for each of the five factors singly and cumulatively, we find that there are no threats of sufficient imminence, intensity, or magnitude to cause a substantial decrease in distribution, or loss of viability of either DPS throughout their range. Therefore, we do not find that either DPS is in danger of extinction (endangered), or likely to become endangered or threatened throughout their range within the foreseeable future. Consequently, listing the Caliente Canyon DPS or the Tehachapi Mountains DPS as threatened or endangered under the Act is not warranted at this time.

Significant Portion of the Range Analysis

The Act defines ''endangered species'' as any species which is ''in danger of extinction throughout all or a significant portion of its range,'' and ''threatened species'' as any species which is ''likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' The definition of ''species'' is also relevant to this discussion. The Act defines the term ''species'' as follows: ''The term 'species' includes any subspecies of fish or wildlife or plants, and any distinct population segment [DPS] of any species of vertebrate fish or wildlife which interbreeds when mature.'' The phrase ''significant portion of its range'' (SPR) is not defined by the statute, and we have never addressed in our regulations: (1) The consequences of a determination that a species is either endangered or likely to become so throughout a significant portion of its range, but not throughout all of its range; or (2) what qualifies a portion of a range as ''significant.''

Two recent district court decisions have addressed whether the SPR language allows the Service to list or protect less than all members of a defined ''species'': *Defenders of Wildlife* v. *Salazar,* 729 F. Supp. 2d 1207 (D. Mont. 2010), concerning the Service's delisting of the Northern Rocky Mountain gray wolf (74 FR 15123, Apr. 12, 2009); and *WildEarth Guardians* v. *Salazar,* 2010 U.S. Dist. LEXIS 105253 (D. Ariz. Sept. 30, 2010), concerning the Service's 2008 finding on a petition to list the Gunnison's prairie dog (73 FR 6660, Feb. 5, 2008). The Service had asserted in both of these determinations that it had authority, in effect, to protect only some members of a ''species,'' as defined by the Act (*i.e.,* species, subspecies, or DPS), under the Act. Both courts ruled that the determinations were arbitrary and capricious on the grounds that this approach violated the plain and unambiguous language of the Act. The courts concluded that reading the SPR language to allow protecting only a portion of a species' range is inconsistent with the Act's definition of ''species.'' The courts concluded that once a determination is made that a species (*i.e.,* species, subspecies, or DPS) meets the definition of ''endangered species'' or ''threatened species,'' it must be placed on the list in its entirety and the Act's protections applied consistently to all members of that species (subject to modification of protections through special rules under sections 4(d) and 10(j) of the Act).

Consistent with that interpretation, and for the purposes of this finding, we interpret the phrase ''significant portion of its range'' in the Act's definitions of ''endangered species'' and ''threatened species'' to provide an independent basis for listing; thus there are two situations (or factual bases) under which a species would qualify for listing: a species may be endangered or threatened throughout all of its range; or a species may be endangered or threatened in only a significant portion of its range. If a species is in danger of extinction throughout an SPR, it, the species, is an ''endangered species.'' The same analysis applies to ''threatened species.'' Therefore, the consequence of finding that a species is endangered or threatened in only a significant portion of its range is that the entire species shall be listed as endangered or threatened, respectively, and the Act's protections shall be applied across the species' entire range.

We conclude, for the purposes of this finding, that interpreting the SPR phrase as providing an independent basis for listing is the best interpretation of the Act because it is consistent with the purposes and the plain meaning of the key definitions of the Act; it does not conflict with established past agency practice (*i.e.,* prior to the 2007 Solicitor's Opinion), as no consistent, long-term agency practice has been established; and it is consistent with the judicial opinions that have most closely examined this issue. Having concluded that the phrase ''significant portion of its range'' provides an independent basis for listing and protecting the entire species, we next turn to the meaning of ''significant'' to determine the threshold for when such an independent basis for listing exists.

Although there are potentially many ways to determine whether a portion of a species' range is ''significant,'' we conclude, for the purposes of this finding, that the significance of the portion of the range should be determined based on its biological contribution to the conservation of the species. For this reason, we describe the threshold for ''significant'' in terms of an increase in the risk of extinction for the species. We conclude that a biologically based definition of ''significant'' best conforms to the purposes of the Act, is consistent with judicial interpretations, and best ensures species' conservation. Thus, for the purposes of this finding, a portion of the range of a species is ''significant'' if its contribution to the viability of the species is so important that, without that portion, the species would be in danger of extinction.

We evaluate biological significance based on the principles of conservation biology using the concepts of redundancy, resiliency, and representation. *Resiliency* describes the characteristics of a species that allow it to recover from periodic disturbance. *Redundancy* (having multiple populations distributed across the landscape) may be needed to provide a margin of safety for the species to withstand catastrophic events. *Representation* (the range of variation found in a species) ensures that the species' adaptive capabilities are conserved. Redundancy, resiliency, and representation are not independent of each other, and some characteristic of a species or area may contribute to all three. For example, distribution across a wide variety of habitats is an indicator of representation, but it may also indicate a broad geographic distribution contributing to redundancy (decreasing the chance that any one event affects the entire species), and the likelihood that some habitat types are less susceptible to certain threats, contributing to

resiliency (the ability of the species to recover from disturbance). None of these concepts is intended to be mutually exclusive, and a portion of a species' range may be determined to be ''significant'' due to its contributions under any one of these concepts.

For the purposes of this finding, we determine if a portion's biological contribution is so important that the portion qualifies as ''significant'' by asking whether, *without that portion,* the representation, redundancy, or resiliency of the species would be so impaired that the species would have an increased vulnerability to threats to the point that the overall species would be in danger of extinction (*i.e.,* would be ''endangered''). Conversely, we would not consider the portion of the range at issue to be ''significant'' if there is sufficient resiliency, redundancy, and representation elsewhere in the species' range that the species would not be in danger of extinction throughout its range if the population in that portion of the range in question became extirpated (extinct locally).

We recognize that this definition of ''significant'' establishes a threshold that is relatively high. On the one hand, given that the consequences of finding a species to be endangered or threatened in an SPR would be listing the species throughout its entire range, it is important to use a threshold for ''significant'' that is robust. It would not be meaningful or appropriate to establish a very low threshold whereby a portion of the range can be considered ''significant'' even if only a negligible increase in extinction risk would result from its loss. Because nearly any portion of a species' range can be said to contribute some increment to a species' viability, use of such a low threshold would require us to impose restrictions and expend conservation resources disproportionately to conservation benefit: Listing would be rangewide, even if only a portion of the range of minor conservation importance to the species is imperiled. On the other hand, it would be inappropriate to establish a threshold for ''significant'' that is too high. This would be the case if the standard were, for example, that a portion of the range can be considered ''significant'' only if threats in that portion result in the entire species' being currently endangered or threatened. Such a high bar would not give the SPR phrase independent meaning, as the Ninth Circuit held in *Defenders of Wildlife* v. *Norton,* 258 F.3d 1136 (9th Cir. 2001).

The definition of ''significant'' used in this finding carefully balances these concerns. By setting a relatively high threshold, we minimize the degree to which restrictions will be imposed or resources expended that do not contribute substantially to species conservation. But we have not set the threshold so high that the phrase ''in a significant portion of its range'' loses independent meaning. Specifically, we have not set the threshold as high as it was under the interpretation presented by the Service in the *Defenders* litigation. Under that interpretation, the portion of the range would have to be so important that current imperilment there would mean that the species would be *currently* imperiled everywhere. Under the definition of ''significant'' used in this finding, the portion of the range need not rise to such an exceptionally high level of biological significance. (We recognize that if the species is imperiled in a portion that rises to that level of biological significance, then we should conclude that the species is in fact imperiled throughout all of its range, and that we would not need to rely on the SPR language for such a listing.) Rather, under this interpretation we ask whether the species would be endangered everywhere without that portion, *i.e.,* if that portion were completely extirpated. In other words, the portion of the range need not be so important that even being in danger of extinction in that portion would be sufficient to cause the remainder of the range to be endangered; rather, the *complete extirpation* (in a hypothetical future) of the species in that portion would be required to cause the remainder of the range to be endangered.

The range of a species can theoretically be divided into portions in an infinite number of ways. However, there is no purpose to analyzing portions of the range that have no reasonable potential to be significant *and* threatened or endangered. To identify only those portions that warrant further consideration, we determine whether there is substantial information indicating that: (1) The portions may be ''significant,'' and (2) the species may be in danger of extinction there or likely to become so within the foreseeable future. Depending on the biology of the species, its range, and the threats it faces, it might be more efficient for us to address the significance question first or the status question first. Thus, if we determine that a portion of the range is not ''significant,'' we do not need to determine whether the species is endangered or threatened there; if we determine that the species is not endangered or threatened in a portion of its range, we do not need to determine if that portion is ''significant.'' In practice, a key part of the portion status analysis is whether the threats are geographically concentrated in some way. If the threats to the species are essentially uniform throughout its range, no portion is likely to warrant further consideration. Moreover, if any concentration of threats applies only to portions of the species' range that clearly would not meet the biologically based definition of ''significant,'' such portions will not warrant further consideration.

Tehachapi Slender Salamander

The Caliente Canyon and the Tehachapi Mountains DPSs together constitute the entirety of the range of the Tehachapi slender salamander. The distinct and geographically separate areas occupied, respectively, by the Caliente Canyon DPS and the Tehachapi Mountains DPS, constitute the two significant portions of the range of the Tehachapi slender salamander. Significant threats to either DPS would constitute a significant threat to the Tehachapi slender salamander in a significant portion of its range. We have previously determined, however, that neither DPS is threatened or endangered across its range. Therefore, we conclude that the Tehachapi slender salamander is not in danger of extinction or likely to become endangered in the foreseeable future, in a significant portion of its range.

We acknowledge that the Ninth Circuit Court of Appeals decision in *Defenders of Wildlife* v. *Norton*, 258 F.3d 1136 (2001) can be interpreted to require that in determining whether a species is threatened or endangered throughout a significant portion of its range, the Service should consider whether lost historical range (as opposed to current range) constitutes a significant portion of the range of the species at issue. While this is not our interpretation of the statute, we conclude that there are no such areas for the Tehachapi slender salamander, the Caliente Canyon DPS, or the Tehachapi Mountains DPS. As we discussed in detail in our assessment of threats to each species, there is no evidence of meaningful range contraction for the species; in fact, the range of the Caliente Canyon DPS and therefore, the species is now known to be larger than previously believed. Therefore, we do not believe the species is threatened or endangered in a significant portion of its range due to lost historical habitat.

We next evaluate whether there are any significant portions of the ranges of either the Caliente Canyon DPS or the

Tehachapi Mountains DPS where the species is in danger of extinction or is likely to become endangered in the foreseeable future.

Caliente Canyon DPS

The Caliente Canyon DPS consists of sections of five canyons, totaling about 9 linear mi (14.5 km). To determine whether the Caliente Canyon DPS is threatened in a significant portion of its range, we first addressed whether any portions of the range of the DPS warrant further consideration. Our analysis indicates that the conservation status of the Caliente Canyon DPS is essentially the same throughout its range; there is no area within the range of the DPS where potential threats to this species are significantly concentrated or are substantially greater than in other portions of the range. And, as we explained in detail in our analysis of the status of the species, none of the threats faced by the species, alone or in combination, are sufficient to place it in danger of extinction now (endangered) or in the foreseeable future (threatened). The main potential threat to the Caliente Canyon DPS is livestock grazing, which occurs throughout most of the range of this DPS; however, the impacts of grazing to the species are minor and are not concentrated in any geographic portion of the range of the DPS. For these reasons, we find that there are no portions of the Caliente Canyon DPS's range that warrant further consideration as significant portions of the range.

Tehachapi Mountains DPS

To determine whether the Tehachapi Mountains DPS is threatened in a significant portion of its range, we also first addressed whether any portions of the range of the DPS warrant further consideration. Our analysis indicates that the conservation status of the Tehachapi Mountains DPS is essentially the same throughout its range; there is no area within the range of the DPS where potential threats to this species are significantly concentrated or are substantially greater than in other portions of the range. And, as we explained in detail in our analysis of the status of the species, none of the threats faced by the species, alone or in combination, are sufficient to place it in danger of extinction now (endangered) or in the foreseeable future (threatened).

A large development project (Tejon Ranch TMV project) is planned within the general vicinity of half of the occurrences of the Tehachapi Mountains DPS. However, the TMV development envelope is configured to avoid all known occurrences and occupied habitat of the species within this DPS. The TMV project, if implemented, will likely affect 108 ac (44 ha) out of the estimated 3,797 ac (1,537 ha) (or less than three percent) of habitat that may be suitable for the Tehachapi Mountains DPS on Tejon Ranch. We do not have evidence that the 108 ac (44 ha) of potentially suitable habitat likely to be affected by the TMV project is significant to the survival and recovery of the DPS. The five occupied canyons that make up the Tehachapi Mountains DPS are widely distributed across the DPS's range. We found no evidence that individuals of this DPS are concentrated in any geographic portion of the range that would increase the vulnerability of this DPS to a particular threat. For these reasons, we find that there are no portions of the Tehachapi Mountains DPS's range that warrant further consideration as significant portions of the range.

We do not find that the Caliente Canyon DPS or the Tehachapi Mountains DPS is in danger of extinction now, nor do we find that either DPS is likely to become endangered within the foreseeable future throughout all or a significant portion of its range. Therefore, listing the Caliente Canyon DPS or the Tehachapi Mountains DPS as threatened or endangered under the Act is not warranted at this time.

We request that you submit any new information concerning the status of, or threats to, these species to our Ventura Fish and Wildlife Office (see **ADDRESSES** section) whenever it becomes available. New information will help us monitor this species and encourage its conservation. If an emergency situation develops for this or any other species, we will act to provide immediate protection.

References Cited

A complete list of references cited is available on the Internet at *http://www.regulations.gov* and upon request from the Ventura Fish and Wildlife Office (see **ADDRESSES** section).

Author

The primary authors of this notice are the staff of the Ventura Fish and Wildlife Office (see **ADDRESSES**).

Authority: The authority for this action is section 4 of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: September 23, 2011.

Rowan Gould,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2011–25522 Filed 10–7–11; 8:45 am]

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Part III

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Endangered Status for the Altamaha Spinymussel and Designation of Critical Habitat; Final Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R4–ES–2008–0107; 92210 1111 0000–B2]

RIN 1018–AV88

Endangered and Threatened Wildlife and Plants; Endangered Status for the Altamaha Spinymussel and Designation of Critical Habitat

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service, list the Altamaha spinymussel (*Elliptio spinosa*), a freshwater mussel endemic to the Altamaha River drainage of southeastern Georgia, as an endangered species under the Endangered Species Act of 1973, as amended (Act), and designate approximately 237.4 kilometers (km) (147.5 miles (mi)) of mainstem river channel as critical habitat in Appling, Ben Hill, Coffee, Jeff Davis, Long, Montgomery, Tattnall, Telfair, Toombs, Wayne, and Wheeler Counties, Georgia. This final rule will implement the Federal protections provided by the Act.

DATES: This rule becomes effective on November 10, 2011.

ADDRESSES: This final rule and final economic analysis are available on the Internet at *http://www.regulations.gov.* Comments and materials received, as well as supporting documentation used in preparing this final rule, are available for public inspection, by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Georgia Ecological Services Office, 105 Westpark Dr., Suite D, Athens, GA 30606; telephone 706–613–9493; facsimile 706–613–6059.

FOR FURTHER INFORMATION CONTACT: Sandra Tucker, Field Supervisor, U.S. Fish and Wildlife Service, Georgia Ecological Services Office (see **ADDRESSES** above). If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION: This document consists of: (1) A final rule to list the Altamaha spinymussel (*Elliptio spinosa*) as endangered; and (2) a final rule to designate critical habitat for this species.

Previous Federal Actions

Federal actions for this species prior to October 6, 2010, are outlined in our proposed rule (75 FR 61664), which was published on that date. Publication of the proposed rule opened a 60-day comment period, which closed on December 6, 2010. We reopened the comment period from May 12, 2011, through June 13, 2011, in order to announce the availability of and receive comments on a draft economic analysis (DEA), and to extend the comment period on the proposed listing and designation (76 FR 27629).

Public Comments

We received comments from the public on the proposed listing action and proposed critical habitat designation, and, in this rule, we respond to these issues in a single comments section. Below, we present the listing analysis first, followed by the analysis for designation of critical habitat.

Background

Species Description

The Altamaha spinymussel (*Elliptio spinosa*) is a freshwater mussel in the family Unionidae, endemic to (found only in) the Altamaha River drainage of southeastern Georgia. The Altamaha River is formed by the confluence of the Ocmulgee and Oconee rivers and lies entirely within the State of Georgia. The species was described by I. Lea in 1836 from a site near the mouth of the Altamaha River in Darien, Georgia (Johnson 1970, p. 303).

This species reaches a shell length of approximately 11.0 centimeters (cm) (4.3 inches (in)). The shell is subrhomboidal or subtriangular in outline and moderately inflated. As the name implies, the shells of these animals are adorned with one to five prominent spines. These spines may be straight or crooked, reach lengths from 1.0 to 2.5 cm (0.39 to 0.98 in), and are arranged in a single row that is somewhat parallel to the posterior ridge. In young specimens, the outside layer or covering of the shell (periostracum) is greenish-yellow with faint greenish rays, but as the animals get older, they typically become a deep brown, although some raying may still be evident in older individuals. The interior layer of the shell (nacre) is pink or purplish (Johnson 1970, p. 303).

Life History and Habitat

Adult freshwater mussels are filter-feeders, siphoning phytoplankton, diatoms, and other microorganisms from the water column. For the first several months, juvenile mussels employ pedal (foot) feeding, extracting bacteria, algae, and detritus from the sediment (Yeager 1994, pp. 217–221; Cope *et al.* 2008, p. 457).

Although the life history of the Altamaha spinymussel has not been studied, the life histories of other mussels in the *Elliptio* genus have been. Internal fertilization results in the female brooding the larvae (glochidia), which when mature are released. To ensure survival, glochidia must come into contact with a specific host fish or fishes to develop into juvenile mussels. Other mussels in the genus *Elliptio* are broadcast releasers, which may release conglutinates that resemble insect larvae. This reproductive strategy depends on clear water during the time of the year when mussels release their glochidia (Hartfield and Hartfield 1996, p. 375). The Altamaha spinymussel is thought to reproduce in late spring and release glochidia by May or June (Johnson 2004, p. 2; Bringolf 2011, pers. comm.). The host fish of the Altamaha spinymussel is currently unknown. Furthermore, juvenile age classes of other mussels are commonly found during surveys; however, no spinymussel recruitment has been evident in surveys conducted since 1990 (Keferl 2008, pers. comm.; Wisniewski 2008, pers. comm.). Research to develop a better understanding of the natural history and the reasons for a lack of recruitment in the species is continuing.

This spinymussel is known only from Georgia in Glynn, Ben Hill, McIntosh, Telfair, Tattnall, Long, Montgomery, Toombs, Wheeler, Appling, Jeff Davis, Coffee, and Wayne Counties. This spinymussel is considered a ''big river'' species; is associated with stable, coarse-to-fine sandy sediments of sandbars, sloughs, and mid-channel islands; and appears to be restricted to swiftly flowing water (Sickel 1980, p. 12). Johnson (1970, p. 303) reported Altamaha spinymussels buried approximately 5.1 to 10.2 cm (2.0 to 4.0 in) below the substrate surface.

Species Distribution and Status

The historical range of the Altamaha spinymussel was restricted to the Coastal Plain portion of the Altamaha River and the lower portions of its three major tributaries, the Ohoopee, Ocmulgee, and Oconee Rivers (Johnson 1970, p. 303; Keferl 2001, pers. comm.). Large-scale, targeted surveys for the mussel have been conducted since the 1960s (Keferl 1993, p. 299). Recent surveys have revealed a dramatic decline in recruitment, the number of populations, and number of individuals within populations throughout the species' historic range (Stringfellow and Gagnon 2001, pp. 1–2; Keferl 1995, pp.

3–6; Keferl 2008 pers. comm.; Wisniewski 2006, pers. comm.).

Ohoopee River

In a survey of the Ohoopee River, Keferl (1981, pp. 12–14) found at least 30 live specimens of the Altamaha spinymussel at seven of eight collection sites, in thinly scattered beds, in the lower 8 kilometers (km) (5 miles (mi)) of the river. Spinymussels were not found higher in the watershed, presumably because there are insufficient flows to support this species. By the early 1990s, however, only two live specimens were found at the same sites (Keferl 1995, pp. 3–6; Keferl 2008 pers. comm.; Wisniewski 2006, pers. comm.). Stringfellow and Gagnon (2001, pp. 1–2) resurveyed these sites using techniques similar to those used by Keferl (1981, p. 12), but did not find any live Altamaha spinymussels in the Ohoopee River. Therefore, the species is currently either extirpated from the Ohoopee River or present in such low numbers that it is undetectable.

Ocmulgee River

The Altamaha spinymussel is known from the Ocmulgee River from its confluence with the Oconee River upstream to Red Bluff in Ben Hill County (approximately 110 km/68.3 mi). Early collecting efforts in the Ocmulgee River near Lumber City yielded many live Altamaha spinymussels. In 1962, Athearn made a single collection of 40 live spinymussels downstream of U.S. Highway 341 near Lumber City (Johnson *et al.* 2008, Athearn database). Researchers collected 19 and 21 live individuals, respectively, during two surveys at Red Bluff (Thomas and Scott 1965, p. 67). In 1986, Stansbery collected 11 live individuals at the U.S. Highway 441 Bridge near Jacksonville, Georgia (Wisniewski 2006, pers. comm.).

The lower Ocmulgee River was surveyed by Keferl in the mid 1990s, during 2000–2001 (Cammack *et al.* 2001, p. 11; O'Brien 2002, p. 2), and in 2004 (Dinkins 2004, pp. 1–1 and 2–1). Over 90 sites have been surveyed since 1993, many of which were repeatedly surveyed, resulting in a total of 19 live Altamaha spinymussels detected at 10 sites, distributed from Jacksonville downstream to the Oconee River confluence.

Oconee River

There are few historical records of Altamaha spinymussels from the Oconee River. Athearn collected 18 spinymussels, including 5 juveniles, at a site in Montgomery County near Glenwood in the late 1960s (Johnson *et al.* 2008, Athearn database). The species has not been collected there since and is probably extirpated from the Oconee River system (Keferl 2008, pers. comm.). In 1995, as part of a dam relicensing study, 41 sites between Lake Sinclair and Dublin were surveyed (EA Engineering 1995, pp. 1–1, 3–1, 3–2, 4–2, and 4–3). One hundred forty-four hours of search time yielded 118 live mussels, but no Altamaha spinymussels. Compared to the other portions of its range, the Oconee River has not been extensively surveyed, in part because the entire mussel fauna of this river appears to be sparse.

Altamaha River

Most surveys for Altamaha spinymussels have been conducted in the Altamaha River. Although methodological differences preclude accurate comparison of mussel abundances over time, there is evidence that higher abundances of Altamaha spinymussels occurred in the Altamaha River historically. Early surveys at the U.S. Route 301 crossing documented 20 individuals in 1963, 7 in 1965, and 43 in 1970. Sickel sampled seven sites downstream of the U.S. Route 1 bridge in 1967. Sixty spinymussels were collected in one 500-square meters (m^2) (5382-square feet (ft^2)) site, and an additional 21 spinymussels were collected in a 400-m^2 (4306-ft^2) (Sickel 1980, p. 11; Wisniewski 2006, pers. comm.) site. One site had five live spinymussels, two sites had one each, and two sites had no Altamaha spinymussels.

From 1993 to 1996, Keferl surveyed 164 sites on the mainstem of the Altamaha River between the Ocmulgee-Oconee River confluence and the Interstate 95 crossing near the river's mouth (approximately 189 km/117 mi.). A total of 63 live Altamaha spinymussels were collected from 18 of these sites, located between the Oconee River and U.S. Route 301 (116 km/72 mi); however, no Altamaha spinymussels were collected below U.S. Route 301 (73 km/45 mi), suggesting absence or extreme rarity in the reach between U.S. Route 301 and the river's mouth (approximately 73 km (45 mi)). In addition, 10 of these sites were clustered within a 4-km (2-mi) reach upstream of the U.S. Route 301 crossing near Jesup; the remaining eight sites were isolated by long distances of habitat with no or sub-detectable numbers of live spinymussels.

O'Brien (2002, pp. 3–4) surveyed 30 sites on the Altamaha River from the confluence of the Ocmulgee and Oconee Rivers downstream to U.S. Route 301 during 2001, including the 18 known Altamaha spinymussel sites, reported by Keferl, within the reach. She collected a total of six live individuals from five different sites and freshly dead shells from two additional sites.

In 2003 and 2004, researchers surveyed 25 sites to collect specimens for host-fish trials (Albanese 2005, pers. comm.). Live Altamaha spinymussels were detected at only four sites. Five of the seven sites documented by O'Brien and all four sites documented during the host-fish surveys were clustered within a short reach (15 km/24 mi) of the Altamaha River just upstream of the U.S. Route 301 crossing near Jesup, Georgia.

To summarize, researchers were able to find 60 Altamaha spinymussels at a single site on the Altamaha River in 1967; in contrast, the largest number of Altamaha spinymussels observed from a single site on the Altamaha River during the 1990s or 2000s was nine (Albanese 2005, pers. comm.).

Summary of Basin-Wide Population Estimates

In 1994, researchers spent 128 search-hours throughout the Altamaha Basin to find 41 spinymussels (Keferl 1995, p. 3). From 1997 through 2006, researchers searched 233 sites throughout the basin to document 34 spinymussels in more than 550 hours of searching (Wisniewski 2006, pers. comm.); from 2007 to 2009, only 23 spinymussels were found from more than 110 sites (Wisniewski 2009, pers. comm.). In summary, the Altamaha spinymussel is considered extirpated from two rivers in its historical range, the Ohoopee (15 km (9 mi)) and Oconee Rivers (45 km (28 mi)), as well as the lower 73 km (45 mi) of the Altamaha River (Table 1). Since 1997, despite extensive survey efforts made by several different researchers, only 57 spinymussels have been observed from 7 sites in the Ocmulgee (110 km (68 mi)) and 15 sites in the upper Altamaha (116 km (72 mi)) combined, and while individual spinymussels have been found scattered throughout this stretch of river, most of these sites have been clustered in the 10 km (6 mi) immediately north of the U.S. Route 301 crossing.

TABLE 1—DECLINE IN RANGE OF THE ALTAMAHA SPINYMUSSEL

River reach	Historically occupied (linear km/mi)	Current habitat	Percent of historical range lost
Ohoopee	15 km/9 mi	Not seen since 1997	4
Oconee	45 km/28 mi	Not seen since 1968	12.5
Ocmulgee	110 km/68.3 mi	Widely scattered	0
Upper Altamaha	116 km/72 mi	Widely scattered individuals	0
Lower Altamaha	73 km/45 mi	Not seen since 1970	20
Total	359 km/222 mi	226 km/140 mi	36.5

Using Georgia Department of Natural Resources (GDNR)'s database, which included many of the surveys mentioned above, Wisniewski *et al.* (2005, p. 2) conducted a test for a temporal change in sites occupied in the Ocmulgee and Altamaha Rivers between the early 1990s and the early 2000s. Live Altamaha spinymussels were detected at 24 of 241 sites (10 percent) sampled before 2000 and at 14 of 120 sites (12 percent) sampled after 2000. Although the percentage of sites occupied is not indicative of a decline, an analysis of 39 sites sampled during both time periods, of which the spinymussel was initially present in 13 of the 39 sites, indicated that the spinymussel was lost from significantly more sites (11 sites) than it colonized (3 sites) between the early 1990s and early 2000s (Wisniewski *et al.* 2005, p. 2). This test is imprecise because the failure to detect Altamaha spinymussels when present could result in both false colonizations (species missed during early surveys but detected in recent survey) and false extirpations (species detected during early survey but missed during recent survey). Thus, although the exact number of extirpations and colonizations between the two time periods may not be accurate, the much higher number of extirpations is suggestive of a decline over this time period.

Summary of Comments and Recommendations

During the open comment periods for the proposed rule (75 FR 61664) and draft economic analysis, we requested that all interested parties submit comments or information concerning the proposed listing and designation of critical habitat for the Altamaha spinymussel. We contacted all appropriate State and Federal agencies (including the State of Georgia, from whom we directly requested comments), county governments, elected officials, scientific organizations, and other interested parties and invited them to comment. Articles concerning the proposed rule and inviting public comment were published by the Associated Press, The Brunswick News and the Florida Times Union. An article was also published by the Center for Biological Diversity.

During the comment periods, we received a total of 79 comments. We received comments supporting the listing of the Altamaha spinymussel from the Georgia Department of Natural Resources–Wildlife Resources Division, the U.S. Army Corps of Engineers, three environmental groups, and 70 individuals including 9 letters and 65 postcards. We received two requests for an extension of the open comment period and notified requestors that the comment period would reopen for the Notice of Availability of the Draft Economic Analysis, published on May 12, 2011. We received no requests for, and therefore did not hold, a public hearing.

Peer Review

In accordance with our peer review policy published in the **Federal Register** on July 1, 1994 (59 FR 34270), we requested the opinions of four knowledgeable individuals with expertise on freshwater mollusks, the Altamaha River Basin, and conservation biology principles. The purpose of peer review is to ensure that the designation is based on scientifically sound data, assumptions, and analyses, including input of appropriate experts and specialists. We received written responses from three of the peer reviewers.

Peer reviewers stated that: (1) The proposal included a thorough and accurate review of the available scientific and commercial data on this mussel and its habitats; (2) the best available scientific data documented substantial declines in its abundance and distribution; and (3) the data supported the proposed listing as endangered with the designation of approximately 237.4 km (147.5 mi) of critical habitat. Two peer reviewers provided additional details and correction about the life history of the spinymussel, one of these reviewers also provided specific recommendations for the primary constituent elements (PCEs). The information provided by the reviewers has been incorporated into the appropriate sections of this final rule or is addressed in the comments below.

We reviewed all comments received for substantive issues and new data regarding the spinymussel, its critical habitat, and the draft economic analysis. Written comments received during the comment periods are addressed in the following summary. For readers' convenience, we have combined similar comments into single comments and responses.

Peer Reviewer Comments

(1) Comment: Water quality standards set by the State of Georgia are based on water quality criteria established by the U.S. Environmental Protection Agency (EPA) for protection of aquatic life, not humans. Mussels are not currently represented in datasets used by EPA for derivation of water quality criteria. If adopted, the proposed criteria for ammonia will be the first to include mussel sensitivity data. Therefore, the statement that many of the standards may not be protective of mussels is accurate.

Our response: We agree, and have incorporated this information into the Physical or Biological Features Section to reflect this comment. Also see Comment 4 below.

(2) Comment: Dissolved Oxygen (DO) concentrations of 33.1 mg/L appear unusually high for a river segment with no dams. It seems appropriate to exclude this value as described by reporting the 10th and 90th percentiles for DO.

Our response: After reviewing the data, we found three data points to be exceptionally high. All three were taken from the same timeframe with the same device, which suggests that the device may not have been calibrated correctly. These three data points have been thrown out, and the concentration range has been recalculated to 0.42–

20.3 mg/l. The benefit of using the 10th and 90th percentiles is that it allows us to exclude the outliers from the data that may be due to device errors.

(3) Comment: Populations of several fish species, particularly anadromous fishes (*e.g.* striped bass (*Morone saxatilis*), Atlantic and shortnose sturgeon (*Acipenser oxyrinchus* and *A. brevirostrum*), American shad (*Alossa sapidissima*), and other herrings), have declined substantially in recent decades. Host trials for spinymussels with 10 species of fish from six families (Centrarchidae, Cyprinidae, Ictaluridae, Moronidae, Acipenseridae, Catostomidae) have been conducted. Unfortunately, none of these trials have produced juvenile spinymussels.

Our response: We agree. One of the largest gaps in knowledge of this species is host fish information. Presence of suitable host fish in the basin is critical for survival of this species. Evaluation of habitat suitability for the spinymussel would be greatly enhanced with knowledge of the host fish occurrence and distribution; suitable habitat must also be present for the host fish(es). Though all 85 fish species native to the Altamaha Basin are still present, populations of several fish species have declined substantially compared to historic numbers. Host fish have been identified for other members of the genus *Elliptio,* and these species should provide a starting point for the spinymussel. Identification of suitable host fish is also critical for development of a propagation program. Laboratory culture of juveniles would allow for a potential population augmentation program and/or could be used to produce organisms for toxicity testing purposes. The Service has incorporated this information into the Physical or Biological Features Section to reflect this comment.

(4) Comment: EPA has recently (2009) proposed to revise the chronic water quality value for ammonia (at pH 8 and 25 C) from 1.2 mg/L to 0.26 mg/L. This value is calculated to protect 95% of aquatic species. Because ammonia toxicity data have not been generated for the Altamaha spinymussel it is prudent for the Service to consider a lower PCE value for ammonia such as 0.22 mg N/L as indicated in the proposal.

Our response: We agree. We believe the value chosen for the PCE for ammonia is well supported, which is why it is being adopted by EPA (Newton *et al.* 2003, p. 2556 and Wang *et al.* 2007, pp. 2041–2043).

(5) Comment: The commenter recommends adding criteria for copper, nickel, and pyrene. Copper toxicity to early life stages of unionids has been reported as low as 6.8 ug/L in a 96-hr test at a water hardness of 177 mg/L (Wang *et al.* 2007, p. 2043). Hardness buffers metal toxicity by reducing bioavailability of metal ions. Hardness values are much lower (20–40 mg/L) in the Altamaha, thus toxicity would be expected at even lower copper concentrations. Chronic criteria should be substantially lower than this acute value.

Nickel toxicity has been reported for juvenile unionids at 190 ug/L in a 96-hr test with soft water (hardness <50 mg/L). Acute and chronic nickel criteria should be lower than 190 ug/L (no citation provided).

Pyrene is a polycyclic aromatic hydrocarbon (PAH) that may be associated with pulp and paper mills among other industrial and urban sources. This PAH is toxic to unionid glochidia (24 h LC50) at 2.63 ug/L in the presence of UV light (no citation provided). Chronic criteria for persistent, bioaccumulative compounds like PAHs should be substantially lower than acute toxicity values.

Our response: The Service routinely consults with other federal agencies regarding the effects of their actions, and uses the best science available. Given the complex and unique conditions inherent in individual consultations, as well as at different times of year and areas of the river, we believe it would not be prudent to set standards for these compounds at this time because temperature, life stage, and other unknowns may have substantial impact on their toxicity (*e.g.,* temperature and copper interaction). Where surrogate science was available and appropriate to establish general guidelines for water quality, it was applied in this manner. However, we do not have sufficient data to develop water quality criteria for copper, nickel, and pyrene at the level of specificity suggested by the commenter.

Comments From the State

Section 4(i) of the Act states, ''the Secretary shall submit to the State agency a written justification for his failure to adopt regulations consistent with the agency's comments or petition.'' Comments received from the State regarding the proposal to designate critical habitat for the Altamaha spinymussel are addressed below.

Because the comments of one peer reviewer (a State of Georgia employee) were adopted by the State, we are including them in our response to State comments. The State supports the designation of critical habitat for the occupied reaches of the Altamaha and Ocmulgee rivers as proposed, including the exclusion of the Altamaha River between U.S. Route 1 and the upper property boundary of Moody Forest Natural Area from proposed critical habitat. Georgia concurs with the Service that the designation of critical habitat in only the currently occupied reaches of the Altamaha and Ocmulgee Rivers would not adequately conserve the Altamaha spinymussel because this range is connected in a linear pattern that could be destroyed by a single event in the Ocmulgee, flowing downstream into the Altamaha. Therefore, the proposed designation of critical habitat in at least one additional tributary that historically harbored the Altamaha spinymussel is necessary to conserve the species.

(6) Comment: One item that appears to be poorly supported is the considerable discussion found within the *Summary of Factors Affecting the Species* regarding contaminants in sediments of the Oconee River as primary threats. In the proposed rule the Service included extensive text on heavy metal toxicity due to kaolin mining/processing as a threat to unionids in the Oconee River Basin. The Service should also include extensive text regarding the presence and operations of Lake Sinclair.

Our response: The effects of contaminants in sediment in the Oconee River and the entire Altamaha Basin are not well understood. However, it is clear that contaminants in sediment are a threat to mussel fauna in the Southeast and are, therefore, a potential threat to the spinymussel that must be evaluated in the Threats Assessment (Cope 2008, pp. 452–459). Currently there are no data to describe the sensitivity of the spinymussel to environmental stressors such as temperature, dissolved oxygen, and contaminants, but tolerances to stressors can be inferred from other mussel species. The effects of these stressors on mussel fauna are often interconnected. Standardized ASTM (American Society for Testing and Materials) guidelines are currently available for toxicity tests with early life stages (glochidia and juveniles) of freshwater mussels. As a result, toxicity and thermal tolerance data are being generated for a growing number of unionid species. The Service considers contaminants in sediment a potential threat to the spinymussel throughout its range. The nearest reservoir is approximately 120 km (75 miles) from the historic range of the spinymussel and approximately 165 km (103 mi.) from occupied habitat, thus, the effects of hypolimnetic discharges are not considered a threat to the Altamaha spinymussel (also see Comment 7 and

Factor E. Other Natural and Man Manmade Factors Affecting Its Continued Existence).

(7) Comment: The Oconee River downstream of Lake Sinclair was generalized as having sparse mussel populations. The proposal strongly suggests that this is a result of contaminants but does not allude to any effects due to the presence of a major dam and hydroelectric generation facility located at Lake Sinclair. Numerous published studies have recognized reservoirs and hydroelectric generation facilities as one of the leading reasons for declines and extinctions of unionids throughout North America.

Our response: The Oconee River downstream of Lake Sinclair to U.S. Route 280 is poorly surveyed for mussels. Available surveys had described the mussel fauna as depauperate (EA Engineering 1995, pp. 1–1, 3–1, 3–2, 4–2, and 4–3). Typically, habitats immediately downstream of dams are unsuitable for unionids due to the highly erosive nature of the substrates during channel forming events (*e.g.,* spring floods), which scour substrates and deposit those benthic organisms occupying these habitats elsewhere. Additionally, eroding substrates are often deposited upon downstream habitats where unionids occur and thus impede their mobility and their ability to siphon or reproduce. Generally, the effects of reservoir operations on river channels are greatest closest to dams and gradually decline as rivers flow downstream. This effect is observed in the Oconee River, which has a deeply entrenched channel near Dublin, Georgia, upstream of the historic range of the spinymussel. Conversely, the Oconee River downstream of U.S. Route 280 near Mt. Vernon (within the historic range of the spinymussel), has a wider, less entrenched channel with good floodplain connectivity, gentle bank slope, and riparian buffers. Mussel fauna diversity greatly increases in the lower portion of the Oconee, suggesting that the habitat is not degraded by dam operations. While the dam at Lake Sinclair certainly has a profound effect on the ecology of the Oconee River, it is 75 miles from the historic range of the spinymussel and, therefore, was not considered a threat (see Factor E. Other Natural and Man Manmade Factors Affecting Its Continued Existence).

(8) Comment: The inclusion of the Lower Oconee River as critical habitat would more adequately conserve the Altamaha spinymussel than the inclusion of the Ohoopee River, as the Oconee River is a much larger watershed and would be less vulnerable to dewatering during periods of extreme drought, which will likely become more frequent in the future. The Oconee River from U.S. 280 in Mt. Vernon downstream to its confluence with the Altamaha River should be designated as an unoccupied stream reach proposed for critical habitat.

Our response: We recognize that critical habitat designated at a particular point in time may not include all of the habitat areas that we may later determine are necessary for the recovery of the species. For these reasons, a critical habitat designation does not signal that habitat outside the designated critical habitat area is unimportant or may not be required for recovery of the species. The Service agrees that it is essential for the conservation of the species that one of the unoccupied tributaries to the Altamaha be included as critical habitat to avoid a linear distribution that might be vulnerable to a single catastrophic event. The Service has determined that only one of the unoccupied rivers is essential. In deciding which of the two rivers to include as critical habitat we looked at all historic records of spinymussel. In the Oconee River, the only record of spinymussels was from a single collection in 1968. The spinymussel has not been seen in the Oconee from any other locations or at any other time and is now considered extirpated from this river. Conversely, spinymussels have been found from multiple locations over several decades in the Ohoopee and were found as recently as 1997. Keferl referred to the Ohoopee as a possible refugia for the species endemic to the Altamaha, including the spinymussel (Keferl 1981, p. 15). Furthermore, the Oconee has many human-induced threats that are not well understood, including: Kaolin mining, agriculture, and municipal water treatment. The Ohoopee has fewer inputs of point source pollution within this basin; however, this river is impacted by municipal water treatment, drought, and, during low flows, vehicle traffic in the river bed. Drought is a natural event which mussel species have evolved to survive. Vehicle traffic in the river bed could be more easily managed than the potential threats to the Oconee, which may need extensive study to be understood. In determining which river would best serve to protect the spinymussel, the Service chose the Ohoopee because it was known to be inhabited by the spinymussel more recently, it was considered high-quality habitat (habitat that includes multiple PCEs), and manmade impacts should be easier to manage.

(9) Comment: The continued declines of the Altamaha spinymussel are likely exacerbated by density-dependence in which too few individuals exist to adequately repopulate the basin at observable levels.

Our response: We agree, and consider this to be the most serious threat faced by this mussel (for further explanation see Factor E. Other Natural and Man Manmade Factors Affecting Its Continued Existence and Determination).

Public Comments

(10) Comment: In the proposed rule, the Service has not adequately considered the cost to other Federal agencies and how the listing might impact civil works programs such as dredging for commercial navigation or ecosystem restoration on the Altamaha, Oconee, and Ocmulgee Rivers.

Our response: The Act and our regulations at 50 CFR 424.11(b) prohibit us from considering the possible economic impacts associated with listing a species. However, we do take into consideration economic impacts associated with designating critical habitat in accordance with section 4(b)(2) of the Act. Under section 7 of the Act, the U.S. Army Corps of Engineers (Corps) will need to consult with us for activities that may affect the Altamaha spinymussel or its critical habitat. We have broadly defined activities that may affect, destroy or adversely modify critical habitat below (see *Application of the ''Adverse Modification'' Standard,* below), and will work with the Corps to ensure that the best available information is used when they consult with us. Our final economic analysis (Industrial Economics, Inc. 2011, pp. ES–2, ES–3, ES–4) found that there would be only marginal incremental administrative costs associated with this critical habitat designation. Incremental administrative costs are costs that would occur only as a result of the critical habitat designation, which are above and beyond costs associated with listing the species (*i.e.,* baseline costs). The economic analysis projects approximately $37,100 of total incremental impacts (over the next 30 years (2011–2040)) using a seven percent discount rate), as the result of critical habitat designation for the Altamaha spinymussel.

In order to estimate the cost of consultation the Service contacted the National Marine Fisheries Service (NMFS) to see how many consultations they conduct for the shortnose sturgeon

in the Altamaha River. NMFS biologists informed us that they average less than one formal consultation on the Altamaha annually and would estimate that they would conduct three formal consultations annually if critical habitat were designated for this species (Bolden 2011, pers. comm.). Because a listed species already occurs in these rivers, the Altamaha spinymussel listing and critical habitat designation would not be likely to prompt a large increase in the need for consultation or the associated costs to the Corps.

(11) Comment: The proposal contains considerable speculation as to the possible causes for reduced populations of the Altamaha spinymussel but provides no substantive detail or analysis concerning the relative importance of factors contributing to the supposed primary stressors, sedimentation and contaminants.

Our response: The Service has monitored the decline of the spinymussel since it first became a candidate species in 1984. Since that time the Service and the State have funded numerous efforts to develop a better understanding of the natural history of this species. Unfortunately, the low numbers of this species have made it difficult to study; therefore, we have analyzed the threats to this species using the best available science on surrogate species. The natural history of this species is likely very similar to other species in the family Unionidae, and it is reasonable to assume that similar threats will affect this species in a similar manner. Each threat is discussed in detail in the Summary of Factors Affecting the Species and is summarized in the Determination sections. A Threats Matrix detailing our best understanding of the relative importance has been developed and has been provided to the commenter. A copy of the Threats Matrix is on file and available upon request. We have also clarified the relative importance of specific threats, as needed, within the Threats Analysis of this rule.

(12) Comment: The proposed rule misrepresents the (EPA's) Total Maximum Daily Load (TMDL) program and the impaired waters identification process and erroneously suggests that the current regulatory process is inadequate and will not afford protection to the spinymussel. The proposed rule implies or states directly that current regulatory water quality management tools are inadequate to protect existing spinymussel populations.

Our response: The completion of and compliance with a TMDL removes a stream from the 303(d) list (list of impaired waterbodies). However, as stated, the stream is then placed on the 305(b) list of impaired streams with a completed TMDL whether or not water quality conditions improve. Furthermore, several waterbodies have been removed from the 303(d) list upon completion of a TMDL, only to return to the 303(d) list due to additional violations. This indicates that while the TMDL program can improve water quality in streams, it does not prevent water quality violations from occurring, which could have a deleterious effect on the Altamaha spinymussel.

(13) Comment: The proposed rule provides little or no justification for the water quality metrics (primary constituent elements, or PCEs) that are suggested as ''necessary for normal behavior, growth, and viability at all life stages.''

Our response: In developing the parameters for the water quality PCE, we used the best available information to create specific guidelines (considering mussel life stage and interactions with variables such as temperature) including temperature, dissolved oxygen, ammonia, pH, and cadmium. How we derived these criteria is explained below. Conversely, there are many possible toxicity issues for which we do not believe there is sufficient information to develop water quality standards that would be protective of the spinymussel at this time (see also response to Comment 5).

Temperature PCE

We believe that the maximum temperature and the maximum daily temperature fluctuation criteria identified in PCE 3 are supported by the best available data generated from direct temperature measurements of the Altamaha River, as well as comparisons to three temperature gauge stations on the Savannah River, which is similar in size, hydrology, and proximity (Wisniewski 2011, pers. comm.). Therefore, a maximum temperature of 32.6 °C with no more than a 2 °C daily fluctuation appears justified. See the Physical or Biological Features discussion to see how these were derived.

Dissolved Oxygen PCE

Comments suggesting that dissolved oxygen in bottom layers of critical habitat may be lower than the PCE are not appropriate because spinymussels are found in the mainstem river in areas of moving water that does not stratify. Therefore, the water should be well-mixed and dissolved oxygen should be consistent throughout the water column.

Ammonia PCE

For ammonia, 1.5 mg N/L is the criteria maximum concentration (CMC) and 0.22 mg N/L is the criteria continuous concentration (CCC). A review of mussel ammonia literature indicates that at least some juvenile mussels are sensitive to ammonia at concentrations as low as 0.093 mg NH3/L in 10-d assays (Newton *et al.* 2003, p. 2556) and 0.37 mg N/L in 28-d tests (Wang *et al.* 2007, pp. 2041–2043). EPA did not include all mussel toxicity test data in derivation of the proposed criteria (2009) because some tests did not use 'standardized' methods (Bringolf 2011, pers. comm.). The Service considered all available mussel ammonia toxicity data in deriving PCEs. The Service arrived at the ammonia PCE values as a compromise between the mussel toxicity literature and the proposed EPA criteria. There are no ammonia toxicity data available for spinymussel, therefore, we believe this to be the most valid approach for establishing a standard.

pH PCE

The Service attempted to determine the 'central range' of pH values in the Altamaha River by generating the 10th and 90th percentiles (the point at which 10% and 90%, respectively, of the observed values fell) of pH. Because the causes of the decline of the spinymussel remain unidentified, and no data are available regarding the optimal pH for this species, it is reasonable to designate a PCE for critical habitat that does not include the extremes of any water quality parameter (Bringolf 2011, pers. comm.). Critical habitat must be supportive of the species, and it is reasonable to assume that extremes of any parameter could be detrimental to this species. Critical habitat PCEs should incorporate the most stable habitats.

Cadmium PCE

Mussel toxicity to cadmium (Cd) is reported to occur at concentrations as low as 16 µg/L in 96-h tests with juveniles (Wang *et al.* 2010, pp. 2056–2057). The Cd criteria for Georgia are 1 µg/L (CMC) and 0.15 µg/L (CCC). However, the commenter suggests that the Cd concentrations required to cause toxicity are 2000 to 13,000 times greater than GA water quality criteria (1 ug/L). The Cd concentration that caused acute toxicity with juvenile mussels is only 16 times higher than the Georgia Cd criteria. Therefore, it is not prudent to assume that Cd is not a significant contributor to decline in spinymussel populations. Early life stages are

generally more sensitive than adults; therefore, PCEs were established based on a survey of all published mussel early-life-stage toxicity data since 1992.

Comment (14): Climate change models do not provide information that is appropriate for making management decisions regarding the Altamaha spinymussel.

Our response: The Service agrees that it would not be appropriate to use climate change models to make management decisions regarding the Altamaha spinymussel. However, the Service acknowledges that climate change could alter the severity of storms and droughts, which could affect spinymussels in the future (See Factor E. Other Natural and Man Manmade Factors Affecting Its Continued Existence, also see the discussion under Critical Habitat, Background).

Comment (15): The Service should consider that factors unrelated to habitat, such as invasive species, may be the most important limiting factor for the Altamaha spinymussel.

Our response: While invasive species may be affecting the Altamaha spinymussel (either directly or indirectly), there is little, if any, information to support that invasive species are the most important limiting factor affecting the Altamaha spinymussel or other mussels native to the Altamaha or Atlantic Slope of Georgia. The flathead catfish (*Pylodictis olivaris*) was likely introduced into the Altamaha River during the 1970s or 1980s, and populations began to greatly increase during the 1990s. Flathead catfish may predate the host fish for the Altamaha spinymussel and other native unionids (see discussion under Factor E. Other Natural or Manmade Factors Affecting Its Continued Existence). However, despite the introduction of this piscivorous (fish eating) fish, most fish and mollusk species known from the Altamaha Basin as well as the remainder of the Atlantic Slope of Georgia, where the flathead catfish has been introduced, appear to be extant and relatively abundant. Similar trends occur in the nearby Flint River Basin where the flathead catfish has been introduced. Despite the introduction of this species and the highly altered nature of the Flint River, mussel species composition is similar to those experienced prior to the introduction of the flathead catfish (Wisniewski 2011, pers. comm.).

The competition between the Asian clam (*Corbicula fluminea*) and native unionids has been examined, but results have been contradictory. Yeager *et al.* (2000, pp. 256–258) suggested that high densities of Asian clam may negatively influence unionid recruitment. However, Vaughn and Spooner (unpublished data, p. 5) indicated that Asian clam densities were generally lower when populations of native unionids were dense, but increased with declining populations of native unionids. Gardner *et al.* (1976, pp. 122–124) hypothesized that the decline in bivalve populations in the Altamaha River co-occurred with the invasion of *Corbicula;* they also admit that ''a combination of factors probably was responsible for the success of *Corbicula* and the decline of other bivalves in the Altamaha River.'' It is likely that the apparent declines in the densities of Altamaha spinymussels are a result of a variety of factors, some of which may be attributed to invasive species. The extent to which they are adversely affected by flathead catfish and Asian clam is currently unknown.

Comment (16): The Service should recognize that suspended solids from biological wastewater treatment plants are often comprised largely of organic matter and that such solids would not be expected to contribute to sedimentation.

Our response: The Service concurs with this comment; we have no information that suspended solids are a threat to the spinymussel at this time.

Comment (17): Sediment issues in the southeastern United States are complicated by a legacy of poor agricultural practices during the 1800s and early 1900s, which raises questions about sources of sediment problems and the relative magnitudes of different sediment sources today. Silvicultural activities generally have only a small, short-lived impact on water quality, especially when compared with other land uses.

Our response: We agree that the primary source of sedimentation is legacy sediment and that silvicutural activities have a small and short-lived impact on water quality (see Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range). Legacy sediment migrating through the floodplains of the Altamaha Basin is likely one of the most severe threats to the spinymussel. As an example, in Murder Creek, a tributary of the Oconee River, over 1.6 m (5.3 ft) of legacy sediment was observed (Jackson *et al.* 2005, p. 1). Much of the eroded sediment was believed to remain in valley storage or in transport as bedload in Georgia's Piedmont streams (Jackson *et al.* 2005, p. 3). Based upon estimates of inputs from various sources and exports via total suspended solids and bedload, sediment exports were greater than sediment inputs. It is assumed that the remainder of the sediment came from excavation and mobilization of stored valley sediments, principally through lateral migration of stream channels and bank erosion (Jackson *et al.* 2005, pg 10). Legacy sediment is an ongoing threat as it moves downstream covering suitable habitat.

Comment (18): The Service should consider that implementation rates for forestry best management practices are high nationally and in Georgia, including the Altamaha River Basin.

Our response: We agree that the rates of implementation for forestry BMPs are high and consider sediment from silvicultural activities to be a small and short-lived impact.

Comment (19): When properly implemented, forestry BMPs protect water quality and habitat for the Altamaha spinymussel. BMPs are critical in mitigating water quality degradation from silviculture, and when appropriately implemented and maintained, are very effective in controlling nonpoint sources of pollution. Because of the overwhelming body of research related to BMPs and their effectiveness for protecting water quality and aquatic habitat, it is not surprising that the Service has recognized in previous regulatory proposals that BMPs are an important component of conservation strategies for freshwater mussels.

Our Response: The Service agrees that BMPs are protective of water quality and mussel habitat, and that industrial forestry activities generally do a good job of implementing BMPs. However, some harvesting operations fail to use BMPs adequately, and localized impacts can and do occur.

Comment (20): The Georgia Forestry Commission's BMP education and monitoring programs are effective at encouraging implementation of forestry BMPs and provide ''reasonable assurance'' that forestry BMPs are implemented effectively in Georgia.

Our response: We generally agree with this comment, particularly on industrial forests. However, there are individual exceptions, with compliance reported by the Georgia Forestry Commission at around 95 percent.

Comment (21): Sustainable forestry certification programs require participants to meet or exceed forestry BMPs and help ensure high rates of BMP implementation.

Our response: The Service agrees that the sustainable forestry program is one of the most effective programs to ensure BMPs are properly implemented.

Comment (22): Preliminary sampling of direct tributaries in forested watersheds within the Altamaha River

Basin suggests that mussel communities are diverse and abundant. The role of lakes in supporting the mussel community within the basin is not known, but could be significant and should be explored further.

Our response: We believe that floodplain lakes within the Altamaha Basin are of little importance to the Altamaha spinymussel as they do not have habitat to sustain the species. Dinkins (2007, p. 4) provides support for this by stating, ''species typically found in the river where the substrate has a dominant sand matrix and/or slight to moderate current during normal flow conditions (*e.g., Elliptio spinosa, Lampsilis dolabraeformis*) were not present in Cogden Lake.'' Cogden Lake is a floodplain lake in the Basin. The Altamaha spinymussel is typically found in association with protected areas around sand bars, in medium to coarse hard-packed sand, with rather swift current near gently sloping, soft banks with its distribution greatly restricted to these habitats (Meador 2009 p. 52, Sickel 1980, pp. 10–11; Wisniewski 2008, p. 2). In general, floodplain lakes within the Altamaha River Basin exhibit habitats that are not conducive to the survival of the Altamaha spinymussel as these habitats typically have little or no flow and silty or muddy substrates.

In conclusion, there is not sufficient evidence to support the existence of potential populations of the Altamaha spinymussel in these floodplain lakes or tributaries.

Comment (23): The summary paragraph within Factor A, *The present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range,* is over-reaching and contains speculative language. Inferences that enforcement of laws and regulations may be subverted to economic interests and citing pending investigations by nongovernmental environmental groups (such as Riverkeepers) should not be relied on as the best scientific information available and are highly speculative regarding impacts to mussels and their habitat.

Our response: The Service considers the best scientific and commercial information available when making listing decisions, and Riverkeepers have provided extensive and detailed field notes concerning water quality violations. Few of these notes were considered sufficient enough to include in this rule; however, the Altamaha Riverkeeper has successfully brought three cases to court (*Altamaha Riverkeeper* v. *Amercord, Inc.,* No. CV 300–042 (S.D. Ga) (Order on Motion for Partial Summary Judgment, Mar. 15, 2001); *Altamaha Riverkeeper* v. *City of Lumber City,* CV–300–043 (S.D. Ga); *Altamaha Riverkeepers* v *City of Cochran,* 162 F. Supp. 2d 1368 (M.D. Ga. 2001)) regarding water quality standard violations (see Factor A discussion below for more detail). We consider these court findings to be relevant information related to enforcement of laws and regulations within the watershed.

Comment (24): Two comments supported additional critical habitat including the entire historic range of the spinymussel, as well as, associated dry lands and wetlands.

Our response: We believe the occupied and unoccupied areas we are designating as critical habitat adequately represent the geographical areas essential for the conservation of the species. See our response to Comment 8.

Comment (25): Why was the area around Plant Hatch excluded from Critical Habitat designation?

Our response: We did not include the section of the Altamaha River between US Route 1 and the upper property boundary of Moody Forest Natural Area from proposed critical habitat because it does not contain the physical or biological features essential to the conservation of the species. Dredging operations and thermal stress in the vicinity of Edwin I. Hatch Nuclear Plant have altered the habitat quality so that the PCEs are not present in this river reach. Habitat within this reach is generally unstable, consisting of coarse, mobile sand.

Summary of Factors Affecting the Species

Section 4 of the Act and its implementing regulations (50 CFR part 424) set forth the procedures for adding species to the Federal Lists of Endangered and Threatened Wildlife and Plants. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1) of the Act. The five listing factors are: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; and (E) other natural or manmade factors affecting its continued existence.

A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Bogan (1993, pp. 599–600 and 603–605) linked the decline and extinction of bivalves to a wide variety of threats including siltation, industrial pollution, municipal effluents, modification of stream channels, impoundments, pesticides, heavy metals, invasive species, and the loss of host fish. The Altamaha spinymussel lives within a large river drainage exposed to a variety of landscape uses. Habitat and water quality for the Altamaha spinymussel face degradation from a number of sources. Primary among these are threats from sedimentation and contaminants within the streams that the spinymussel inhabits.

Sickel (1980, p. 12) characterized the habitat of the Altamaha spinymussel as coarse-to-fine-grain sandbars, and suggested that this may make the Altamaha spinymussel susceptible to adverse effects from sediment (siltation). Sediments deposited on the stable sandbars required by the Altamaha spinymussel could make sandbars unstable, result in suffocation, or simply change the texture of the substrate, making them unsuitable for the species. Sedimentation, including siltation from surface runoff, has been implicated as a factor in water quality impairment in the United States and has contributed to the decline of mussel populations in streams throughout the country (Ellis 1936, pp. 39–41; Coon *et al.* 1977, p. 284; Marking and Bills 1979, pp. 209–210; Wilber 1983, pp. 25–57; Dennis 1984, pp. 207–212; Aldridge *et al.* 1987, pp. 25–26; Schuster *et al.* 1989, p. 84; Wolcott and Neves 1991, pp. 1–6; Houp 1993, p. 96; Bogan 1993, pp. 603–605; Waters 1995, pp. 53–77; Richter *et al.* 1997, p. 1084).

Specific impacts on mussels from sediments include reduced feeding and respiratory efficiency, disrupted metabolic processes, reduced growth rates, increased substrata instability, and the physical smothering of mussels (Ellis 1936, pp. 39–41; Stansbery 1970, p. 10; Markings and Bills 1979, pp. 209–210; Kat 1982, p. 124; Aldridge *et al.* 1987, pp. 25–26; Hartfield and Hartfield 1996, p. 375; Brim Box and Mossa 1999, pp. 99–102; TNC 2004, p. 4; Cope 2008, pp. 452–459). Many southeastern streams have increased turbidity levels due to siltation (van der Schalie 1938, p. 56). Since turbidity is a limiting factor that impedes the ability of sight-feeding fishes to forage (Burkhead and Jenkins 1991, pp. 324–325), turbidity within the Altamaha River Basin during the times that Altamaha spinymussels

attempt to reproduce may reduce the ability of the host fish to find glochidia, and may contribute to the decline of the spinymussel by reducing its efficiency at infecting the fish hosts necessary for reproduction. In addition, sediment can eliminate or reduce the recruitment of juvenile mussels (Brim Box and Mossa 1999, pp. 101–102), interfere with feeding activity (Dennis 1984, pp. 207–212), and act as a vector in delivering contaminants to streams (Salomons *et al.* 1987, p. 28).

From 1700 to 1970, agricultural practices in the Southern Piedmont physiographic province resulted in extreme soil erosion, removing more than 17.8 cm (7 in.) of soil across the landscape (Trimble 1974, p. 1). The Ocmulgee, Oconee, and Ohoopee rivers all drain through the Piedmont and were directly affected by this erosion and resulting sedimentation. In 1938, van der Schalie (p. 56) reported the Altamaha River as being yellow in color, due to the large amount of suspended silt originating from intensive farming and road construction occurring in the headwaters. The sediment from these practices moved into stream channels and valleys, covering most of the original bottomlands (Trimble 1974, p. 26) and is now referred to as legacy sediment (Jackson *et al.* 2005, pg. 3). As a result, stream profiles have been dramatically altered with unstable sediment deposits being dissected and streams being incised with entrained sediment migrating downstream to be deposited in stream channels and floodplains (Trimble 1974, pp. 116–121; Jackson *et al.* 2005, pg 1). The GDNR, Environmental Protection Division (EPD 2007, p. iii) reported to EPA that approximately 75 percent of the average sediment load in the Altamaha River Basin resulted from row crops and that it contributed an average sediment load of 1 ton per acre per year. The EPD concluded that this sediment is probably a legacy of past land use. The mobilization of legacy sediments, principally through lateral migration of stream channels and bank erosion is an ongoing threat as it moves downstream covering suitable habitat (Jackson *et al.* 2005, p. 10). Large -scale sediment movement and deposition may result in increased embeddedness, which would generally decrease habitat quality (Bringolf 2011, pers. comm.). The degree to which rocks (gravel, cobble, and boulders) and snags are covered or sunken into the silt, sand, or mud of the stream bottom is a measure of embeddedness, and is a parameter evaluated in the riffles and runs of streams (also see Our Response to Comment 17). Although it is the historical, anthropogenic land use that created the legacy sediment, the volume of legacy sediment still migrating through the Altamaha River Basin is a significant threat to the spinymussel.

Studies of the fish populations in the Altamaha River Basin were conducted in 2000 by the GDNR Wildlife Resources Division (WRD). The Index of Biotic Integrity (IBI) and modified Index of Well-Being (IWB) rate fish populations as being in Excellent, Good, Fair, Poor, or in Very Poor condition, and were applied by the WRD to identify impaired fish populations in the Altamaha River. Stream segments with fish populations rated as Poor or Very Poor were listed as Biota Impacted. A lack of fish habitat due to stream sedimentation was generally the cause of a low IBI score.

Five Mile Creek (14.5 km/9 mi), Bullard Creek (12.8 km/8 mi), and Jacks Creek (14.5 km/9 mi) were rated as ''Very Poor'' and placed on the State of Georgia's 303(d) list of impaired waters due to a significant impact on fish (EPD 2007a, pp. 1–2). These three streams eventually feed into the mainstem of the Altamaha River via larger channels. As sediment moves through the basin, habitat is periodically buried. WRD recommends that there be no net increase in sediment delivered to the impaired stream segments so that these streams will recover over time (EPD 2007a, p. 26). Agriculture and roads were identified as the major sources of sediment with silviculture, mining sites, grazing, and urban development also contributing nonpoint sources of sediment (EPD 2007a, p. 9). Agriculture, including row crops, poultry farms, and pastures, constitute 15.5 percent of the land cover in the Piedmont and 32.7 percent of the land cover in the Coastal Plain (GDNR 2005, pp. 97, 132).

In addition to agriculture, there are numerous sources of sediment within the Altamaha River Basin, including silviculture, unpaved roads, kaolin mines, and construction sites. A threat assessment conducted by TNC (2004, p. 9) listed sediment from urban, industrial, and nonpoint sources (NPSs) as a threat to the spinymussel. The EPD (2007, p. v) reported that, while historical row crop-based land use contributes the majority of sediment in the Altamaha River (75 percent), that among other sources, approximately 17.3 percent of the total sediment load is from roads; 4.3 percent from grasses and wetlands; 1.5 percent from urban lands; and 1.0 percent from quarries, strip mines, and gravel pits. In addition, estimates of the contribution from construction could not be obtained, but could represent a comparatively high sediment load on a per -acre basis (EPD 2007, p. v).

Industrial forest management is practiced on approximately 8,000 hectares (40,000 acres) or 33 percent of the floodplain of the Altamaha River (TNC 1997, p. 19). Typical forest management regimes in the Altamaha River Basin use timber harvest methods and conduct other activities that result in ground disturbances. These ground disturbances can result in transport of sediment to streams during and after precipitation events. In addition, forest management operations often require miles of unpaved roads to extract timber and to provide access for management activities. The majority of sediment from forestry occurs from roads and site preparation activities (EPD 2007a, p. 11). These roads, in conjunction with existing unpaved county roads that are prevalent throughout the Altamaha River Basin, contribute to sediment loading in streams after precipitation events. Through an agreement with the EPD, the Georgia Forestry Commission (GFC) is responsible for implementing the use of Best Management Practices (BMPs) to reduce erosion and sediment from activities related to forestry, such as timber harvest, haul road construction, stream crossings, stream side management zones, site preparation, and reforestation. However, the Erosion and Sediment Control Act (O.C.G.A. 12–7–1) exempts commercial forestry activities from the need to acquire permits and meet the minimum requirements of that act (Georgia's BMPs for Forestry 2009, p. 64). Therefore, compliance with BMPs is voluntary and is dependent on education about BMPs to reduce sediment from reaching the Altamaha River (EPD 2007a, p. 28) (also see our Response to Comments 18, 19, 20 and 21), but appears to be high.

A number of kaolin mines are located along the Fall Line, a geologic land form that separates the Piedmont and Coastal Plain physiographic provinces, within the Oconee and Ocmulgee River Basins. The operation of these mines and their supporting infrastructure, including haul roads and settling ponds, have the potential to increase downstream sediment loads if adequate erosion control measures are not maintained to stabilize areas subjected to mining-associated ground disturbances (Lasier 2004, p. 139).

In addition, sediment can act as a vector in delivering contaminants (such as heavy metals, ammonia, chlorine, numerous organic compounds) to streams (Salomons *et al.* 1987, p. 28; TNC 2004, p. 9). Because spinymussels are filter-feeders and bury themselves in

the substrate, they are exposed to metals dissolved in water, contained within suspended particles, and deposited in bottom substrates (Naimo 1995, p. 341). Cope *et al.* (2008, pp. 452–459) described potential routes of a variety of contaminants absorbed by mussels in various stages of their lifecycle. Contaminants contained in point and nonpoint discharges can degrade water and substrate quality and adversely impact, if not destroy, mussel populations (Horne and McIntosh 1979, pp. 127–132; McCann and Neves 1992, pp. 80–87; Havlik and Marking 1987, p. 14).

Contaminants associated with industrial and municipal effluents may cause decreased oxygen, increased acidity, and other water chemistry changes that may be lethal to mussels, particularly during the highly sensitive early life stages (Sheehan *et al.* 1989, pp. 139–140; Keller and Zam 1991, pp. 541–543; Bogan 1993, pp. 603–604; Goudreau *et al.* 1993, pp. 216–227; TNC 2004, pp. 8–9). Exposure to sublethal levels of toxic metals can alter growth, filtration efficiency, enzyme activity, and behavior (Naimo 1995, pp. 341, 354). In laboratory experiments, mussels suffered mortality when exposed to 16 ug/L, 96-h EC50 cadmium (Wang *et al.* 2010), 0.093 mg N/L, 10-d LC50 ammonia (Newton *et al.* 2003), 39 ug/L, 96-h LC50 chromium (Keller and Zam 1991), 16 ppm arsenic trioxide, 6.8 ug/L, 96-h EC50 copper (Wang *et al.* 2007), and 151 ug/L, 96-h EC50, hardness ~45 mg/L zinc (Wang *et al.* 2010); however, effects depend upon the length of exposure and mussel life stage (Havlik and Marking 1987, p. 1). The adults of certain species may tolerate short-term exposure (Keller 1993, p. 701), but low levels of some metals may inhibit glochidial attachment in others (Huebner and Pynnönen 1992, p. 2353; Jacobson *et al.* 1993, pp. 881–882) likely due to toxicity to glochidia. Mussel recruitment may be reduced in habitats with low but chronic heavy metal and other toxicant inputs (Yeager *et al.* 1994, p. 217; Naimo 1995, pp. 347 and 351–352; Ahlstedt and Tuberville 1997, p. 75). Researchers found that several heavy metals were found to have toxic effects at different levels and duration of exposure; however, no toxicity studies have been conducted specifically on the Altamaha spinymussel (Havlik and Marking 1987, p. 3; Naimo 1995, p. 341; Keller and Lydy 1997, p. 4). Furthermore, differences between controlled laboratory experiments and field conditions (with multiple and unknown variables) make it difficult to predict how contaminants affect wild populations (Wisniewski 2008, pers. comm.).

From 2000 to 2008, many stream segments in the Altamaha Basin have been listed on the State's 303(d) list of impaired waters for a variety of reasons. Once a stream segment is listed as impaired, the State must complete a plan to address the issue causing the impairment; this plan is called a Total Maximum Daily Load (TMDL). Completion of the plan is generally all that is required to remove the stream segment from the 303(d) list and does not mean that water quality has changed. Once the TMDL is completed, the stream segment may be placed on the 305(b) list of impaired streams with a completed TMDL. Many of these stream segments have appeared repeatedly on the 303(d) list. The Ohoopee River and Little Ohoopee River have been listed on nearly every report for almost every violation. Other stream segments that have repeatedly been identified on the 303(d) list from 2000 until 2008 include Big Cedar Creek, Doctors Creek, Jacks Creek, Milligan Creek, Oconee Creek, Pendleton Creek, Rocky Creek, Sardis Creek, Swift Creek, Tiger Creek, and Yam Gandy Creek. This demonstrates a chronic threat, from multiple sources of pollution, scattered across the basin.

In 2000, the Altamaha River was listed on the 303(d) list of impaired waters due to excessive mercury levels in fish tissue. In 2002, EPA Region 4 established a TMDL for mercury levels for the Altamaha River from its confluence of the Oconee and Ocmulgee Rivers to Penholloway Creek (149.5 km/92.9 mi) including Appling, Jeff Davis, Long, Tattnall, Tombs, and Wayne Counties. This river segment is entirely within the current or historic range of the spinymussel with four National Pollutant Discharge Elimination System (NPDES) permitted facilities, including:

- Rayonier Inc.-Jesup (67 million gallons per day (MGD));
- Edwin I. Hatch Nuclear Power Plant (Plant Hatch) (43.4 MGD);
- Jesup Water Pollution Control Plant (WPCP) (2.5 MGD); and
- Glennville WPCP (0.88 MGD) (EPA 2002a, pp. 1–5).

This 149.5-km (92.9-mi) segment of the Altamaha River, from the confluence of the Oconee and Ocmulgee Rivers to Penholloway Creek, was removed from the 303(d) list in 2002 because the TMDL was completed; it is currently listed as a stream supporting its designated use (fishing).

In 2000, EPD added 23 stream segments, totaling 411.9 km (256 mi), to the 303(d) list for not meeting dissolved oxygen standards (EPD 2002, p. 1). All of these segments are within tributaries to the Altamaha River within the range of the spinymussel. Between 2000 and 2001, there were nine NPDES permitted discharges with effluent limits for oxygen -consuming substances identified in the Altamaha River Basin watershed above the 23 stream segments listed (EPD 2002, p. 11). Nonpoint source runoff from natural sources contributed oxygen-demanding pollutants (EPD 2002, p. 12). Upon completion of a TMDL in 2002, these river segments were removed from the 303(d) list.

In 2006, EPD listed 18 stream segments totaling 280 km (174 mi) as impaired due to fecal coliform bacteria in excess of water quality standards (EPD 2007c, pp. 1–2). All of these stream segments are tributaries to the Altamaha River within the current or historic range of the species. Between 2005 and 2006, there were 10 municipal wastewater treatment plants that discharged more than 0.1 MGD, along with four confined animal feed operations that were considered sources of fecal coliform. Nonpoint sources include wildlife, livestock grazing, livestock access to streams, application of manure to pastureland and cropland, leaking sanitary sewer lines, leaking septic systems, land application systems (6 in the basin), and landfills (43 in the basin) (EPD 2007c, pp. 10–16). Even after the completion of the TMDL, six of these stream segments remain on the 303(d) list.

In 2008, EPD listed 583 km (362 mi.) of tributaries to the Altamaha River to the 305(b)/303(d) list of impaired waters, and all of these stream segments have completed TMDLs (EPD 2008 pp. A–130–A–134). The draft 2010 305(b)/303(d) list of impaired waters for the Altamaha River included all of the stream segments from the 2008 list and added an additional 48 km (30 mi). These are all tributaries to the Altamaha or Ohoopee Rivers within the current or historic range of the Altamaha spinymussel. These stream segments are listed as impaired for a variety of reasons (*e.g.,* dissolved oxygen, fecal coliform, and mercury levels within fish tissue). All of these river segments, such as the Ohoopee River (including the historic range of the spinymussel), have TMDLs but are still considered impaired.

More than 161 km (100 mi) of the Ohoopee River and its tributaries were added to the 303(d) list in 2000 due to excessive mercury levels in fish tissue. The primary source of mercury is believed to be deposition of atmospheric mercury. During 1998–1999, there were seven municipal wastewater treatment

facilities (EPA 2002b, pp. 1–3) and as many as 170 sources of air emissions in the watershed (EPA 2002b, p. 18). These sources of mercury impacted all of the extirpated range of the spinymussel on the Ohoopee River, which is a major tributary to the Altamaha River. A TMDL was established in 2002; however, based on additional information gathered since 2002, EPA will begin revising needed load reductions in 2011 (EPA 2002b, p. 2). These segments of the Ohoopee remain on the 303(d) list.

In 2006, EPD added five stream segments, totaling 64.3 km (40 mi), within the Ohoopee drainage to the 303(d) list for not meeting dissolved oxygen standards (EPD 2007b, p. 1). All of these segments are within the range of the spinymussel. During 2004–2005, there were eight NPDES permitted discharges with effluent limits for oxygen-consuming substances identified in the Altamaha River Basin watershed (EPD 2007b, p. 10). There were four animal feeding lots and six wastewater land application operations that were identified as sources of oxygen-demanding nutrients. Nonpoint source runoff from forestry, row crop agriculture, pastureland, urban development, and natural sources also contribute oxygen-demanding pollutants (EPD 2007b, pp. 13–15). Upon completion of a TMDL in 2007, these five river segments were removed from the 303(d) list.

In addition, there have been illegal effluent discharges into the Ohoopee that may have an adverse impact on the Altamaha spinymussel. For instance, the wastewater treatment discharge from Rogers State Prison enters the Ohoopee River approximately 10 km (6 mi) upstream of the largest historical population of Altamaha spinymussels known in the Ohoopee River. The Altamaha Riverkeeper reported fecal coliform discharges from the prison that exceeded the prison's NPDES permit (Holland 2002, pers. comm.).

The Altamaha Riverkeeper, a conservation group that works to maintain the quality of the Altamaha River system, has discovered a number of illegal discharges that could impact the Altamaha spinymussel. In 2001, a court found that Amercord Inc. had violated its NPDES permit multiple times at its Lumber City tire plant by discharging quantities of cyanide, copper, zinc, and lead into the Ocmulgee River in excess of permit limitations (*Altamaha Riverkeeper* v. *Amercord, Inc.,* No. CV 300–042 (S.D. Ga.) (Order on Motion for Partial Summary Judgment, Mar. 15, 2001)). In a second case, following allegations of discharges into the Ocmulgee River from Lumber City's waste treatment pond in excess of its NPDES permit, Lumber City agreed to implement several short- and long-term wastewater treatment improvements, which are expected to protect a population of Altamaha spinymussels (*Altamaha Riverkeeper* v. *City of Lumber City,* CV–300–043 (S.D. Ga.)). The Altamaha Riverkeeper also discovered that from July 1995 to April 2001, the City of Cochran's waste treatment pond had discharged in violation of its NPDES permit (*Altamaha Riverkeepers* v. *City of Cochran,* 162 F. Supp. 2d 1368, 1369–70 (M.D. Ga. 2001)). The City had been releasing ferric sulfate (used to treat fecal coliform) into Jordan Creek, a tributary of the Ocmulgee River approximately 80 km (50 mi) upstream of known populations of Altamaha spinymussels.

Sediment in the Oconee River carries toxic loads of heavy metals presumably discharged from municipal wastewater treatment plants and kaolin-mining settling ponds (Lasier 2004, pp. 139–140, 144–151). Wastewater treatment plants and kaolin mines often employ settling ponds to allow pollutants to settle and turbidity to decrease. Copper sulfate and aluminum sulfate are often used as algaecides, to reduce algae blooms, and as flocculants to force precipitation of turbid waters and, in water treatment processes, to improve the sedimentation or filterability of small particles.

Lasier (2004, pp. 150–151) reported ''abnormally'' high levels of chromium, copper, mercury, and zinc in the lower Oconee river that would indicate a ''significant'' impact to the quality of sediment and pore water (the water in contact with the river bottom, and the water in which mussels reside). TNC (2004, p. 9) found water quality and sediment quality reflected ''significant'' inputs of pollution with concentrations of heavy metals (including cadmium, copper, chromium, lead, and zinc) at levels above regional and national concentrations. Shoults-Wilson (2008, pp. 86–92) sampled sites throughout the Altamaha River Basin to evaluate the presence of heavy metals in the water column and in the sediment and compared the bioaccumulation of heavy metals by Asian clams to *E. hopetonensis* (an Altamaha River endemic). Sampling of sites upstream and downstream of potential point sources of heavy metals demonstrated ''significantly'' elevated bioaccumulation of cadmium, copper, and mercury below inputs from kaolin processing, as well as elevated zinc and chromium below Plant Hatch, the Rayonier pulp mill in Jesup, Georgia, and the Amercord tire facility. Mussels in the Altamaha River Basin may accumulate trace elements from the fine fraction of sediment as well as the water column.

The cumulative effects of effluent from wastewater treatment plants and kaolin mines on Altamaha spinymussel habitat have not been quantified; however, mussels appear to be among the most intolerant organisms to heavy metals (Keller and Zam 1991, p. 545), and several heavy metals are lethal, even at relatively low levels (Havlik and Marking 1987, p. 3). Most metals are persistent in the environment, remaining available for uptake, transportation, and transformation by organisms until they are removed from the river (Hoover 1978, pp. 28–38; Lasier 2004, p. 140) through processes such as washing out to sea, leaching through the soil, or being taken up by an organism that is then removed from the river.

In areas of heavy agricultural use in the Southeast, surface runoff can move pesticides, including malathion and other insecticides, into surface water (McPherson *et al.* 2003, pp. 1–2). Stream ecosystems are negatively impacted when nutrients are added at concentrations that cannot be assimilated (TNC 2004, p. 7). The effects of pesticides on mussels may be particularly profound, potentially altering metabolic activities or resulting in delayed mortality (Fuller 1974, pp. 252–253; Havlik and Marking 1987, pp. 9–11; Moulton *et al.* 1996, pp. 132–136); commonly used pesticides have been directly implicated in a North Carolina mussel die-off (Fleming *et al.* 1995, pp. 877–879). The Oconee, Ocmulgee, and Ohoopee River systems contain significant acreage in cotton and onion farming. Malathion, one of the most important pesticides used in cotton farming, inhibits physiological activities of mussels (Kabeer *et al.* 1979, pp. 71–72) and may decrease the ability of mussels to respire and obtain food. Malathion toxicity (24 h LC50) has been reported as low as 8 mg/L for glochidia of *Lampsilis siliquoidea* and other unionid species (Keller and Ruessler 1997, p. 1).

The operations of Plant Hatch, located on the Altamaha River in Appling County, may pose a threat to the Altamaha spinymussel. On September 14, 2001, the Service received Joint Public Notice 940003873 from the Corps, Savannah District, describing a project to expand and maintain Plant Hatch's intake basin within the Altamaha River. Implementation of this permit authorized annual dredging of

the plant intake basin and authorized removing 33,965 cubic meters (44,424 cubic yards) of material biannually from the intake basin. While the amount of material removed annually is generally far less than the amount permitted (Dodd 2008, pers. comm.), annual dredging could negatively impact the Altamaha spinymussel by decreasing channel stability (creating a potential head cut), altering sediment transport dynamics, increasing sedimentation and turbidity downstream during dredging operations, and decreasing habitat quality for host fishes. It is unknown how far downstream these impacts extend.

Impacts to aquatic fauna through entrainment of potential host fishes and thermal discharges may also occur. Plant Hatch takes in water to create steam, and then uses the steam to generate electricity. Following a cooling process, the water is returned to the river, and although it has been cooled, the water temperature is warmer than the ambient temperature of the river. Plant Hatch has made substantial efforts to reduce thermal discharges through the construction of cooling towers that have significantly reduced the thermal plume. However, thermal discharges could still negatively impact the Altamaha spinymussel from heat stress; higher water temperatures can increase the sensitivity of mussels to certain pollutants (Augspurger *et al.* 2003, p. 2574). Pandolfo *et al.* (2010, pp. 693–698) also reported that high water temperatures can increase the sensitivity of early life stages of mussels to copper). These effects would be exacerbated during years of low rainfall, when less water would be available to dissipate the heat of the Plant Hatch effluent. Plant Hatch also monitors fish entrainment, so if the host fish of the spinymussel was known, management efforts could be made to reduce the potential of this impact.

In summary, the loss and modification of habitat is a significant threat to the Altamaha spinymussel. Degradation from sedimentation and contaminants threatens the habitat and water quality necessary to support the Altamaha spinymussel. Sediment from unpaved roads, kaolin mines, past and current agriculture practices, silviculture, and construction sites within the Altamaha River Basin can suffocate Altamaha spinymussels and make stable sandbars required by Altamaha spinymussels unstable or change the texture of the substrate, rendering them unsuitable for the species. Contaminants associated with industrial and municipal effluents (*e.g.,* heavy metals, ammonia, chlorine, numerous organic compounds) may cause decreased oxygen, increased acidity, and other water chemistry changes that are lethal to mussels, particularly the highly sensitive early life stages of mussels; exposure to sublethal levels of toxic metals can alter growth, filtration efficiency, enzyme activity, and behavior. As a result we have determined that the present or threatened destruction, modification, or curtailment of the Altamaha spinymussel's habitat or range is a threat to the continued existence of the Altamaha spinymussel throughout its range.

B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

The Altamaha spinymussel is not a commercially valuable species, nor are the streams that it inhabits subject to commercial mussel harvesting activities. However, this species has been actively sought for scientific and private collections (Keferl 2008, pers. comm.); such activity may increase if the species becomes rarer. Overcollection may have been a localized factor in the decline of this species, particularly in the Ohoopee River where a 1986 collection consisted of at least 30 live individuals (Keferl 2008, pers. comm.). Although the GDNR can regulate the number of mussels collected with a Scientific Collection Permit, the localized distribution and small size of known populations renders them extremely vulnerable to overzealous recreational or scientific collecting. However, we have no specific information indicating that overcollection is currently a threat or that overcollecting may occur in the future.

Therefore, we find that overutilization for commercial, recreational, scientific, or educational purposes is not a threat to the Altamaha spinymussel at this time.

C. Disease or Predation

Diseases of freshwater mussels are poorly known, and we have no specific information indicating that disease occurs within Altamaha spinymussel populations or poses a threat. Juvenile and adult mussels are preyed upon by some invertebrate species (particularly as newly metamorphosed juveniles), parasites (for example, nematodes, trematodes, and mites), a few vertebrate species (for example, otter, raccoon, and turtles) and some fish. However, we have no evidence of any specific declines in the Altamaha spinymussel due to predation.

In summary, diseases and predation of freshwater mussels remain largely unstudied and are not considered a threat to the Altamaha spinymussel.

D. The Inadequacy of Existing Regulatory Mechanisms

The Altamaha spinymussel is listed as a high-priority species by the State of Georgia (GDNR 2005, p. 135) and has recently been listed as Endangered under Georgia's Endangered Wildlife Act (EWA). Under the EWA, it is unlawful to intentionally harm, disturb, or sell a protected animal, unless authorized, or to cause the destruction of habitat of protected animals on State-owned lands. The EWA specifically states, however, that rules and regulations promulgated under the EWA shall not impede construction of any nature. Thus, protection under the EWA prevents unlawful capture or killing of the listed species, but does not prevent habitat changes that lead to population loss.

Sources of nonpoint-source pollution include timber operations (see Our Response to Comments 18, 19, 20 and 21), clearing of riparian vegetation, urbanization, road construction, and other practices that allow sediment to enter streams (TNC 2004, p. 13). Although BMPs for sediment and erosion control are often recommended or required by local ordinances for construction projects, compliance, monitoring, and enforcement of these recommendations are often poorly implemented. Furthermore, Georgia's Erosion and Sediment Control Act exempts commercial forestry activities from the need to acquire permits and meet the minimum requirements of the Erosion and Sediment Control Act (Georgia's BMPs for Forestry 2009, p. 64). While compliance rates are high in the state, compliance with BMPs is voluntary and is dependent on education on proper implementation of BMPs to reduce sediment from reaching the Altamaha River (EPD 2007a, p. 28). Although historical row crop-based land use contributes the majority of sediment to the Altamaha River, other sources continue to contribute to the total sediment load (See discussion under Factor A).

Point-source discharges within the range of the Altamaha spinymussel have been reduced since the inception of the Federal Clean Water Act (33 U.S.C. 1251 *et seq.*), but this may not provide adequate protection for filter-feeding organisms that can be impacted by extremely low levels of contaminants. Municipal wastewater plants continue to discharge large amounts of effluent and, in some circumstances, in excess of permitted levels (see discussion under Factor A). There is no specific

information on the sensitivity of the Altamaha spinymussel to common industrial and municipal pollutants, and very little information on other freshwater mollusks. Current State and Federal regulations regarding pollutants are assumed to be protective of freshwater mollusks; however, this species may be more susceptible to some pollutants than test organisms commonly used in bioassays. For example, several recent studies have suggested that EPA's criteria for ammonia may not be protective of freshwater mussels (Augspurger *et al.* 2003, p. 2571; Newton *et al.* 2003, pp. 2559–2560; Mummert *et al.* 2003, pp. 2548–2552). New ammonia criteria have been proposed by EPA (2009) that would be more protective of unionids. Wang *et al.* (2007a, p. 2036, 2007b, p. 2048, 2010, p. 2053) have also reported toxicity data for unionid early life stages for chlorine, metals and ammonia. In a review of the effects of eutrophication on mussels, Patzner and Muller (2004, p. 329) noted that stenoecious (narrowly tolerant) species disappear as waters become more eutrophic. They also refer to studies that associate increased levels of nitrate with the decline and absence of juvenile mussels (Patzner and Muller 2004, pp. 330–333). Other studies have also suggested that early life stages of mussels are sensitive to inorganic chemicals such as chlorine, metals, and ammonia (Keller and Zam 1991, pp. 543–545; Goudreau *et al.* 1993, p. 221; Naimo 1995, pp. 354–355). Therefore, it appears that a lack of adequate research and data prevents existing regulations, such as the Clean Water Act (administered by EPA and the Corps), from being fully utilized or effective.

In summary, some regulations exist that protect the species and its habitat; however, these regulations enforced by the State provide little direct protection of Altamaha spinymussel and only if protection of the spinymussel will not inhibit economic development. Nonpoint-source pollution is not regulated, and the Clean Water Act does not adequately protect the habitat from degradation caused by point-source pollutants. As described under Factor A, there have been a number of recent illegal effluent discharges into the Altamaha River Basin, in excess of permit limits, that may have impacted the Altamaha spinymussel, and other investigations are pending (*Altamaha Riverkeeper* v. *Amercord, Inc.,* No. CV 300–042 (S.D. Ga) (Order on Motion for Partial Summary Judgment, Mar. 15, 2001); *Altamaha Riverkeeper* v. *City of Lumber City,* CV–300–043 (S.D. Ga); (*Altamaha Riverkeepers* v *City of Cochran,* No. CV–447–2)). Thus, existing regulations are not effective at protecting the spinymussel and its habitat from sedimentation and lethal contaminants. Therefore, we find the existing regulatory mechanisms are inadequate to ameliorate the current threats to the Altamaha spinymussel throughout its range.

E. Other Natural or Manmade Factors Affecting Its Continued Existence

Withdrawal of surface water within the Altamaha Basin for thermoelectric power generation, public water supplies, commercial industrial uses, and agriculture has a dramatic effect on flow rates (TNC 2004, p. 8). No major dams are located on the Altamaha River system within the known historical range of the Altamaha spinymussel, and the nearest reservoir is approximately 165 km (102.5 mi) from occupied habitat. However, the dams that form Sinclair Reservoir on the Oconee River and Jackson and Tobesofkee Reservoirs in the Ocmulgee River Basin can influence downstream mussels and their populations through changes in flows that result from electrical power generation and water storage (TNC 2004, p. 6) (see Our Response to Comment 7). Within the Altamaha River Basin, 1,149 MGD was withdrawn for thermoelectric power generation in 1990 (Marella and Fanning 1990, pp. 14–17); water withdrawals of this magnitude can cause drastic flow reductions and alterations that may strand mussels on sandbars, resulting in mortality of individuals and harm to populations. Laurens County, Georgia, which includes the City of Dublin, withdrew 2.64 MGD for public water supplies, 12.79 MGD for commercial industrial use, and 5.57 MGD for agricultural uses in 1990 (Marella and Fanning 1990, p. 16). In 1990, the total amount of surface water withdrawn from the Altamaha River Basin was approximately 1,315 MGD (Marella and Fanning 1990, p. 61). This information regarding water withdrawals dates back to 1990, which is the most recent comprehensive effort to study water withdrawals from this watershed. As development pressures continue to grow, water withdrawals are expected to increase.

Drought conditions were prevalent in Georgia between 1998 and 2002, and again in 2007 and 2008, which may have negatively affected the Altamaha spinymussel. Georgia averages 127 cm (50 in) of precipitation annually (U.S. Geological Survey 1986, p. 195; GDNR 2005, p. 41) but received less than 102 cm (40 in) of precipitation annually during recent droughts in 2000, 2002, and 2007 (Knaak and Joiner 2007, pp. 1–2). The Ohoopee River and many other streams in the basin suffered reduced flow rates, and the Ohoopee River was reported to have low water levels with an estimated average depth of 15 cm (6 in) in the main channel during summer surveys (Stringfellow and Gagnon 2001, p. 3) when normal channel depth is several feet or more. Normally, mussels will bury themselves in the river bottom as a mechanism to survive a drought, but many mussels may have died from desiccation during this prolonged drought (Keferl 2008, pers. comm.). Although the effects of the drought on the Altamaha spinymussel have not been quantified, mussel declines as a direct result of drought have been documented (Golladay *et al.* 2004, p. 494; Haag and Warren 2003, p. 1165). Furthermore, there is a growing concern that climate change may lead to increased frequency of severe storms and droughts (Golladay *et al.* 2004, p. 504; McLaughlin *et al.* 2002, p. 6074; Cook *et al.* 2004, p. 1015) (see Comment 14). Reduction in local water supplies due to drought is also compounded by increased human demand and competition for surface and ground water resources for power production, irrigation, and consumption (Golladay *et al.* 2004, p. 504).

In addition, low flow conditions provide access to the river margins and channels for all-terrain vehicles (ATV) and four-wheel drive vehicles (TNC 2004, p. 12; Stringfellow and Gagnon 2001, p. 3). During a survey in 2001, Stringfellow and Gagnon (2001, p. 3) observed heavy ATV and four-wheel drive vehicle traffic and high levels of erosion near bridges and homes. They encountered several groups of ATV users, 2 to 12 persons per group, riding in the river channel. Because water levels were so low, ATV use of the stream extended to all portions of the channel, including pools, runs, and dried sandbars. Observations on the Ohoopee River during low flow in October of 2006 revealed extensive ATV traffic that destroyed mussel beds (Rickard 2006, personal observation). These vehicles may directly crush mussels and may also destabilize stream banks and increase sedimentation rates, burying mussels or impairing feeding, respiration, metabolism, and reproductive success (Stringfellow and Gagnon 2001, p. 3).

Nonindigenous species such as the flathead catfish and the Asian clam have been introduced to the Altamaha Basin and may be adversely affecting the Altamaha spinymussel. Flathead catfish are fast-growing fish that are dominant predators in river systems and are usually exclusively piscivorous in their

adult stage (Bourret *et al.* 2008, p. 413; Sakaris *et al.* 2006, p. 867). Since its introduction outside its native range, the flathead catfish has altered the composition of native fish populations through predation (Bourett *et al.* 2008, p. 413; Sakaris *et al.* 2006, p. 867; Sea Grant, 2006, p. 2; Pine *et al.* 2005, p. 902). Flatheads were introduced to the Altamaha Basin in the 1970s (USGS 2009, unpaginated).

Although the host fish or fishes of the Altamaha spinymussel have not been identified, in other native freshwater mussels, various centrarchids (sunfish), ictalurids (catfish), and catostomids (suckers) have been identified as hosts of the larvae. Other species of mussels in the genus *Elliptio* are known to parasitize various species of *Etheostoma* and *Percina* (darters), and other stream-adapted fish species (Haag and Warren 2003, p. 80). Flatheads introduced in the Altamaha River eliminated bullhead catfish (*Ameiurus sp.*) and caused an 80 percent decline in redbreast sunfish (*Lepomis auritus*) (Sea Grant 2006, p. 2); centrarchids and ictalurids were dominant prey items (Sakaris 2006, p. 867). Other potential centrachid host fish such as the largemouth bass (*Micropterus salmoides*) and bluegill (*L. macrochirus*) have all suffered population declines (Harrison 2001, pers. comm.), as well as the robust redhorse (*Moxostoma robustum*), shortnose sturgeon (*Acipenser brevirostrum*), and shad (*Alosa sapidissima*) (TNC 2004, p. 5). Some of these declines may be attributable, at least in part, to flathead catfish (TNC 2004, p.5). If one or more of these species is the host fish for the Altamaha spinymussel, the spinymussel's breeding success and recruitment could be reduced by the presence of flathead catfish (Keferl 2001, pers. comm).

Asian clams were observed in the Altamaha River in 1971, and are believed to have been introduced in the Ocmulgee River in 1968 or 1969 (Gardner 1976, p. 117). Surveys have found large numbers of Asian clams in the Altamaha Basin for more than 25 years (Gardner *et al.* 1976, pp. 118–124; Stringfellow and Gagnon 2001, p. 2; O'Brien, pers. comm., 2001). The invasion of Asian clams in the Altamaha River has been accompanied by drastic declines in populations of native mussels, although it is unknown if the clams competitively excluded the mussels or simply colonized their habitat when they declined due to other factors (Gardner 1976, p. 124). Asian clams may pose a direct threat to native species through competition for available resources (space, minerals, or food), resulting in decline or local extirpation (Williams *et al.* 1993, p. 7; Bogan 1993, p. 605).

The linear nature of the Altamaha spinymussel's habitat, reduced range, and very small population size make this species vulnerable to random detrimental or catastrophic events. Small, isolated populations may experience decreased demographic viability (population birth and death rates, immigration and emigration rates, and sex ratios), increased susceptibility of extinction from stochastic environmental factors (*e.g.,* weather events, disease), and an increased threat of extinction from genetic isolation and subsequent inbreeding depression and genetic drift. Surviving populations of spinymussels are small (see summary of Basin-wide Population Estimates), extremely localized, and vulnerable to habitat modification, toxic spills, progressive degradation from contaminants (see discussions under Factors A and D), and natural catastrophic changes to their habitats (for example, flood scour and drought). Low numbers of individuals may also increase inbreeding and reduce genetic diversity (Lynch 1996, pp. 493–494) (see Our Response to Comment 9).

In summary, a variety of natural and manmade factors currently threatens the Altamaha spinymussel. Withdrawal of surface water within the Altamaha Basin for thermoelectric power generation, public water supplies, commercial industrial uses, and agriculture can cause drastic flow reductions and alterations that may strand mussels on sandbars, resulting in mortality of individuals and harm to populations. Recurring drought and water withdrawal, combined with impacts of off-road vehicles, has reduced flows and destabilized stream banks required to support this mussel. Nonindigenous species, such as flathead catfish and the Asian clam, have potentially adversely impacted populations of the spinymussel's host fish, thereby affecting recruitment, and may directly impact the spinymussel through competition for resources. Lastly, because the Altamaha spinymussel populations are so small and isolated, any factor (*i.e.,* habitat change or natural and manmade factors) that results in a decline in habitat or individuals may be problematic for the long-term recovery of this species. Therefore, we have determined that other natural and manmade factors are threats to the continued existence of the Altamaha spinymussel throughout its range.

Determination

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the Altamaha spinymussel. Section 3 of the Act defines an ''endangered species'' as ''any species which is in danger of extinction throughout all or a significant portion of its range'' and a ''threatened species'' as ''any species which is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' As described in detail above, the species is currently at risk throughout all of its range due to ongoing threats of habitat destruction and modification (Factor A), inadequacy of existing regulatory mechanisms (Factor D), and other natural or manmade factors affecting its continued existence (Factor E). This species' extremely small and isolated populations make it particularly susceptible to extinction at any time due to threats described under Factors A, D, and E.

The Altamaha spinymussel has been observed at only 22 sites since 2000, despite extensive survey efforts made by several different researchers. Most of these sites are clustered geographically within short reaches of the lower Ocmulgee River and the Altamaha River upstream of U.S. Route 301, and there are long reaches with no or undetectable numbers of Altamaha spinymussels separating these groups of sites. Meador (2009, p. 51) attempted to estimate abundance of Altamaha spinymussel in the mainstem Altamaha, but was unable to capture, tag, and recapture sufficient individuals for an assessment. Recent surveys of the Ohoopee River and the analysis presented by Wisniewski *et al.* (2005) suggest that the species may still be declining. Finally, the comparatively low numbers of Altamaha spinymussels collected during recent surveys of the Altamaha and Ocmulgee Rivers further suggests that this species has declined substantially from historical levels. To summarize, researchers were able to find 60 Altamaha spinymussels at a single site on the Altamaha River in 1967; in contrast, the largest number of Altamaha spinymussels observed from a single site on the Altamaha River during the 1990s or 2000s was nine (Albanese 2005, pers. comm.).

The remaining small spinymussel populations are threatened by a variety of factors that are expected to persist indefinitely and impact, or have the potential to impact, remaining spinymussel habitat. These factors include siltation, industrial pollution, municipal effluents, modification of

stream channels, pesticides, heavy metals, invasive species, loss of host fish, water withdrawal, recurring drought, and loss of genetic viability. In addition, as described under Factor D, existing regulatory mechanisms are inadequate to ameliorate the current threats to the Altamaha spinymussel and its habitat. We believe the remaining small, isolated populations of spinymussels are not large enough to be resilient against any of the above factors acting on the species itself or its habitat. Furthermore, we believe these threats, particularly the threats to populations resulting from habitat degradation, small population size, and drought, are current and are projected to continue into the future. If the present trends that negatively affect the species and its limited and restricted habitat continue, the Altamaha spinymussel is in immediate danger of extinction throughout all of its range; therefore, proposing threatened status is not appropriate.

We find that the Altamaha spinymussel is presently in danger of extinction throughout its entire range, based on the immediacy and magnitude of the threats described above. Based on our analysis, we have no reason to believe that the negative population trends for the Altamaha spinymussel will improve, nor will the effects of current threats acting on the species be ameliorated in the foreseeable future. Therefore, we are listing the Altamaha spinymussel as an endangered species throughout all of its range.

Furthermore, because we find that the Altamaha spinymussel is endangered throughout all of its range, there is no reason to consider its status in a significant portion of its range. Consequently, we are listing the Altamaha spinymussel as an endangered species under the Act.

Critical Habitat

Background

Critical habitat is defined in section 3 of the Act as:

(i) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features

(I) Essential to the conservation of the species and

(II) Which may require special management considerations or protection; and

(ii) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided under the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the prohibition against Federal agencies carrying out, funding, or authorizing the destruction or adverse modification of critical habitat. Section 7(a)(2) requires consultation on Federal actions that may affect critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation does not allow the government or public to access private lands. Such designation does not require implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Where a landowner seeks or requests Federal agency funding or authorization for an action that may affect a listed species or critical habitat, the consultation requirements of section 7(a)(2) of the Act would apply, but even in the event of a destruction or adverse modification finding, the Federal action agency's and the applicant's obligation is not to restore or recover the species, but to implement reasonable and prudent alternatives to avoid destruction or adverse modification of critical habitat.

For inclusion in a critical habitat designation, the habitat within the geographical area occupied by the species at the time it was listed must contain the physical or biological features essential to the conservation of the species, and be included only if those features may require special management considerations or protection. Critical habitat designations identify, to the extent known using the best scientific and commercial data available, habitat areas that provide essential life-cycle needs of the species (areas on which are found the physical or biological features essential for the conservation of the species). Under the Act and regulations at 50 CFR 424.12, we can designate critical habitat in areas outside the geographical area occupied by the species at the time it is listed only when we determine that those areas are essential for the conservation of the species and that designation limited to those areas occupied at the time of listing would be inadequate to ensure the conservation of the species.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific and commercial data available. Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658)), and our associated Information Quality Guidelines, provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

When we are determining which areas we should designate as critical habitat, our primary source of information is generally the information developed during the listing process for the species. Additional information sources may include articles in peer-reviewed journals, conservation plans developed by States and counties, scientific status surveys and studies, biological assessments, or other unpublished materials and expert opinion or personal knowledge.

Habitat is often dynamic, and species may move from one area to another over time. In particular, we recognize that climate change may cause changes in the arrangement of occupied habitat river reaches. Climate change may lead to increased frequency and duration of severe storms and droughts (Golladay *et al.* 2004, p. 504; McLaughlin *et al.* 2002, p. 6074; Cook *et al.* 2004, p. 1015). Drought conditions in 2000–2001 and 2007–2008 greatly reduced the habitat of the spinymussel in the Ohoopee River and rendered the populations vulnerable to anthropogenic disturbances, such as water extraction and vehicles within the riverbed (Keferl 2008, pers. comm.; Stringfellow and Gagnon 2001, p. 3).

The information currently available on the effects of global climate change and increasing temperatures does not make sufficiently precise estimates of the location and magnitude of the

effects. Nor are we currently aware of any climate change information specific to the habitat of the Altamaha spinymussel that would indicate what areas may become important to the species in the future. Therefore, we were unable to determine what additional areas, if any, may be appropriate to include in the critical habitat for this species. Furthermore, we recognize that designation of critical habitat may not include all of the habitat areas we may eventually determine, based on scientific data not now available to the Service, that are necessary for the recovery of the species. For these reasons, a critical habitat designation does not signal that habitat outside the designated area is unimportant or may not be required for recovery of the species.

Areas that are important to the conservation of the species, but are outside the critical habitat designation, will continue to be subject to conservation actions we implement under section 7(a)(1) of the Act. These areas are also subject to the regulatory protections afforded by the section 7(a)(2) jeopardy standard, as determined on the basis of the best available scientific information at the time of the agency action. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans (HCPs), or other species conservation planning efforts if new information available to these planning efforts calls for a different outcome.

Methods

As required by section 4(b) of the Act, we used the best scientific data available in determining occupied areas that contain the features that are essential to the conservation of the Altamaha spinymussel, and unoccupied areas that are essential for the conservation of the Altamaha spinymussel.

We have reviewed the available information pertaining to historical and current distribution, life history, and habitat requirements of this species. Our sources included: Peer-reviewed scientific publications; unpublished survey reports; unpublished field observations by the Service, State, and other experienced biologists; and notes and communications from qualified biologists or experts.

Physical or Biological Features

In accordance with sections 3(5)(A)(i) and 4(b)(1)(A) of the Act and regulations at 50 CFR 424.12, in determining which areas within the geographical area occupied at the time of listing to designate as critical habitat, we consider the physical or biological features essential to the conservation of the species which may require special management considerations or protection. These include, but are not limited to:

(1) Space for individual and population growth and for normal behavior;

(2) Food, water, air, light, minerals, or other nutritional or physiological requirements;

(3) Cover or shelter;

(4) Sites for breeding, reproduction, and rearing of offspring; and

(5) Habitats that are protected from disturbance or are representative of the historical, geographical, and ecological distribution of a species.

We consider the physical or biological features to be the primary constituent elements (PCEs) laid out in the appropriate quantity and spatial arrangement essential for the conservation of the species. We derive the PCEs from the biological needs of the species as described in the Background section of this proposal. Unfortunately, little is known of the specific habitat requirements for the Altamaha spinymussel other than that they require flowing water, stable river channels, and adequate water quality. Altamaha spinymussel mussel larvae also require a currently unknown fish host for development to juvenile mussels. To identify the physical or biological needs of the species, we have relied on current conditions at locations where the species survives, the limited information available on this species and its close relatives, and factors associated with the decline and extirpation of these and other aquatic mollusks from extensive portions of the Altamaha River Basin.

Space for Individual and Population Growth and for Normal Behavior

The Altamaha spinymussel is historically associated with the main stem of the Altamaha River and its larger tributaries (greater than 500 cubic feet per second (cfs) Mean Monthly Discharge (MMD)), and does not occur in smaller tributaries. Spinymussels are generally associated with stable, coarse-to-fine sandy sediments of sandbars, sloughs, and mid-channel islands, and they appear to be restricted to swiftly flowing water (Sickel 1980, p. 12). Sandbars, sloughs, and mid-channel islands provide space for the spinymussel and also provide cover, shelter, and sites for breeding, reproduction, and growth of offspring. Sandbars, sloughs, and mid-channel islands are dynamic habitats formed and maintained by water quantity, channel slope, and sediment input to the system through periodic flooding, which maintains connectivity and interaction with the flood plain. Changes in one or more of these parameters can result in channel degradation or channel aggradation, with serious effects to mollusks. Therefore, we believe that stream channel stability and floodplain connectivity are essential to the conservation of the Altamaha spinymussel.

Water

The Altamaha spinymussel is a riverine-adapted species that depends upon adequate water flow and is not found in ponds or lakes. Continuously flowing water is a habitat feature associated with all surviving populations of this species. Flowing water maintains the river bottom, sandbars, sloughs, and mid-channel islands habitat where this species is found, transports food items to the sedentary juvenile and adult life stages of the Altamaha spinymussel, removes wastes, and provides oxygen for respiration for this species.

The ranges of standard physical and chemical water quality parameters (such as temperature, dissolved oxygen, pH, and conductivity) that define suitable habitat conditions for the Altamaha spinymussel have not been investigated. However, as relatively sedentary animals, mussels must tolerate the full range of such parameters that occur naturally within the streams where they persist. Both the amount (flow) and the physical and chemical conditions (water quality) where this species currently exists vary widely according to season, precipitation events, and seasonal human activities within the watershed. Conditions across their historical ranges vary even more due to geology, geography, and differences in human population densities and land uses. In general, the species survives in areas where the magnitude, frequency, duration, and seasonality of water flow is adequate to maintain stable sandbar, slough, and mid-channel-island habitats (for example, sufficient flow to remove fine particles and sediments without causing degradation), and where water quality is adequate for year-round survival (for example, moderate to high levels of dissolved oxygen, low to moderate input of nutrients, and

relatively unpolluted water and sediments). Therefore, adequate water flow and water quality (as defined below) are essential to the conservation of the Altamaha spinymussel.

It is apparent that heat stress from increased water temperature makes mussels more sensitive to contaminants. A growing body of literature is addressing the acute thermal tolerance of mussels, (Pandolfo *et al* 2009, p. 347; 2010a, p. 959; 2010b, p. 691). Pandolfo *et al.* (2010a, p. 959) reported upper lethal temperatures for early life stages of 8 species of unionid mussels and the average median lethal temperature (LT50) was 31.6 °C. Pandolfo *et al.* (2009, p. 347) reported a measurable physiological indicator of stress (*i.e.,* increased heart rate) in juvenile mussels exposed to temperatures as little as 3 °C above ambient (*i.e.* 30 °C). Pandolfo *et al.* (2010b, p. 691) clearly demonstrated an interaction between temperature and sensitivity to copper in juveniles of three mussel species: fatmucket (*Lampsilis siliquoidia*), pink heelsplitter (*Potamilus alatus*), and black sandshell (*Ligumia recta*). In short, mussels exposed to copper were less able to withstand thermal stress. Clearly stressors do not occur in isolation and more multiple-stressor research is desperately needed. Because thermal tolerance data do not exist for spinymussel or other Altamaha mussel species, we are left to use the best available data to approximate spinymussel thermal tolerance, and we believe this to be the most valid approach for establishing a thermal PCE for spinymussel. Pandolfo *et al.* (2010a, p. 959) indicates that the lowest 48-hr LT50 (median lethal temperature) was 33.8 °C.

In addition to physiological stress due to temperature itself, temperature greatly influences the form (and thereby the toxicity) of other compounds, most notably ammonia. Higher temperatures result in a shift from the nontoxic ammonium ion (NH_4^+) to the highly toxic ammonia ion (NH_3). Ammonia may be one of the primary limiting factors in reaches of river downstream from point and nonpoint sources of nitrogen such as municipal wastewater treatment facilities and agricultural fields, among others (Bringolf 2011, pers. comm.).

These rivers (in the Altamaha Basin), like most Atlantic Slope drainages in Georgia receive a majority of their water through overland flow and runoff whereas streams in the southwestern part of Georgia receive a large proportion of their water though groundwater discharges, which have greater influences on stream flows and temperatures. Additionally, streams in the southwestern part of Georgia are greatly affected by agricultural withdrawals, which can reduce or eliminate the volume of groundwater being discharged into waters in this part of the state and thus affect water temperatures in these creeks and rivers more than waters in other basins. The Altamaha River in the historical and current range of the Altamaha spinymussel is largely forested and rural and exhibits those conditions most similar to the Savannah River gauge near Port Wentworth (02198840). Unlike the Savannah River near the gauge in Augusta (02197000), the Altamaha River Basin in the area that is designated as critical habitat is more than 165 km (103 miles) from the nearest reservoir and thus the effects of hypolimnetic discharges are not considered a threat to the Altamaha spinymussel. (Layzer and Madison 1995, pp. 340–344; Watters 2000, p. 265; Wisniewski 2011, pers. comm.).

The water quality metrics PCE was derived using data collected from the Altamaha River and its tributaries within the historical range of the Altamaha spinymussel. Temperature measurements collected throughout the Altamaha, Ocmulgee, and Oconee rivers in this area ranged from 8.6 °C to 32.6 °C (47.5 to 90.7 °F). Observations of historical United States Geological Survey (USGS) gauge data at several sites on the Altamaha River near Jesup indicated that the maximum water temperature observed between 1974 and 1984 was 32 °C (89.7 °F) (Dyar and Alhadef 1997, p. 26). Since none of the USGS gauge stations on the Altamaha River or its major tributaries include recent temperature data, we downloaded daily stream temperature data from the USGS gauge stations found on the nearby Savannah River, which is similar to the Altamaha River in size and its location within the Coastal Plain physiographic province of Georgia. Three gauge stations on the Savannah River collect temperature data: Savannah River at Augusta (02197000), Savannah River near Port Wentworth, upstream of Interstate 95 (02198840), and Savannah River at Port Wentworth (02198920). At the gauge station in Augusta, the maximum water temperature recorded in the 323 days within the day period of record (4/21/2010–3/9/2011) was 24.8 °C (76.6 °F) and the maximum daily water temperature fluctuation was 5.7 °C (42.3 °F). The maximum water temperature recorded in the 3,835 days within the period of record (10/13/1999–3/9/2011) for the Savannah River near Port Wentworth was 31.7 °C (89.1 °F) with a maximum daily water temperature fluctuation of 2.1 °C (35.8 °F). The maximum water temperature recorded in the 3,883 days within the period of record (11/5/1999–3/9/2011) for the Savannah River at GA highway 25 in Port Wentworth was 32.4 °C (90.3 °F) with a maximum daily water temperature fluctuation of 3.7 °C (38.7 °F).

Although the maximum daily water fluctuations of the Savannah River at Augusta (02197000) and the Savannah River at Port Wentworth (02198920) are greater than the daily temperature fluctuation recommended in the PCEs of the Altamaha spinymussel listing proposal, it is important to note that these sites are located in or immediately downstream of major industrial/urban areas or dams which likely contribute to the greater daily fluctuations in water temperatures. Furthermore, temperatures on the Savannah River in Augusta are influenced by hypolimnetic discharges from Clarks Hill Reservoir and New Savannah Bluff Lock and Dam, which are located immediately upstream of the USGS gauge station. Therefore, water temperatures at the Savannah River gauge (02198840) upstream of Port Wentworth, which is located in a densely forested and rural area and well downstream of any potential hypolimnetic discharges are likely more similar to those temperatures and fluctuations observed in the Altamaha River (Wisniewski 2011, pers. comm.).

A natural flow regime that includes periodic flooding and maintains connectivity and interaction with the flood plain is critical for the exchange of nutrients, spawning activities for potential host fish, and sand bar maintenance. In 2007, persistent severe drought conditions throughout the southeastern United States created record low discharges (streamflow) in the Altamaha River at the U.S. Geological Survey (USGS) gauge station in Doctortown, Georgia. During the driest portions of the 2006–2009 drought period, the lowest discharges observed were 25 percent of the MMD for the 77-year period of record for the Doctortown gauge. Despite record low flows, native unionids (mussels) appeared to persist throughout most of the Lower Altamaha River Basin.

The numeric standards for pollutants and water quality parameters (for example, dissolved oxygen, pH, heavy metals) have been adopted by the State of Georgia under the Clean Water Act (33 U.S.C. 1251 *et seq.*). Water quality standards set by the State of Georgia are based on water quality criteria

established by EPA for protection of aquatic life. That said, mussels are not currently represented in datasets used by EPA for derivation of water quality criteria. Some of these standards (particularly organic and heavy metal contaminants) may not adequately protect Altamaha spinymussels, or are not being appropriately measured, monitored, or achieved in some reaches (see discussions under Factors A and D). While Georgia's pH criterion is a range of 6.0 to 8.5 under the adopted State standards, data compiled by the GDNR indicate that pH at 159 sites in the Altamaha River Basin averaged 6.9 and ranged from 4.9 to 9.1, which means many sites are outside of the range adopted by the State. Potential contaminants such as ammonia may be more lethal at pH levels at the edges of the observed range. Therefore, we removed outliers from this data set by generating the 10th and 90th percentiles for pH, which were 6.1 to 7.7 standard units. These levels are likely more representative of natural pH levels associated with the Altamaha River Basin and would likely reduce lethal contaminant associations between other chemicals in the watershed.

Current Georgia TMDLs for waters supporting warm-water fishes require a daily average dissolved oxygen (DO) concentration of 5.0 mg/l and a minimum of 4.0 mg/l. The mean DO concentration of 217 measurements made in known spinymussel sites throughout the Altamaha River Basin was 8.7 mg/l and ranged from 0.42 mg/l to 20.3 mg/l. The 10th and 90th percentiles for DO were 4.3 and 9.7 mg/l, which are similar to the observations of Golladay *et al.* (2004, pp. 501–503). A daily average DO concentration of 5.0 mg/l and a minimum DO concentration of 4.0 mg/l should provide adequate protection for the Altamaha spinymussel.

Other factors that can potentially alter water quality are droughts and periods of low-flow, nonpoint-source runoff from adjacent land surfaces (for example, excessive amounts of nutrients, pesticides, and sediment), and random spills or unregulated discharge events. This could be particularly harmful during drought conditions when flows are depressed and pollutants are more concentrated. Adequate water quality is essential for normal behavior, growth, and viability during all life stages of the Altamaha spinymussel.

Food

Unionid mussels, such as the Altamaha spinymussel, filter algae, detritus, and bacteria from the water column (Williams *et al.* 2008, p. 67). Although the life history of the Altamaha spinymussel has not been studied, the life histories of other mussels in the *Elliptio* genus indicate that adult freshwater mussels are filter-feeders, siphoning phytoplankton, diatoms, and other microorganisms from the water column. For the first several months, juvenile mussels employ pedal (foot) feeding, extracting bacteria, algae, and detritus from the sediment (Yeager *et al.* 1994, pp. 217–221; Cope *et al.* 2008, p. 457). Food availability and quality for the Altamaha spinymussel in sandbars, sloughs, and mid-channel-island habitats are affected by habitat stability, floodplain connectivity, flow, and water quality.

Sites for Breeding, Reproduction, or Rearing

Freshwater mussels require a host fish for transformation of larval mussels (glochidia) to juvenile mussels (Williams *et al.* 2008, p. 68); therefore, the presence of the appropriate host fish is essential to the conservation of the Altamaha spinymussel. The specific fish host(s) for the Altamaha spinymussel is unknown; however, other species of mussels in the genus *Elliptio* are known to parasitize various species of *Etheostoma, Percina,* and other stream-adapted fish species (Haag and Warren 2003, p. 80). Eighty-five fish species representing 22 families are native to the Altamaha River Basin. Five families account for 65 percent of the native fish species in the Altamaha River Basin. The family Cyprinidae comprises 20 percent of the fish species, while Centrarchidae, Catostomidae, Ictaluridae, and Percidae comprise 15 percent, 12 percent, 11 percent, and 8 percent of the species, respectively. These families are known to be suitable hosts for most unionids in North America. All 85 species native to the Altamaha River Basin are still present within the basin; however, populations of several fish species, particularly anadromous fishes (*e.g.,* striped bass, Atlantic and shortnose sturgeon, American shad and other herrings), have declined substantially in recent decades and, if used as hosts, may be related to declines in Altamaha spinymussel abundance. Host trials with 10 species of fish from six families (Centrarchidae, Cyprinidae, Ictaluridae, Moronidae, Acipenseridae, Catostomidae) did not produce any juvenile Altamaha spinymussels (R. Bringolf 2010, pers. comm.).

Juvenile Altamaha spinymussels require stable sandbar, slough, and mid-channel-island habitats for growth and survival. Excessive sediments or dense growth of filamentous algae can expose juvenile mussels to entrainment or predation and be detrimental to the survival of juvenile mussels (Hartfield and Hartfield 1996, pp. 372–374). Geomorphic instability can result in the loss of interstitial habitats and juvenile mussels due to scouring or deposition (Hartfield 1993, pp. 372–373). Therefore, stable sandbar, slough, and mid-channel-island habitats with low to moderate amounts of filamentous algae growth are essential to the conservation of the Altamaha spinymussel.

Periodic floodplain connectivity that occurs during wet years provides habitats for spawning and foraging activities to fishes requiring floodplain habitats for successful reproduction and recruitment to adulthood. Barko *et al.* (2006, pp. 252–256) found several fish species benefited from the resource exploitation of floodplain habitats that were not typically available for use during hydrologically normal years. Furthermore, Kwak (1988, pp. 243–247) and Slipke *et al.* (2005, p. 289) indicated that periodic inundation of floodplain habitats increased successful fish reproduction, which leads to increased availability of native host fishes for unionid reproduction. However, Rypel *et al.* (2009, p. 502) indicated that unionids tended to exhibit minimal growth during high flow years. Therefore, optimal flooding of these habitats would not be too frequent and should occur at similar frequencies to that of the natural hydrologic regime of the Altamaha River.

Primary Constituent Elements (PCEs) for the Altamaha Spinymussel

Based on the above needs and our current knowledge of the life history, biology, and ecology of the species, we have determined that the Altamaha spinymussel's PCEs are:

(1) Geomorphically stable river channels and banks (channels that maintain lateral dimensions, longitudinal profiles, and sinuosity patterns over time without an aggrading or degrading bed elevation) with stable sandbar, slough, and mid-channel-island habitats of coarse-to-fine sand substrates with low to moderate amounts of fine sediment and attached filamentous algae.

(2) A hydrologic flow regime (the magnitude, frequency, duration, and seasonality of discharge over time) necessary to maintain benthic habitats where the species are found and to maintain connectivity of rivers with the floodplain, allowing the exchange of nutrients and sediment for sand bar maintenance, food availability, and spawning habitat for native fishes.

(3) Water quality necessary for normal behavior, growth, and viability of all life stages, including specifically temperature (less than 32.6 °C (90.68 °F) with less than 2 °C (3.6 °F) daily fluctuation)), pH (6.1 to 7.7), oxygen content (daily average DO concentration of 5.0 mg/l and a minimum of 4.0 mg/l), an ammonia level not exceeding 1.5 mg N/L, 0.22 mg N/L (normalized to pH 8 and 25 °C (77 °F)), and other chemical characteristics.

(4) The presence of fish hosts (currently unknown) necessary for recruitment of the Altamaha spinymussel. The continued occurrence of diverse native fish assemblages currently occurring in the basin will serve as an indication of host fish presence until appropriate host fishes can be identified for the Altamaha spinymussel.

This final designation is designed to conserve those areas containing the PCEs in the appropriate spatial arrangement and quantity essential to the conservation of the species.

Units are designated based on sufficient PCEs present to support at least one of the species' life history functions. In this final designation, all occupied areas (Units 1, 2, and 3) contain all PCEs and support multiple life processes. The unoccupied area (Unit 4) contains PCEs 1, 2 and 4, but does not currently meet the water quality standard (see Unit 4 below).

Special Management Considerations or Protections

When designating critical habitat, we assess whether the areas within the geographical area occupied by the species at the time of listing contain features that are essential to the conservation of the species and whether those features may require special management considerations or protection. None of the critical habitat units being designated for this species have been designated as critical habitat for other species under the Act. Large areas of upland habitat adjacent to the designated critical habitat are currently protected or receive special management; 13.4 km (8.4 mi.) on both sides of the river and 75.9 km (47.0 mi) on one side of the river only are managed as conservation properties through easements with 300' buffers on many timber lands and active management on lands owned by the State and The Nature Conservancy (see Table 2). However, approximately 148 km (92 mi) have no protection. Various activities in or adjacent to each of the critical habitat units described in this final rule may affect one or more of the PCEs and may require special management considerations or protection. Some of these activities include, but are not limited to, those discussed in the ''Summary of Factors Affecting the Species,'' above. Features in all the final critical habitat units may require special management due to threats posed by land-use runoff and point- and nonpoint-source water pollution (see discussion under Factor A and Factor D). Other activities that may affect PCEs in the final critical habitat units include those listed in the ''Effects of Critical Habitat'' section below.

In summary, we find that the areas we are designating as critical habitat that were occupied at the time of listing contain the physical or biological features essential to the conservation of the Altamaha spinymussel, which may require special management considerations or protection. Special management consideration or protection may be required to eliminate, or to reduce to negligible levels, the threats affecting each unit and to preserve and maintain the essential features that the final critical habitat units provide to the Altamaha spinymussel. We are also designating areas outside the geographical area occupied by the species at the time of listing that have been determined to be essential for the conservation of the species. Additional discussions of threats facing individual sites are provided in the individual unit descriptions.

Criteria Used to Identify Critical Habitat

As required by section 4(b) of the Act, we used the best scientific data available in determining areas within the geographical area occupied by the species that contain the physical or biological features essential to the conservation of the Altamaha spinymussel (see above), and areas outside of the geographical area occupied by the species that are essential for the conservation of the species. We are designating as critical habitat all river channels that are currently occupied by the species. We are also designating a specific area not currently occupied but that was historically occupied, because we have determined (1) That the area is essential for the conservation of the Altamaha spinymussel, and (2) that designating only occupied habitat is not sufficient to conserve this species.

When determining final critical habitat boundaries, we make every effort to avoid including developed areas such as lands covered by buildings, pavement, and other structures because such lands usually lack PCEs for endangered or threatened species. Areas designated as critical habitat for the Altamaha spinymussel include only stream channels within the ordinary high-water line, and do not contain any developed areas or structures. The ordinary high-water line defines the stream channel and is the point on the stream bank where water is continuous and leaves some evidence such as erosion or aquatic vegetation.

Occupied Stream Reaches Designated as Critical Habitat

We have defined occupied habitat as those stream reaches known to be currently occupied by the Altamaha spinymussel. We used information from surveys and reports prepared by the GDNR, private contractors, and Service field records to identify the specific locations occupied by the Altamaha spinymussel.

Currently, the limited occupied habitat for this species is extremely scattered and isolated. The Altamaha spinymussel persists in scattered portions of the Altamaha and Ocmulgee Rivers (see *Population Estimates and Status* above). We have determined that all occupied areas contain features essential to the conservation of the species.

River habitats are highly dependent upon upstream and downstream channel habitat conditions for their maintenance. Therefore, where one occurrence record was known from a river reach, we considered the entire reach between the uppermost and lowermost locations as occupied habitat, as discussed below.

The Altamaha spinymussel is currently known to survive in scattered populations along 223 km (138 mi) of the Ocmulgee and upper Altamaha Rivers extending from Telfair and Ben Hill Counties to Long and Wayne Counties, Georgia, except for a 2.7-km (1.7-mi) reach of river in the vicinity of the Plant Hatch facility. From 1997 through 2009, researchers searched 336 sites throughout the basin and documented 57 Altamaha spinymussels, with all occurrences widely scattered throughout its current range. There are no known barriers to movement in this range; therefore, we consider the entire 223-km (138-mi) reach between the uppermost and lowermost collection sites for the Altamaha spinymussel as occupied habitat. In the area designated as critical habitat, boundaries extend from the nearest downstream landmark at both ends of the reach.

Unoccupied Stream Reaches Designated as Critical Habitat

In identifying unoccupied river reaches that could be essential for the conservation of the Altamaha spinymussel, we first considered the availability of potential habitat throughout the historical range that may be suitable for the survival and persistence of the species. We also eliminated from consideration free-flowing rivers or river segments without any historical records of occurrence (that is the Little Ocmulgee River and the upper portions of the Oconee and Ocmulgee Rivers). We eliminated the lower portion of the Altamaha River from consideration because of poor water quality and limited habitat availability. The lower Oconee River was initially eliminated due to poor water quality and limited habitat availability, however, recent mussel surveys have demonstrated that water quality is likely adequate for the spinymussel and suitable habitat is available. However, only one tributary is needed as critical habitat, and the lower Oconee only has one known observation of spinymussels from 1968, conversely the Ohoopee has multiple reports of spinymussel with the most recent in 1997. See our response to Comment 8.

We have identified 14.4 km (9 mi) of habitat in the Ohoopee River that is currently unoccupied by the Altamaha spinymussel and that meets the criteria for designation as critical habitat. Historical records of Altamaha spinymussel occurred in the lower portions of the Ohoopee River. Keferl (1981, p. 15) referred to the Ohoopee as a possible refuge for the Altamaha spinymussel. However, extreme drought and all-terrain vehicle disturbance appear to have extirpated the species from otherwise suitable habitat.

The unoccupied stream reach we are designating as critical habitat was historically occupied (*i.e.,* prior to 1997; see Table 1). We believe that this reach is essential for Altamaha spinymussel conservation because the range of the Altamaha spinymussel has been severely curtailed, occupied habitats are limited and isolated, and population sizes are extremely small, and the area meets the selection criteria identified below. Furthermore, the occupied habitats are contiguous, placing them at high risk of extirpation and extinction from stochastic events. The inclusion of essential unoccupied areas, in a separate tributary, will provide habitat for population reintroduction, reduce the level of stochastic threats to the species' survival, and decrease the risk of extinction for this species.

The area designated as critical habitat that is not known to be currently occupied meets all of the following criteria:

(1) It contains sufficient PCEs (for example, such characteristics as geomorphically stable channels, perennial water flows, and appropriate benthic substrates) to support life history functions of the Altamaha spinymussel;

(2) It supports diverse aquatic mollusk communities, including the presence of closely related species requiring PCEs similar to the Altamaha spinymussel; and

(3) It is adjacent to currently occupied areas where there is potential for natural dispersal and reoccupation by the Altamaha spinymussel.

(4) It is essential to the conservation of the species.

Critical Habitat Designation

We are designating four units, totaling approximately 237.4 km (147.5 mi), as critical habitat for the Altamaha spinymussel. Georgia owns navigable stream bottoms within the ordinary high-water line. All units are considered navigable and, as stated below, critical habitat is designated for the stream channel within the ordinary high-water line only. Accordingly, the State of Georgia owns the stream bottoms within all of the areas designated as critical habitat. Lands adjacent to critical habitat units are either in private ownership or conservation status. Table 2 identifies the critical habitat units, occupancy of the units, the approximate extent designated as critical habitat, and provides information on adjacent land ownership and conservation status.

TABLE 2—OCCUPANCY AND OWNERSHIP OF LANDS ADJACENT TO CRITICAL HABITAT UNITS FOR ALTAMAHA SPINYMUSSEL

Unit	Location	Occupancy	Total length km (mi)	Private km (mi)	Conservation/ private km (mi)	Conservation km (mi)
1	Ocmulgee River	Occupied	110 (68.3)	89.2 (55.4)	14.3 (8.8)	6.4 (4.0)
2A	Upper Altamaha River A	Occupied	31.4 (19.5)	2.7 (1.7)	21.6 (13.4)	7.1 (4.4)
2B	Upper Altamaha River B	Occupied	30.7 (19.1)	22.9 (14.2)	7.8 (4.9)	0 (0)
3	Middle Altamaha River	Occupied	50.9 (31.6)	18.8 (11.7)	32.1 (19.9)	0 (0)
4	Lower Ohoopee River	Unoccupied	14.4 (9.0)	14.4 (9.0)	0 (0)	0 (0)
Total			237.4 (147.5)	148 (92)	75.9 (47)	13.4 (8.4)

* Ownership is categorized by private ownership on both banks of the river (Private), conservation area on one bank and private on the other (Conservation/Private), and conservation area on both banks (Conservation).

The critical habitat units include the river channels below the ordinary high water mark. As defined in 33 CFR 329.11, the ordinary high water mark on nontidal rivers is the line on the shore established by the fluctuations of water and indicated by physical characteristics, such as a clear, natural line impressed on the bank; shelving; changes in the character of soil; destruction of terrestrial vegetation; the presence of litter and debris; or other appropriate means that consider the characteristics of the surrounding areas. For each stream reach designated as a critical habitat unit, the upstream and downstream boundaries are described generally below. More precise definitions are provided in the Regulation Promulgation section at the end of this rule.

We present brief descriptions of all units and reasons why they meet the definition of critical habitat for the Altamaha spinymussel:

Unit 1: Ocmulgee River, Ben Hill, Telfair, Coffee, and Jeff Davis Counties

Unit 1 includes 110 km (68.3 mi) of the lower Ocmulgee River from the confluence of House Creek with the Ocmulgee River at Red Bluff Landing in Ben Hill and Telfair Counties, downstream to the Altamaha River (at the confluence of the Oconee and Ocmulgee Rivers, Jeff Davis and Telfair Counties). Live Altamaha spinymussels have been collected from 11 sites within Unit 1, the uppermost near Red Bluff (Thomas and Scott 1965, p. 67). Surveys

conducted since 1997 on the Ocmulgee River have yielded 19 Altamaha spinymussels from 7 sites (Cammack *et al.* 2001, p. 11; O'Brien 2002, p. 2; Dinkins 2004, pp. 1–1, 2–1). The entire reach of the Ocmulgee River that composes Unit 1 is occupied. This unit contains all of the PCEs.

The Altamaha spinymussel and its habitat may require special management considerations or protection to address changes in the existing flow regime due to activities such as impoundment, water diversion, or water withdrawal; alteration of water chemistry or water quality; and changes in streambed material composition and quality from activities that would release sediments or nutrients into the water, such as deadhead logging (instream log salvage), construction projects, livestock grazing, timber harvesting, and off-road vehicle use.

Unit 2: Upper Altamaha River, Wheeler, Toombs, Montgomery, Jeff Davis, Appling, and Tatnall Counties

Unit 2 includes a total of 62.1 km (38.6 mi) of the Altamaha River from the confluence of the Ocmulgee and Oconee Rivers (Wheeler and Jeff Davis Counties) downstream to the confluence of the Altamaha and Ohoopee Rivers (Appling and Tattnall Counties).

Unit 2A includes 31.4 km (19.5 mi) of the Altamaha River from the confluence of the Ocmulgee and Oconee Rivers to Route 1.

Unit 2B includes 30.7 km (19.1 mi) of the Altamaha River from the upstream boundary of Moody Forest to the confluence of the Altamaha and Ohoopee Rivers.

However, we are not including in this critical habitat designation a stretch of the Altamaha River from U.S. Route 1 downstream to the State-owned property of Moody Forest (2.7 km (1.7 mi)), which includes Plant Hatch. This area does not contain the PCEs necessary for the Altamaha spinymussel due to:

(1) Dredging for intake pipes at Plant Hatch, which destabilizes the river channel and banks, sandbar, slough, and mid-channel-island habitats and disrupts the movement of coarse-to-fine sand substrates with low to moderate amounts of fine sediment; and

(2) Thermal discharges from Plant Hatch that reduce water quality.

In the upper Altamaha River, historic surveys collected Altamaha spinymussels from 15 sites, while recent surveys have collected live Altamaha spinymussels from only 2 sites; dead shells have been collected from an additional 14 sites (Sickel 1980; Keferl 1995, p. 3; Cammack *et al.* 2001, p. 11, O'Brien 2002, p. 2; Wisniewski 2009, pers. comm.). The entire reach of the Altamaha River that composes Unit 2 is occupied. This unit contains all of the PCEs.

The Altamaha spinymussel and its habitat may require special management considerations or protection to address changes in the existing flow regime due to activities such as impoundment, water diversion, or water withdrawal; alteration of water chemistry or water quality; and changes in streambed material composition and quality from activities that would release sediments or nutrients into the water, such as deadhead logging (instream log salvage), construction projects, livestock grazing, timber harvesting, and off-road vehicle use.

Unit 3: Middle Altamaha River, Tattnall, Appling, Wayne, and Long Counties

Unit 3 includes approximately 50.9 km (31.6 mi) of the Altamaha River from the confluence with the Ohoopee (Tattnall and Appling Counties) downstream to U.S. Route 301 (Wayne and Long Counties). Historic and recent surveys of the middle Altamaha River have yielded live Altamaha spinymussels from 26 sites. Shell material was found at an additional 13 sites (Keferl 1981, p. 14; Keferl 1995, p. 3; Cammack *et al.* 2001, p. 11; O'Brien 2002, p. 2; Wisniewski 2009, pers. comm.). The entire reach of the Altamaha River that composes Unit 3 is occupied. This unit contains all of the PCEs.

The Altamaha spinymussel and its habitat may require special management considerations or protection to address changes in the existing flow regime due to such activities as impoundment, water diversion, or water withdrawal; alteration of water chemistry or water quality; and changes in streambed material composition and quality from activities that would release sediments or nutrients into the water, such as deadhead logging (instream log salvage), construction projects, livestock grazing, timber harvesting, and off-road vehicle use.

Unit 4: Lower Ohoopee River, Tattnall County

Unit 4 includes the lower 14.4 km (9 mi) of the Ohoopee River, from 2.2 km (1.3 mi) upstream of Tattnall County Road 191, downstream to the confluence of the Ohoopee and the Altamaha River in Tattnall County, Georgia.

The Altamaha spinymussel historically occupied this stretch of the Ohoopee River but has not been found here since the mid-1990s (Stringfellow and Gagnon 2001, pp. 1–2) and is considered extirpated. Historic collections were made from seven sites (Keferl 1981, p. 14). Keferl (1981, p. 15) considered the Ohoopee to contain excellent habitat that would serve as a refuge for declining mussel populations. This stretch of the Ohoopee River contains PCEs 1, 2, and 4 for the Altamaha spinymussel, and continues to support four species commonly associated with the presence of the Altamaha spinymussel: *Elliptio dariensis* (75 percent of sites with *E. spinosa*), *E. hopetonensis* (93 percent), *E. shepardiana* (80 percent), and *Lampsilis dolabraeformis* (90 percent). *Lampsilis splendida* was found at 72 percent of sites (Wisniewski 2009, pers. comm.). The Ohoopee does not meet state water quality standards for mercury, however, EPA will begin revising needed load reductions in 2011 (EPA 2002b, p. 2).

Critical habitat units 1, 2, and 3 are contiguous, making them very vulnerable to a catastrophic event that could eliminate all known occupied habitat for the Altamaha spinymussel. Therefore, we believe that the stream segment within this unit is essential to the conservation of the species because reestablishing the Altamaha spinymussel on a separate tributary such as the Ohoopee River would significantly reduce the impact of stochastic threats to the species' survival.

Effects of Critical Habitat Designation

Section 7 Consultation

Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that actions they fund, authorize, or carry out are not likely to destroy or adversely modify critical habitat. Decisions by the courts of appeals for the Fifth and Ninth Circuits Courts of Appeals have invalidated our definition of ''destruction or adverse modification'' (50 CFR 402.02) (see *Gifford Pinchot Task Force* v. *U.S. Fish and Wildlife Service,* 378 F.3d 1059 (9th Cir. 2004) and *Sierra Club* v. *U.S. Fish and Wildlife Service et al.,* 245 F.3d 434, 442F (5th Cir. 2001)), and we do not rely on this regulatory definition when analyzing whether an action is likely to destroy or adversely modify critical habitat. Under the statutory provisions of the Act, we determine destruction or adverse modification on the basis of whether, with implementation of the proposed Federal action, the affected critical habitat would remain functional (or retain those physical or biological features that relate to the ability of the

area to periodically support the species) to serve its intended conservation role for the species.

If a species is listed or critical habitat is designated, section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species or to destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. As a result of this consultation, we document compliance with the requirements of section 7(a)(2) through our issuance of:

(1) A concurrence letter for Federal actions that may affect, but are not likely to adversely affect, listed species or critical habitat; or

(2) A biological opinion for Federal actions that may affect, and are likely to adversely affect, listed species or critical habitat.

When we issue a biological opinion concluding that a project is likely to jeopardize the continued existence of a listed species or destroy or adversely modify critical habitat, we also provide reasonable and prudent alternatives to the project, if any are identifiable. We define ''reasonable and prudent alternatives'' at 50 CFR 402.02 as alternative actions identified during consultation that:

- Can be implemented in a manner consistent with the intended purpose of the action,
- Can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction,
- Are economically and technologically feasible, and
- Would, in the Director's opinion, avoid jeopardizing the continued existence of the listed species or destroying or adversely modifying critical habitat.

Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 require Federal agencies to reinitiate consultation on previously reviewed actions in instances where we have listed a new species or subsequently designated critical habitat that may be affected and the Federal agency has retained discretionary involvement or control over the action (or the agency's discretionary involvement or control is authorized by law). Consequently, Federal agencies may sometimes need to request reinitiation of consultation with us on actions for which formal consultation has been completed, if those actions with discretionary involvement or control may affect subsequently listed species or designated critical habitat.

Federal activities that may affect Altamaha spinymussel or its designated critical habitat require section 7 consultation under the Act. Activities on State, Tribal, local, or private lands requiring a Federal permit (such as a permit from the U.S. Army Corps of Engineers under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or a permit from us under section 10 of the Act) or involving some other Federal action (such as funding from the Federal Highway Administration, Federal Aviation Administration, or the Federal Emergency Management Agency) are subject to the section 7 consultation process. Federal actions not affecting listed species or critical habitat, and actions on State, Tribal, local, or private lands that are not federally funded, authorized, or permitted, do not require section 7 consultations.

Application of the Jeopardy and Adverse Modification Standard

Jeopardy Standard

Prior to and following listing and designation of critical habitat, the Service applies an analytical framework for jeopardy analyses that relies heavily on the importance of the core area population (middle mainstem Altamaha) to the survival and recovery of the species. The section 7(a)(2) analysis is focused not only on these populations but also on the habitat conditions necessary to support them.

The jeopardy analysis usually expresses the survival and recovery needs of the species in a qualitative fashion without making distinctions between what is necessary for survival and what is necessary for recovery. Generally, if a proposed Federal action is incompatible with the viability of the affected core area population, inclusive of associated habitat conditions, a jeopardy finding is considered to be warranted, because of the relationship of the core area population to the survival and recovery of the species as a whole.

Adverse Modification Standard

The key factor related to the adverse modification determination is whether, with implementation of the proposed Federal action, the affected critical habitat would continue to serve its intended conservation role for the species, or would retain its current ability for the PCEs to be functionally established. Activities that may destroy or adversely modify critical habitat are those that alter the physical or biological features to an extent that appreciably reduces the conservation value of critical habitat for the Altamaha spinymussel.

Section 4(b)(8) of the Act requires us to briefly evaluate and describe, in any proposed or final regulation that designates critical habitat, activities involving a Federal action that may destroy or adversely modify such habitat, or that may be affected by such designation.

Activities that, when carried out, funded, or authorized by a Federal agency, may affect critical habitat and, therefore, should result in consultation for the Altamaha spinymussel include, but are not limited to:

(1) Actions that would alter the geomorphology of their stream and river habitats. Such activities could include, but are not limited to, instream excavation or dredging, impoundment, channelization, and discharge of fill materials. These activities could cause aggradation or degradation of the channel bed elevation or significant bank erosion, result in entrainment or burial of these mollusks, and cause other direct or cumulative adverse effects to these species and their life cycles.

(2) Actions that would significantly alter the existing flow regime. Such activities could include, but are not limited to, impoundment, water diversion, water withdrawal, and hydropower generation. These activities could eliminate or reduce the habitat necessary for growth and reproduction of these mollusks.

(3) Actions that would significantly alter water chemistry or water quality (for example, temperature, pH, contaminants, and excess nutrients). Such activities could include, but are not limited to, hydropower discharges, or the release of chemicals, biological pollutants, or heated effluents into surface water or connected groundwater at a point source or by dispersed release (nonpoint source). These activities could alter water conditions that are beyond the tolerances of these mollusks and result in direct or cumulative adverse effects to the species and their life cycles.

(4) Actions that would significantly alter stream bed material composition and quality by increasing sediment deposition or filamentous algal growth. Such activities could include, but are not limited to, construction projects, livestock grazing, timber harvest, off-road vehicle use, and other watershed

and floodplain disturbances that release sediments or nutrients into the water. These activities could eliminate or reduce habitats necessary for the growth and reproduction of these mollusks by causing excessive sedimentation and burial of the species or their habitats, or nutrient enrichment leading to excessive filamentous algal growth. Excessive filamentous algal growth can cause reduced night-time dissolved oxygen levels through respiration and prevent mussel glochidia from settling into stream sediments.

Exemptions and Exclusion

Application of Section 4(a)(3) of the Act

The Sikes Act Improvement Act of 1997 (Sikes Act) (16 U.S.C. 670a) required each military installation that includes land and water suitable for the conservation and management of natural resources to complete an integrated natural resources management plan (INRMP) by November 17, 2001. An INRMP integrates implementation of the military mission of the installation with stewardship of the natural resources found on the base. Among other things, each INRMP must, to the extent appropriate and applicable, provide for fish and wildlife management; fish and wildlife habitat enhancement or modification; wetland protection, enhancement, and restoration where necessary to support fish and wildlife; and enforcement of applicable natural resource laws.

The National Defense Authorization Act for Fiscal Year 2004 (Pub. L. 108–136) amended the Act to limit areas eligible for designation as critical habitat. Specifically, section 4(a)(3)(B)(i) of the Act (16 U.S.C. 1533(a)(3)(B)(i)) now provides: ''The Secretary shall not designate as critical habitat any lands or other geographical areas owned or controlled by the Department of Defense, or designated for its use, that are subject to an integrated natural resources management plan prepared under section 101 of the Sikes Act (16 U.S.C. 670a), if the Secretary determines in writing that such plan provides a benefit to the species for which critical habitat is proposed for designation.''

There are no Department of Defense lands within the critical habitat designation for this species. Therefore, there are no specific lands that meet the criteria for exemption from the designation of critical habitat under section 4(a)(3) of the Act.

Application of Section 4(b)(2) of the Act

Section 4(b)(2) of the Act states that the Secretary must designate or revise critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat. The Secretary may exclude an area from critical habitat if he determines that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless he determines, based on the best scientific data available, that the failure to designate such area as critical habitat will result in the extinction of the species. In making that determination, the legislative history is clear that the Secretary has broad discretion regarding which factors to use and how much weight to give to any factor.

Under section 4(b)(2) of the Act, we must consider the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat. For example, we consider whether there are lands owned or managed by the Department of Defense (DOD) where a national security impact might exist. We also consider whether landowners have developed any conservation plans for the area, or whether there are conservation partnerships that would be encouraged by designation of, or exclusion of lands from, critical habitat. In addition, we look at any tribal issues, and consider the government-to-government relationship of the United States with tribal entities. We also consider the economic impacts, environmental impacts, and any social impacts that might occur because of the designation.

Under section 4(b)(2) of the Act, in considering whether to exclude a particular area from the designation, we must identify the benefits of including the area in the designation, identify the benefits of excluding the area from the designation, and determine whether the benefits of exclusion outweigh the benefits of inclusion. If, based on this analysis, we determine that the benefits of exclusion outweigh the benefits of inclusion, we can exclude the area only if such exclusion would not result in the extinction of the species.

In the proposed rule, we requested information on why any area should or should not be designated as critical habitat as provided by section 4 of the Act (16 U.S.C. 1531 *et seq.*), including whether the benefit of designation would outweigh threats to the species caused by designation such that the designation of critical habitat is prudent. In this instance, we have examined all comments submitted with respect to providing adequate protection and management for the Altamaha spinymussel. None of the comments provided sufficient information to satisfy the criteria necessary for exclusion from final critical habitat.

In preparing this final rule, we determined that the lands within the designation of critical habitat for the Altamaha spinymussel are not owned or managed by the Department of Defense, and there are no other known national security impacts expected from the designation; there are currently no conservation partnerships for the spinymussel; and the designation does not include any tribal lands or trust resources. Since the critical habitat designation includes only aquatic areas that are generally held in public trust, involves no Tribal lands, and includes no areas presently under special management or protection provided by a legally operative plan or agreement for the conservation of this mussel, we believe that, other than economics, there are no other relevant impacts to evaluate under section 4(b)(2).

Economic Analysis (EA)

We prepared an economic analysis that is consistent with the ruling of the United States Court of Appeals for the Tenth Circuit in *New Mexico Cattle Growers Ass'n* v. *United States Fish and Wildlife Service,* 248 F.3d 1277 (2001), and that was available for public review and comment during the comment period for the proposed rule. The final economic analysis is available on the Internet at *http://www.regulations.gov.* The final EA (Industrial Economics 2011) considers the potential economic effects of actions relating to the conservation of the Altamaha spinymussel, including costs associated with sections 4, 7, and 10 of the Act, and including those attributable to designating critical habitat. It further considers the economic effects of protective measures taken as a result of other Federal, State, and local laws that aid habitat conservation for the Altamaha spinymussel in essential habitat areas. The EA considers both economic efficiency and distributional effects. In the case of habitat conservation, efficiency effects generally reflect the ''opportunity costs'' associated with the commitment of resources to comply with habitat protection measures (for example, lost economic opportunities associated with restrictions on land use).

The final EA states that incremental impacts stem primarily from administrative costs of section 7 consultations, and are relatively small. Present value incremental impacts of spinymussel conservation are estimated

to be $37,100 total over the analysis timeframe (2011 to 2040), applying a seven percent discount rate. All of these impacts stem from the administrative cost of addressing adverse modification of critical habitat during section 7 consultations. Because the region is primarily rural, the Service and contacted stakeholders do not anticipate that designation of critical habitat for the spinymussel will have substantial impact on economic activity. Accordingly, a small number of section 7 consultations are expected during the analytic timeframe, most of which will occur in habitat currently occupied by the spinymussel.

The majority of the incremental impacts are related to electric power generation and transmission. Over the 30-year analytic timeframe, four hydropower plants in the region will renew their operating licenses and will, therefore, conduct section 7 consultations with the Service. In addition, this analysis assumes that the Edwin I. Hatch nuclear power plant will conduct informal section 7 consultations with the Service for periodic dredging operations, and regional utilities will conduct on average one consultation per year for construction and repair of electric power lines. In comparison, the analysis projects that relatively few section 7 consultations will be required for transportation and recreation activities.

Based on the best available information, including the prepared economic analysis, we believe that all of the four units are essential for the conservation of the spinymussel. Critical habitat aids in the conservation specifically by protecting the primary constituent elements on which the spinymussel depends. It can also result in benefits by providing information to the public, local and State governments, Federal agencies, and other entities engaged in activities or long-range planning in areas essential to the conservation of the spinymussel. Conservation of the Altamaha spinymussel and essential features of its habitats will require habitat management, protection, and restoration, which will be facilitated by knowledge of habitat locations and the physical or biological features of those habitats. We conclude that these benefits of inclusion outweigh the above-described costs of designation for all areas we are designating as critical habitat in this rule.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing encourages and results in conservation actions by Federal, State, and private agencies; groups; and individuals. The Act provides for possible land acquisition and cooperation with the States and requires that recovery actions be carried out for all listed species. The protection required of Federal agencies and the prohibitions against taking and harm are discussed, in part, below.

Section 7(a) of the Act, as amended, requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat, if any is being designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of such a species or to destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into formal consultation with the Service.

Federal activities that may affect the Altamaha spinymussel include, but are not limited to, the carrying out or the issuance of permits for reservoir construction, stream alterations, discharges, wastewater facility development, water withdrawal projects, pesticide registration, mining, and road and bridge construction. It has been the experience of the Service, however, that nearly all section 7 consultations have been resolved so that species have been protected and the project objectives have been met.

Listing the Altamaha spinymussel initiates the development and implementation of a rangewide recovery plan for the species. This plan will bring together Federal, State, and local agency efforts for the conservation of this species. Recovery plans establish a framework for agencies to coordinate their recovery efforts. The plans set recovery priorities and estimate the costs of the tasks necessary to accomplish the priorities. They also describe the site-specific actions necessary to achieve conservation and survival of each species.

Listing also will require us to review any actions on Federal lands and activities under Federal jurisdiction that may affect the Altamaha spinymussel; allow State plans to be developed under section 6 of the Act; encourage scientific investigations of efforts to enhance the propagation or survival of the species under section 10(a)(1)(A) of the Act; and promote habitat conservation plans on non-Federal lands under section 10(a)(1)(B) of the Act.

The Act and its implementing regulations found at 50 CFR 17.21 set forth a series of general prohibitions and exceptions that apply to all endangered wildlife. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to take (includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt any of these), import or export, ship in interstate commerce in the course of commercial activity, or sell or offer for sale in interstate or foreign commerce any listed species. It also is illegal to possess, sell, deliver, carry, transport, or ship any wildlife that has been taken illegally. Certain exceptions apply to agents of the Service and State conservation agencies.

Permits may be issued to carry out otherwise prohibited activities involving endangered wildlife species under certain circumstances. Regulations governing permits are set forth at 50 CFR 17.22 and 17.23. Such permits are available for scientific purposes, to enhance the propagation or survival of the species and for incidental take in connection with otherwise lawful activities.

Under the Interagency Cooperative Policy for Endangered Species Act Section 9 Prohibitions, published in the **Federal Register** on July 1, 1994 (59 FR 34272), we identify to the maximum extent practicable those activities that would or would not constitute a violation of section 9 of the Act if the Altamaha spinymussel is listed. The intent of this policy is to increase public awareness as to the effects of this listing on future and ongoing activities within a species' range. We believe, based on the best available information that the following actions will not result in a violation of the provisions of section 9 of the Act, provided these actions are carried out in accordance with existing regulations and permit requirements:

(1) Possession, delivery, or movement, including interstate transport that does not involve commercial activity, of specimens of this species that were legally acquired prior to the addition of the Altamaha spinymussel to the Federal List of Endangered or Threatened Wildlife;

(2) Development and construction activities designed and implemented under State and local water quality regulations and implemented using

approved best management practices; and

(3) Any actions that may affect the Altamaha spinymussel that are authorized, funded, or carried out by a Federal agency (such as bridge and highway construction, pipeline construction, hydropower licensing), when the action is conducted in accordance with the consultation requirements for listed species under section 7 of the Act.

Potential activities that we believe will likely be considered a violation of section 9 of the Act if this species becomes listed, include, but are not limited to, the following:

(1) Unauthorized possession, collecting, trapping, capturing, harming, killing, harassing, sale, delivery, or movement, including interstate and foreign commerce, or attempting any of these actions, with the Altamaha spinymussel;

(2) Unlawful destruction or alteration of their habitats (such as unpermitted instream dredging, impoundment, channelization, or discharge of fill material) that impairs essential behaviors, such as breeding, feeding, or sheltering, or results in killing or injuring the Altamaha spinymussel;

(3) Discharge or water withdrawal permits that results in harm or death to any individuals of this species or that results in degradation of its occupied habitat to an extent that essential behaviors such as breeding, feeding, and sheltering are impaired; and

(4) Unauthorized discharges or dumping of toxic chemicals or other pollutants into waters supporting the Altamaha spinymussel that kills or injures or otherwise impairs essential life-sustaining requirements, such as reproduction, food, or shelter.

Other activities not identified above will be reviewed on a case-by-case basis to determine if a violation of section 9 of the Act may be likely to result from such activity. The Service does not consider the description of future and ongoing activities provided above to be exhaustive; we provide them simply as information to the public.

If you have questions regarding whether specific activities will likely violate the provisions of section 9 of the Act, contact the Georgia Ecological Services Office (see **ADDRESSES**). Requests for copies of regulations regarding listed species and inquiries about prohibitions and permits should be addressed to the U.S. Fish and Wildlife Service, Ecological Services Division, 1875 Century Boulevard, Atlanta, GA 30345 (phone 404–679–7313; fax 404–679–7081).

Required Determinations

Regulatory Planning and Review—Executive Order 12866

The Office of Management and Budget (OMB) has determined that this rule is not significant under Executive Order 12866 (E.O. 12866). OMB bases its determination upon the following four criteria:

(a) Whether the rule will have an annual effect of $100 million or more on the economy or adversely affect an economic sector, productivity, jobs, the environment, or other units of the government.

(b) Whether the rule will create inconsistencies with other Federal agencies' actions.

(c) Whether the rule will materially affect entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients.

(d) Whether the rule raises novel legal or policy issues.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.,* as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the RFA to require Federal agencies to provide a statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities.

Small entities include small organizations, such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; as well as small businesses. Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than $5 million in annual sales, general and heavy construction businesses with less than $27.5 million in annual business, special trade contractors doing less than $11.5 million in annual business, and agricultural businesses with annual sales less than $750,000. To determine whether potential economic impacts to these small entities are significant, we consider the types of activities that might trigger regulatory impacts under this rule, as well as the types of project modifications that may result. In general, the term ''significant economic impact'' is meant to apply to a typical small business firm's business operations.

To determine if the rule could significantly affect a substantial number of small entities, we consider the number of small entities affected within particular types of economic activities (*e.g.,* housing development, grazing, oil and gas production, timber harvesting). We apply the ''substantial number'' test individually to each industry to determine if certification is appropriate. However, the SBREFA does not explicitly define ''substantial number'' or ''significant economic impact.'' Consequently, to assess whether a ''substantial number'' of small entities is affected by this designation, this analysis considers the relative number of small entities likely to be impacted in an area. In some circumstances, especially with critical habitat designations of limited extent, we may aggregate across all industries and consider whether the total number of small entities affected is substantial. In estimating the number of small entities potentially affected, we also consider whether their activities have any Federal involvement.

Designation of critical habitat only affects activities authorized, funded, or carried out by Federal agencies. Some kinds of activities are unlikely to have any Federal involvement and so will not be affected by critical habitat designation. In areas where a listed species already occurs; *e.g.,* the short-nosed sturgeon, Federal agencies already are required to consult with the National Marine Fisheries Service under section 7 of the Act on activities they authorize, fund, or carry out that may affect the sturgeon. Federal agencies also must consult with us if their activities may affect critical habitat. Designation of critical habitat, therefore, could result in an additional economic impact on small entities due to the requirement to reinitiate consultation for ongoing Federal activities (see *Application of the ''Adverse Modification'' Standard* section).

In our final economic analysis of the proposed critical habitat designation, we evaluated the potential economic effects on small business entities resulting from conservation actions

related to the listing of the Altamaha spinymussel and the proposed designation of critical habitat. The analysis is based on the estimated impacts associated with the proposed rulemaking as described in chapters 3 through 5 and appendix A of the analysis and evaluates the potential for economic impacts related to: (1) Power generation and transmission; (2) transportation; (3) other activities (agriculture, recreation and forestry); and (4) impacts to small entities and the energy industry.

According to the final EA, impacts on small entities due to this rule are expected to be modest because the incremental costs of the rule are estimated to be administrative in nature. The final EA evaluated the incremental impacts of the critical habitat designation for the Altamaha spinymussel over the next 30 years, which was determined to be the appropriate period for analysis because limited planning information is available for most activities to forecast activity levels for projects beyond a 30-year timeframe. Applying a seven percent discount rate, electric power generation and transmission is estimated to incur the largest impact at $26,700 over the next 30 years (2011–2040), overall incremental impacts associated with the designation are estimated at $37,100 over the same time period.

In summary, we considered whether this designation will result in a significant economic effect on a substantial number of small entities. Based on the above reasoning and currently available information, we concluded that this rule will not result in a significant economic impact on a substantial number of small entities. Therefore, we are certifying that the designation of critical habitat for the spinymussel will not have a significant economic impact on a substantial number of small entities, and a regulatory flexibility analysis is not required.

Energy Supply, Distribution, or Use—Executive Order 13211

Pursuant to Executive Order 13211, ''Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use,'' issued May 18, 2001, Federal agencies must prepare and submit a ''Statement of Energy Effects'' for all ''significant energy actions.'' The purpose of this requirement is to ensure that all Federal agencies ''appropriately weigh and consider the effects of the Federal Government's regulations on the supply, distribution, and use of energy.''

The Office of Management and Budget (OMB) has provided guidance for implementing E.O. 13211 that outlines nine outcomes that may constitute ''a significant adverse effect'' when compared without the regulatory action under consideration. The economic analysis finds that incremental impacts of the designation of critical habitat are the subject of the analysis under Executive Order 13211. The potential effects of this designation on power production were considered in the economic analysis. As described in Chapter 4, estimated incremental impacts to the energy industry as a result of critical habitat designation for the spinymussel are minor and administrative in nature. Therefore, the rule is not expected to affect the production, distribution, or use of energy, and none of the above criteria are relevant to this analysis.

Unfunded Mandates Reform Act

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), the Service makes the following findings:

(a) This rule will not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, tribal governments, or the private sector and includes both ''Federal intergovernmental mandates'' and ''Federal private sector mandates.'' These terms are defined in 2 U.S.C. 658(5)–(7). ''Federal intergovernmental mandate'' includes a regulation that ''would impose an enforceable duty upon State, local, or tribal governments'' with two exceptions. It excludes ''a condition of Federal assistance.'' It also excludes ''a duty arising from participation in a voluntary Federal program,'' unless the regulation ''relates to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and tribal governments under entitlement authority,'' if the provision would ''increase the stringency of conditions of assistance'' or ''place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding,'' and the State, local, or tribal governments ''lack authority'' to adjust accordingly. At the time of enactment, these entitlement programs were: Medicaid; AFDC work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement. ''Federal private sector mandate'' includes a regulation that ''would impose an enforceable duty upon the private sector, except (i) A condition of Federal assistance or (ii) a duty arising from participation in a voluntary Federal program.''

The designation of critical habitat does not impose a legally binding duty on non-Federal government entities or private parties. Under the Act, the only regulatory effect is that Federal agencies must ensure that their actions do not jeopardize the continued existence of the species, or destroy or adversely modify critical habitat under section 7. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply; nor would listing these species or designating critical habitat shift the costs of the large entitlement programs listed above on to State governments.

(b) We do not believe that this rule will significantly or uniquely affect small governments because the Altamaha spinymussel only occurs in navigable waters in which the river bottom is owned by the State of Georgia. However, the adjacent upland properties are owned by private entities, the State, or Federal partners (see Table 2). As such, a Small Government Agency Plan is not required.

Takings

In accordance with Executive Order 12630 (''Government Actions and Interference with Constitutionally Protected Private Property Rights''), we have analyzed the potential takings implications of designating critical habitat for the Altamaha spinymussel in a takings implications assessment. The takings implications assessment concludes that this designation of critical habitat for the Altamaha spinymussel does not pose significant takings implications.

Federalism

In accordance with Executive Order 13132 (Federalism), the rule does not have significant Federalism effects. A Federalism assessment is not required. In keeping with Department of the Interior and Department of Commerce

policy, we requested information from, and coordinated development of this critical habitat designation with appropriate State resource agencies in Georgia. The critical habitat designation may have some benefit to this government in that the areas that contain the features essential to the conservation of the species are more clearly defined, and the PCEs of the habitat necessary to the conservation of the species are specifically identified. While making this definition and identification does not alter where and what federally sponsored activities may occur, it may assist these local governments in long-range planning (rather than waiting for case-by-case section 7 consultations to occur).

Where State and local governments require approval or authorization from a Federal agency for actions that may affect critical habitat, consultation under section 7(a)(2) would be required. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency.

Civil Justice Reform

In accordance with E.O. 12988 (Civil Justice Reform), the Office of the Solicitor has determined that the rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order. We are designating critical habitat in accordance with the provisions of the Act. This final rule uses standard property descriptions and identifies the PCEs within the designated areas to assist the public in understanding the habitat needs of the Altamaha spinymussel.

Paperwork Reduction Act of 1995

This rule does not contain any new collections of information that require approval by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This rule will not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. 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.

National Environmental Policy Act (NEPA)

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), need not be prepared in connection with regulations adopted under section 4(a)(1) of the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

Also, it is our position that, outside the jurisdiction of the U.S. Court of Appeals for the Tenth Circuit, we do not need to prepare environmental analyses as defined by NEPA in connection with designating critical habitat under section 4(a)(3) of the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This position was upheld by the U.S. Court of Appeals for the Ninth Circuit (*Douglas County* v *Babbitt,* 48 F. 3d 1495 (9th Cir. 1995), cert. denied 516 U.S. 1042 (1996)).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994, ''Government-to-Government Relations with Native American Tribal Governments'' (59 FR 22951), Executive Order 13175, and the Department of Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 ''American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act'', we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes.

We have determined that there are no tribal lands occupied at the time of listing that contain the features essential for the conservation, and no tribal lands that are unoccupied areas that are essential for the conservation, of the Altamaha spinymussel. Therefore, we have not designated critical habitat for the Altamaha spinymussel on Tribal lands.

References Cited

A complete list of all references cited in this rulemaking is available upon request from the Field Supervisor, Georgia Ecological Services Office (see **FOR FURTHER INFORMATION CONTACT**) and at Docket No. FWS–R4–ES–2008–0107.

Author(s)

The primary author of this package is the staff of the Georgia Ecological Services Office (see **FOR FURTHER INFORMATION CONTACT**).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Regulation Promulgation

Accordingly, we hereby amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

■ 2. Amend § 17.11(h) by adding ''Spinymussel, Altamaha'' in alphabetical order under CLAMS to the List of Endangered and Threatened Wildlife, to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
*	*	*	*	*	*		*
CLAMS							
*	*	*	*	*	*		*
Spinymussel, Altamaha.	*Elliptio spinosa*	U.S.A. (GA)	Entire	E	796	17.95(f)	NA
*	*	*	*	*	*		*

■ 3. Amend § 17.95(f) by adding an entry for ''Altamaha spinymussel (*Elliptio spinosa*)'' after the entry for ''Georgia Pigtoe (*Pleurobema hanleyianum*)'' to read as set forth below:

§ 17.95 Critical habitat—fish and wildlife.

* * * * *

(f) *Clams and Snails.*

* * * * *

Altamaha spinymussel (*Elliptio spinosa*).

(1) Critical habitat units are depicted for Appling, Ben Hill, Coffee, Jeff Davis, Long, Montgomery, Tattnall, Telfair, Toombs, Wayne, and Wheeler Counties, Georgia, on the maps below.

(2) The primary constituent elements (PCEs) of critical habitat for the Altamaha spinymussel are the habitat components that provide:

(i) Geomorphically stable river channels and banks (channels that maintain lateral dimensions, longitudinal profiles, and sinuosity patterns over time without an aggrading or degrading bed elevation) with stable sandbar, slough, and mid-channel-island habitats of coarse-to-fine sand substrates with low to moderate amounts of fine sediment and attached filamentous algae.

(ii) A hydrologic flow regime (the magnitude, frequency, duration, and seasonality of discharge over time) necessary to maintain benthic habitats where the species are found and to maintain connectivity of rivers with the floodplain, allowing the exchange of nutrients and sediment for sand bar maintenance, food availability, and spawning habitat for native fishes.

(iii) Water quality necessary for normal behavior, growth, and viability of all life stages, including specifically temperature (less than 32.6 °C (90.68 °) with less than 2 °C (3.6 °F) daily fluctuation), pH (6.1 to 7.7), oxygen content (daily average DO concentration of 5.0 mg/l and a minimum of 4.0 mg/l), an ammonia level not exceeding 1.5 mg N/L, 0.22 mg N/L (normalized to pH 8 and 25 °C (77 °F)), and other chemical characteristics.

(iv) The presence of fish hosts (currently unknown) necessary for recruitment of the Altamaha spinymussel. The continued occurrence of diverse native fish assemblages currently occurring in the basin will serve as an indication of host fish presence until appropriate host fishes can be identified for the Altamaha spinymussel.

(3) Critical habitat does not include manmade structures existing on the effective date of this rule and not containing one or more of the PCEs, such as buildings, bridges, aqueducts, airports, and roads, and the land on which such structures are located.

(4) *Critical habitat unit maps.* Maps were developed from USGS 7.5 minute quadrangles, and critical habitat unit upstream and downstream limits were then identified by longitude and latitude using decimal degrees.

(5) **Note:** Index map of critical habitat units for the Altamaha spinymussel follows:

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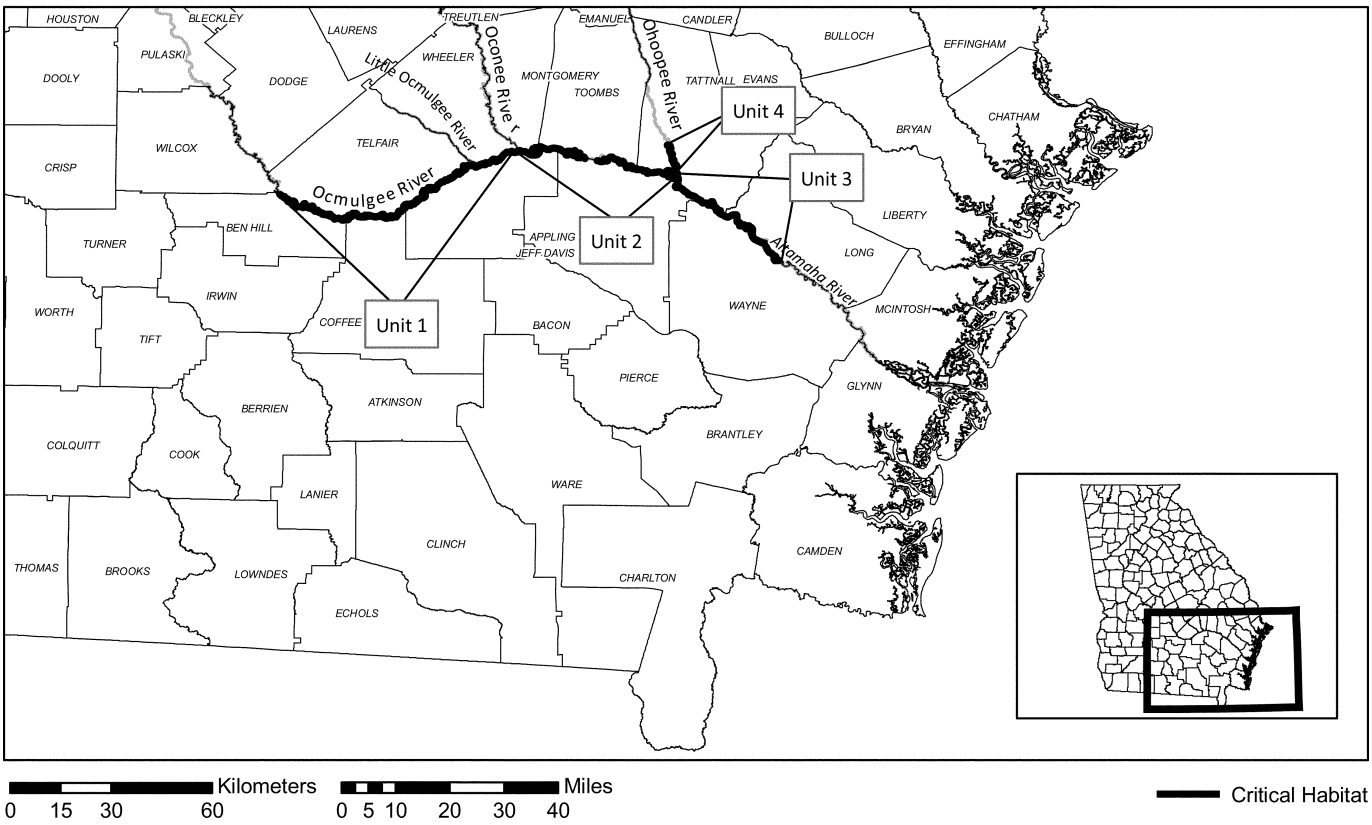
Altamaha Spinymussel (*Elliptio spinosa*) Critical Habitat in Georgia

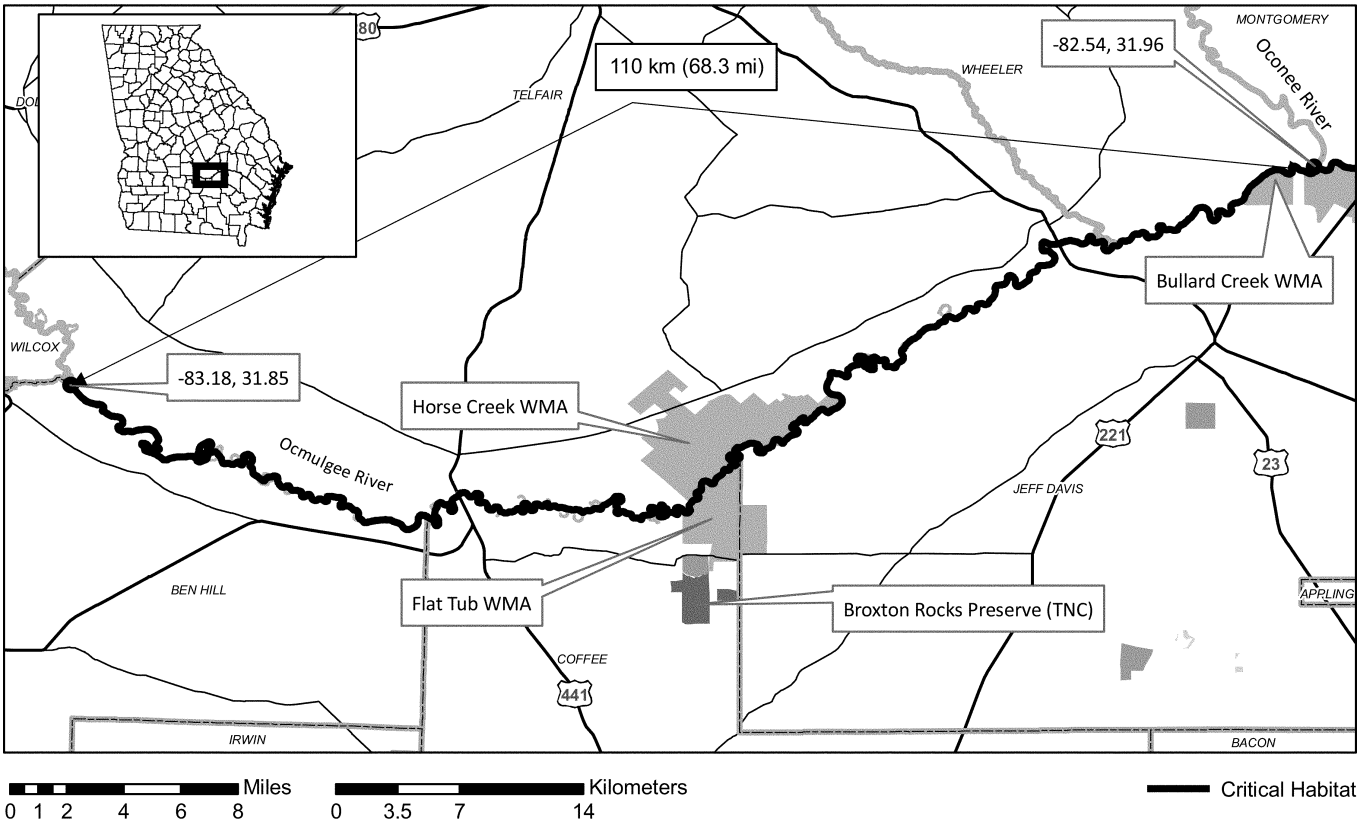


(6) *Unit 1:* Ocmulgee River, Ben Hill, Telfair, Coffee, and Jeff Davis Counties, Georgia.

(i) Unit 1 includes the channel of the Ocmulgee River from the confluence of House Creek with the Ocmulgee at Red Bluff Landing (longitude −83.18, latitude 31.85), Ben Hill and Telfair Counties, Georgia, downstream to Altamaha River (longitude −82.54, latitude 31.96), at the confluence of the Oconee and Ocmulgee Rivers, Jeff Davis and Telfair Counties, Georgia.

(ii) **Note:** Map of Unit 1 (Ocmulgee River) follows:

Unit 1 of Altamaha Spinymussel (*Elliptio spinosa*) Critical Habitat in Georgia

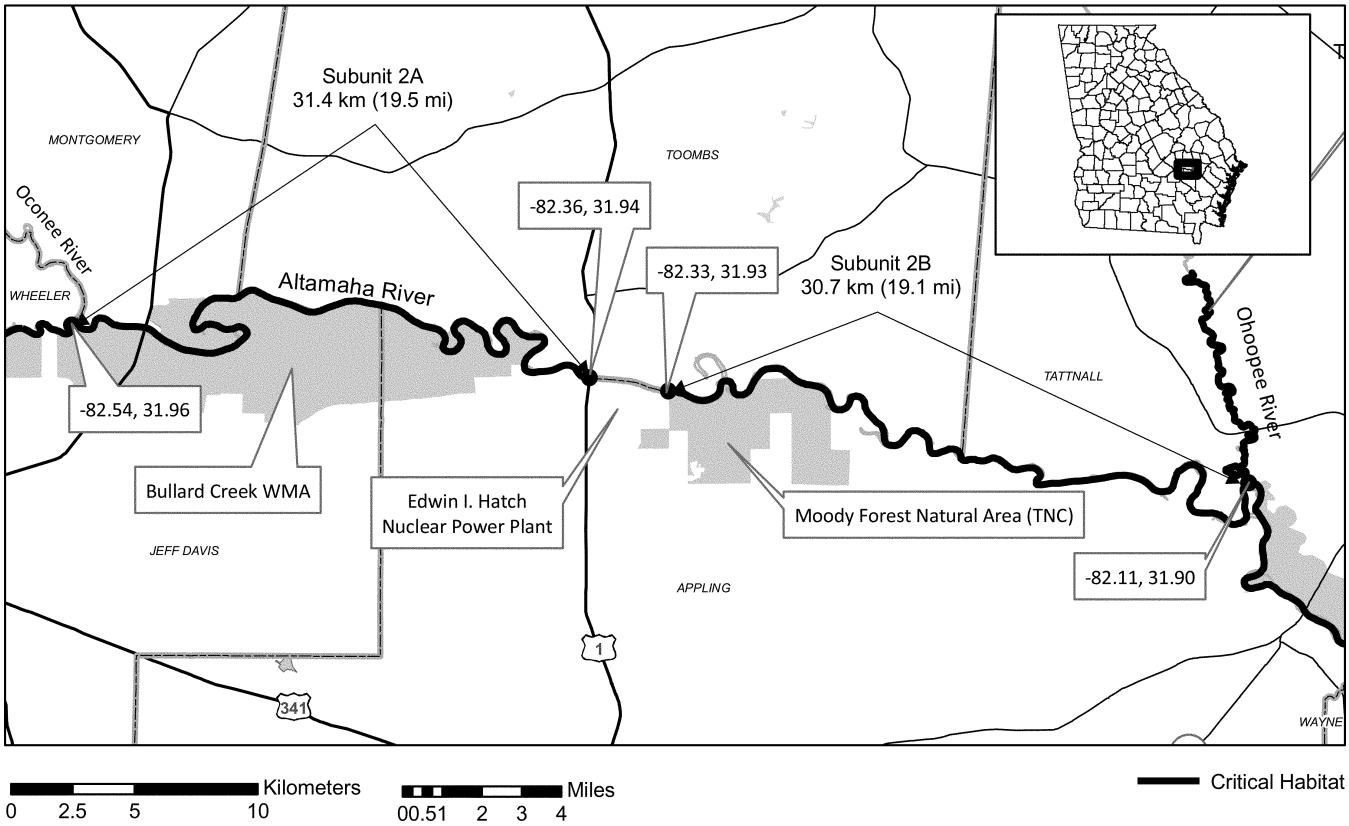


(7) *Unit 2:* Upper Altamaha River, Wheeler, Toombs, Montgomery, Jeff Davis, Appling, and Tattnall Counties, Georgia.

(i) Unit 2 includes the channel of the Altamaha River from the confluence of the Ocmulgee and Oconee Rivers (longitude −82.54, latitude 31.96), Wheeler and Jeff Davis Counties, Georgia, downstream to the US 1 crossing (longitude −82.36, latitude 31.94), and from the western edge of Moody Forest (longitude −82.33, latitude 31.93) downstream to the confluence of the Altamaha and Ohoopee Rivers (longitude −82.11, latitude 31.90), Appling and Tattnall Counties, Georgia.

(ii) **Note:** Map of Unit 2 (Upper Altamaha River) follows:

Unit 2 of Altamaha Spinymussel (*Elliptio spinosa*) Critical Habitat in Georgia

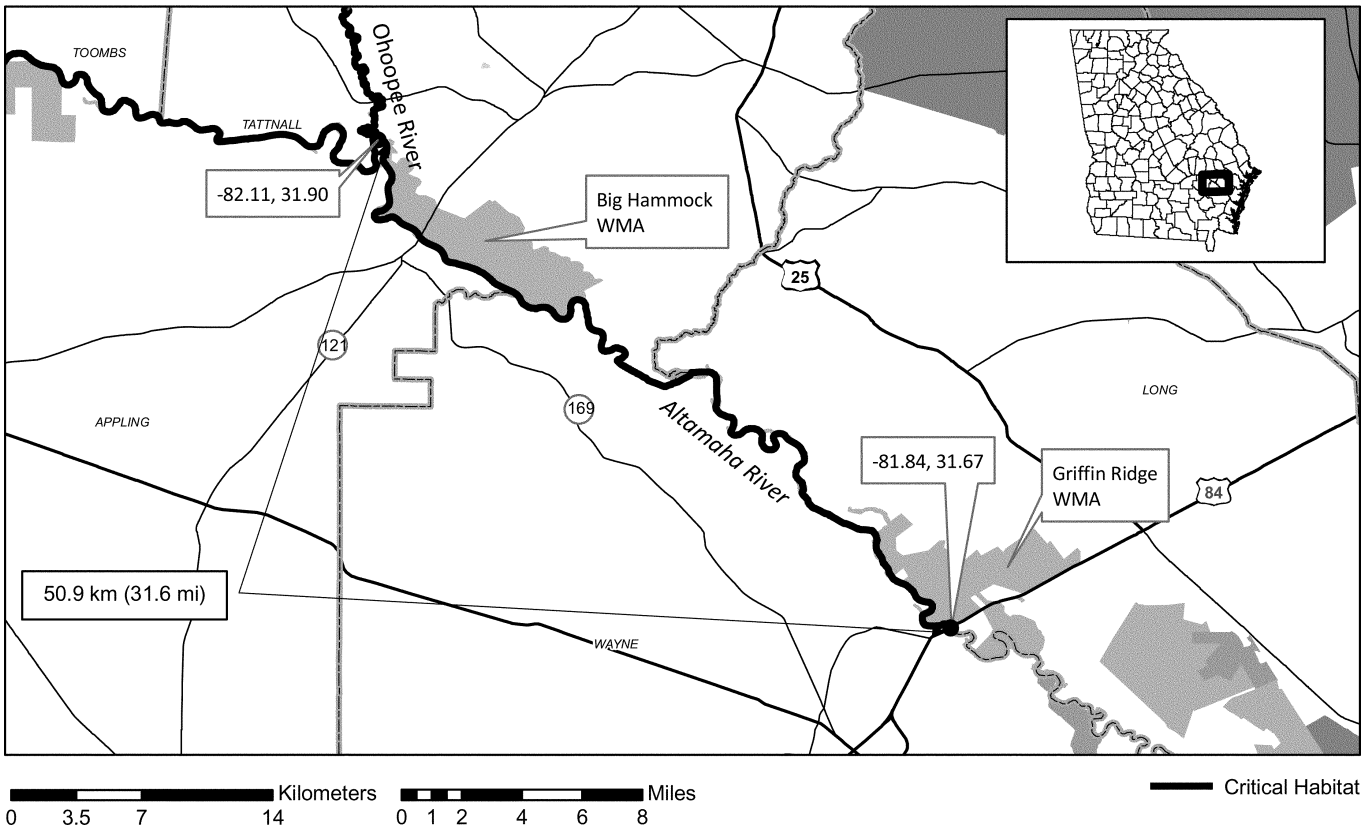


(8) *Unit 3:* Middle Altamaha River, Tattnall, Appling, Wayne, and Long Counties, Georgia.

(i) Unit 3 includes the channel of Altamaha River, extending from the confluence with the Ohoopee (longitude −82.11, latitude 31.90), Tattnall and Appling Counties, Georgia, downstream to U.S. Route 301 (longitude −81.84, latitude 31.67), Wayne and Long Counties, Georgia.

(ii) **Note:** Map of Unit 3 (Middle Altamaha River) follows:

Unit 3 of Altamaha Spinymussel (*Elliptio spinosa*) Critical Habitat in Georgia

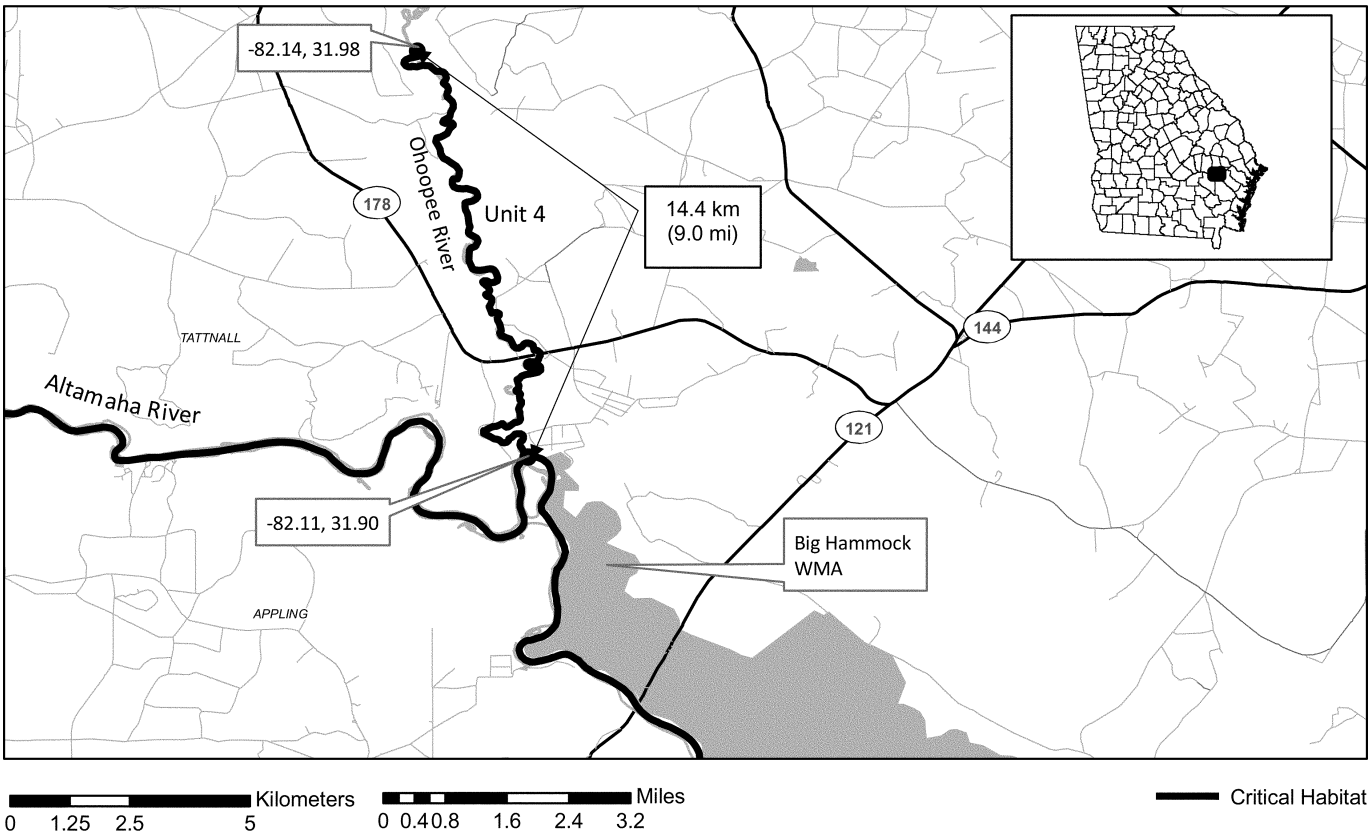


(9) *Unit 4:* Lower Ohoopee River, Tattnall County, Georgia.

(i) Unit 4 includes the channel of the Ohoopee River, starting 2.2 km (1.3 mi) upstream of Tattnall County Road 191 (longitude −82.14, latitude 31.98), Tattnall County, Georgia, downstream to the confluence of the Ohoopee River with the Altamaha River (longitude −82.11, latitude 31.90), Tattnall County, Georgia.

(ii) **Note:** Map of Unit 4 (Lower Ohoopee River) follows:

Unit 4 of Altamaha Spinymussel (*Elliptio spinosa*) Critical Habitat in Georgia



* * * * *

Dated: September 23, 2011.

Eileen Sobeck,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2011–25539 Filed 10–7–11; 8:45 am]

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FEDERAL REGISTER

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Part IV

Department of Homeland Security

Coast Guard

46 CFR Parts 108, 117, et al.

Lifesaving Equipment: Production Testing and Harmonization With International Standards; Interim Final Rule

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Parts 108, 117, 133, 160, 164, 180, and 199

[Docket No. USCG–2010–0048]

RIN 1625–AB46

Lifesaving Equipment: Production Testing and Harmonization With International Standards

AGENCY: Coast Guard, DHS.

ACTION: Interim rule.

SUMMARY: The Coast Guard is amending its regulations for certain lifesaving equipment, including launching appliances (winches and davits), release mechanisms, survival craft (lifeboats, inflatable liferafts, and inflatable buoyant apparatuses), rescue boats, and automatic disengaging devices. The amended regulations harmonize the Coast Guard's design, construction, and performance standards for this lifesaving equipment with international standards. In addition, the regulations provide for the use of qualified independent laboratories, instead of Coast Guard inspectors, during the approval process and for production inspections of certain types of lifesaving equipment. Because the International Maritime Organization (IMO) has recently changed its international standards for lifeboat release mechanisms, the Coast Guard is issuing these amended regulations as an interim rule and will finalize the regulations after proposing amendments as necessary to address the recent IMO changes regarding release mechanisms. Additionally, recent IMO action modified the international standards for liferafts, and the Coast Guard is proposing new changes to its regulations to implement the modified international standards. The Coast Guard is publishing the proposal regarding liferafts separately in the Proposed Rules section of this issue of the **Federal Register.**

DATES: This interim rule is effective November 10, 2011. The Director of the Federal Register has approved the incorporation by reference of certain publications listed in this rule as of November 10, 2011.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2010–0048 and are available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet by going to *http://www.regulations.gov,* inserting USCG–2010–0048 in the ''Keyword'' box, and then clicking ''Search.''

Viewing incorporation by reference material. You may inspect the material incorporated by reference at U.S. Coast Guard Headquarters, 2100 Second Street, SW., Stop 7126, Washington, DC 20593–7126 between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–372–1385. Copies of the material are available as indicated in the ''Incorporation by Reference'' section of this preamble.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, e-mail or call Mr. George Grills, P.E., Commercial Regulations and Standards Directorate, Office of Design and Engineering Standards, Lifesaving and Fire Safety Division (CG–5214), Coast Guard; telephone 202–372–1385, e-mail *George.G.Grills@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–493–0402.

SUPPLEMENTARY INFORMATION:

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  B. Small Entities
  C. Assistance for Small Entities
  D. Collection of Information
  E. Federalism
  F. Unfunded Mandates Reform Act
  G. Taking of Private Property
  H. Civil Justice Reform
  I. Protection of Children
  J. Indian Tribal Governments
  K. Energy Effects
  L. International Trade Impacts
  M. Technical Standards
  N. Coast Guard Authorization Act Sec. 608 (46 U.S.C. 2118(a))
  O. Environment

I. Abbreviations

ASTM American Society for Testing and Materials
CFR Code of Federal Regulations
COLREG International Regulations for Preventing Collisions at Sea
DHS Department of Homeland Security
EPA Environmental Protection Agency
FRP Fiber Reinforced Plastic
GSA General Services Administration
IMO International Maritime Organization
ISO International Organization for Standardization
LSA Life-saving Appliance
MRA Mutual Recognition Agreement
MSC Maritime Safety Committee of the International Maritime Organization
NAICS North American Industry Classification System
NEPA National Environmental Policy Act 1969 (42 U.S.C. 4321–4370f)
NPRM Notice of Proposed Rulemaking
NTTAA National Technology Transfer and Advancement Act (15 U.S.C. 272 note)
OCMI Officer in Charge, Marine Inspection
OIRA Office of Information and Regulatory Affairs
OMB Office of Management and Budget
SNPRM Supplemental Notice of Proposed Rulemaking
SOLAS International Convention for Safety of Life at Sea, 1974, as amended
§ Section symbol
UL Underwriters Laboratories
U.S.C. United States Code
USCG United States Coast Guard
US/EC MRA Agreement between the United States and European Community on the mutual recognition of certification of conformity for marine equipment

II. Regulatory History

On August 31, 2010, the Coast Guard published a notice of proposed rulemaking (NPRM) titled ''Lifesaving Equipment: Production Testing and Harmonization with International Standards'' in the **Federal Register**. *See* 75 FR 53458. The comment period for the NPRM closed on November 29, 2010, and we received three letters in the docket, containing 29 comments, which are summarized and responded to below. No public meeting was requested for this rulemaking and we did not hold one.

The Coast Guard is promulgating these amended regulations as an interim rule, rather than as a final rule, because we plan to propose additional amendments as necessary to address recent changes to international standards regarding performance requirements for release mechanisms of lifeboats. In May 2011, the International Maritime Organization's (IMO) Maritime Safety Committee (MSC) amended its international standards regarding release mechanisms. These IMO amendments only affect release mechanisms with respect to their operating characteristics and a new requirement to use corrosion-resistant materials for certain critical components. These IMO amendments are presented in IMO Resolution MSC.320(89) ''Adoption of amendments to the International Life-saving

Appliance (LSA) Code.'' A copy of the IMO amendments are available from IMO and also upon request sent to Mr. Grills, as listed in **FOR FURTHER INFORMATION CONTACT**, above. The Coast Guard plans to publish in a future **Federal Register** document proposed changes to Coast Guard regulations to implement the IMO amendments the Coast Guard determines appropriate for purposes of harmonization and consistency with international standards. We will finalize this interim rule at the same time we issue any final rule for the forthcoming proposed changes to implement the IMO amendments.

Additionally, IMO also recently adopted two new resolutions that affect the interim rule regarding inflatable liferafts and inflatable buoyant apparatuses. The two new resolutions, Adoption of Amendments to the International Life-Saving Appliance (LSA) Code (MSC.293(87)) and Adoption of Amendments to the Revised Recommendation on Testing of Life-Saving Appliances (MSC.295(87)), affect capacity requirements for such liferafts, and by extension inflatable buoyant apparatuses, but do not affect any other part of the interim rule. The Coast Guard proposes changes to the interim rule to address these two new resolutions, and that proposal is published separately in this issue of the **Federal Register** as a Supplemental Notice of Proposed Rulemaking (SNPRM).

III. Basis and Purpose

The Coast Guard is charged with ensuring that lifesaving equipment used on vessels subject to inspection by the United States meets specific design, construction, and performance standards. *See* 46 U.S.C. 3306. The Coast Guard carries out this charge through the approval of lifesaving equipment per 46 CFR part 2, subpart 2.75. The approval process includes: Pre-approving lifesaving equipment designs, overseeing prototype construction, witnessing prototype testing, and monitoring production of the equipment for use on U.S. vessels. *See* 46 CFR part 159. At each phase of the approval process, the Coast Guard sets specific standards to which lifesaving equipment must be built and tested. Third parties, referred to as independent laboratories, sometimes assist the Coast Guard in its approval process by performing or witnessing tests and inspections, as well as witnessing production, as authorized by the Coast Guard. *See, e.g.,* 46 CFR 160.151–13(a) (manufacturers must arrange for an independent laboratory to inspect a prototype liferaft during fabrication). This rulemaking revises those specific standards for launching appliances, release mechanisms, survival craft, rescue boats, and automatic disengaging devices, and expands the use of independent laboratories in the Coast Guard's approval process.

A. International Standards

International safety standards for the lifesaving equipment addressed by this rulemaking are established by the Parties to SOLAS, including the United States, acting through the IMO. The international standards for lifesaving equipment (IMO standards) addressed by this rulemaking implement the requirements of Chapter III of SOLAS. The IMO standards specify design, construction, performance, and testing requirements for required lifesaving equipment, including launching appliances, release mechanisms, survival craft, rescue boats, and automatic disengaging devices. The primary IMO standards implementing Chapter III of SOLAS are—

- International Life-saving Appliance Code (''LSA Code'') (IMO Resolution MSC.48(66), as amended by IMO Resolutions MSC.207(81), MSC.218(82), MSC.272(85), and MSC.293(87)); *see* SOLAS Chapter III, Regulation 4; [1] and
- Revised recommendation on testing of life-saving appliances (''Recommendation on Testing'') (IMO Resolution MSC.81(70), as amended by IMO Resolutions MSC.226(82), MSC.274(85), and MSC.295(87)); *see* SOLAS Chapter III, Regulation 4.[2]

The United States actively participated in the negotiations that led to the development of these IMO standards. The Coast Guard considers these IMO standards to represent the best available standards for lifesaving appliances and to be appropriate for lifesaving appliances for all vessels subject to inspection by the United States. In order to facilitate international commerce with other contracting governments to SOLAS that follow IMO standards, and to achieve the benefits of the increased safety of adhering to these IMO standards, the Coast Guard has, pursuant to 46 U.S.C. 3306 and 46 CFR 159.005–7(c), deemed compliance by U.S. flag ships with the IMO standards as compliance with Coast Guard domestic regulations.

In this interim rule, the Coast Guard harmonizes its regulations for certain lifesaving equipment with international standards by incorporating the IMO standards into regulations in 46 CFR part 160.

B. Independent Laboratories

The Coast Guard has a long history of recognizing the qualifications of independent laboratories, working under the Coast Guard's oversight, to do work traditionally conducted by Coast Guard inspectors. In 1979, the Coast Guard promulgated 46 CFR part 159 establishing procedures and standards for accepting independent laboratories for witnessing or performing certain tests and conducting inspections for certain equipment and materials requiring Coast Guard approval. *See* 44 FR 73038 (December 17, 1979). The Coast Guard promulgated 46 CFR part 159 under the authority in 46 U.S.C. 481 (1976) (Regulations for vessels subject to Coast Guard inspection).[3] In 1983, Congress revised and recodified the maritime laws of the United States moving the relevant authority for 46 CFR part 159 to new 46 U.S.C. 3306.[4] *See* Public Law 98–89 Partial

[1] As discussed above, IMO recently adopted IMO Resolution MSC.293(87). The only amendment to the LSA Code made by this resolution relevant to this rulemaking affects capacity requirements for inflatable life rafts and inflatable buoyant apparatuses. This amendment is discussed in more detail in the SNPRM.

[2] As discussed above, IMO recently adopted IMO Resolution MSC.295(87). The only amendment to the revised recommendation on testing made by this resolution relevant to this rulemaking affects tests, accounting for the change in capacity requirements, for inflatable liferafts and inflatable buoyant apparatuses. This amendment is discussed in more detail in the SNPRM.

[3] In 1979, the authority for 46 CFR part 159 also included 46 U.S.C. 391, which covered ''vessels carrying certain cargoes in bulk.'' The broader authority under 46 U.S.C. 481 covered vessels subject to inspection and certification by the United States Coast Guard and directed ''the Secretary of the Department in which the Coast Guard is operating * * * shall prescribe such rules and regulations as may be necessary for vessels subject to inspection and certification by the United States Coast Guard with respect to the following matters: (1) Lifesaving equipment, including but not limited to, the number, type, size, capacity, details of construction, methods of operation, stowage, maintenance, manning, use, testing, and inspection of such equipment, and drills and exercises necessary to assure proper functioning and use of such equipment * * *'' The Coast Guard determined that the use of independent laboratories for witnessing or performing certain tests and inspections was ''necessary'' to carry out its responsibilities under this statutory section. In the notice of proposed rulemaking proposing 46 CFR part 159, the Coast Guard explained that ''the Coast Guard's marine inspection responsibilities increased while the number of personnel available to perform these inspections has not increased at a comparable rate.'' 43 FR 49440 (October 23, 1978). The Coast Guard promulgated part 159 to ''free some of the Coast Guard's limited field personnel for other duties with no change in the quality of the approved equipment or material.'' *Id.;* see also 44 FR 73038 (December 17, 1979) (Final Rule document promulgating part 159).

[4] Section 3306 directs ''the Secretary shall prescribe necessary regulations to ensure proper execution of, and to carry out, this part [addressing

Continued

Revision of Title 46, U.S.C. ''Shipping''; House Report No. 98–338 (August 1, 1983), 1983 U.S.C.C.A.N. 924, 954–53.

The authority for current 46 CFR part 159 is 46 U.S.C. 3306, which ''contains broad authority to prescribe regulations for proper inspection and certification of vessels,'' House Report No. 98–338 (August 1, 1983), 1983 U.S.C.C.A.N. 924, 954–53, including the specific requirement to prescribe regulations to carry out the statutory requirements ''in the most effective manner,'' 46 U.S.C. 3306(a). The Coast Guard still finds the use of independent laboratories in the Coast Guard's approval process to be ''the most effective manner'' of executing and carrying out its obligations under section 3306.

Independent laboratories, accepted by the Coast Guard under 46 CFR part 159, assist the Coast Guard in its approval process by performing or witnessing certain tests and conducting certain inspections required for Coast Guard approval of equipment and materials. When performing or witnessing tests, independent laboratories must follow Coast Guard standards and procedures, and may deviate from those standards and procedures only to require more stringent standards and procedures, and only with Coast Guard approval. *See* 46 CFR 159.007–3. Additionally, all accepted independent laboratories must be impartial and disinterested in the outcome of inspections and tests. *See* 46 CFR 159.010–3(a)(3)–(5) (requiring an independent laboratory not be owned or controlled by a manufacturer, vendor, or supplier of materials for the equipment or material to be inspected; not be dependent on acceptance as an independent laboratory to remain in business, and not advertise or promote equipment or materials that the independent laboratory inspects or tests).

The Coast Guard reviews independent laboratory test and inspection reports when determining the approvability of equipment and materials. The Coast Guard currently allows accepted independent laboratories to witness tests of almost all types of shipboard equipment, including certain lifesaving equipment. *See, e.g.,* 46 CFR 160.010–9(a) (approval and production tests in subpart 160.010, addressing buoyant apparatuses, must be conducted by an independent laboratory); 46 CFR 160.151–13(a) (manufacturers must arrange for an independent laboratory to inspect a prototype liferaft during fabrication); and 46 CFR 160.151–31(a) (production inspections and tests of inflatable liferafts must be carried out in accordance with the procedures for independent laboratory inspection).

Current regulations in 46 CFR part 160, however, require Coast Guard inspectors to be involved in all phases of the approval process of winches, davits, release mechanisms, lifeboats, and rescue boats. *See* 46 CFR part 160, subparts 160.015 (winches), 160.032 (davits), 160.033 (release mechanisms), 160.035 (lifeboats), and 160.056 (rescue boats).

Requiring Coast Guard inspectors to directly perform all phases of the approval process, however, can cause scheduling delays and increased expenses for manufacturers of lifesaving equipment. For example, Coast Guard inspectors are not always able to meet manufacturers' schedules due to competing inspection demands and resource constraints. This can impede productivity and affect the availability of Coast Guard approved equipment for U.S. flag vessels. Third-party certification bodies may qualify as accepted independent laboratories and are often available locally with greater convenience to manufacturers.

Additionally, many manufacturers produce lifesaving equipment for multiple flag nations' vessels, and must have their equipment approved by each nation. Manufacturers often use third-party certification bodies for testing and inspection to satisfy certification requirements from other nations. Unless these third parties are qualified to witness tests and perform inspections on behalf of more than one nation, manufacturers must have their equipment inspected and tested by more than one national representative, which carries potential complications and delays.

The Coast Guard has found, through past experiences with U.S. flag vessel inspections and shipboard equipment approvals, that permitting independent laboratories to do work under appropriate Coast Guard oversight ultimately promotes safety, flexibility, and autonomy by permitting experts from industry to engage more directly in the inspection processes while preserving the Coast Guard's safety and stewardship role in the maritime community.

In this interim rule, the Coast Guard extends the use of independent laboratories, under the oversight of Coast Guard inspectors, in the approval process for additional lifesaving equipment. The Coast Guard requires manufacturers to use an independent laboratory for prototype fabrication and production oversight, and provides the option in certain cases for manufacturers to use an independent laboratory, again overseen by the Coast Guard, for pre-approval review and prototype testing oversight.

C. Other Revisions

In this interim rule, the Coast Guard also revises the structure of certain subparts affected by this rulemaking, and makes additional conforming, appliance-specific changes to these subparts not related to harmonization with international standards or use of independent laboratories.

IV. Discussion of the Comments and Changes

The Coast Guard's regulations addressing lifesaving equipment are found in 46 CFR part 160. Each subpart addresses a specific type of lifesaving equipment. The Coast Guard is amending these subparts to:

- Harmonize its regulations with IMO standards for launching appliances (winches and davits), release mechanisms, survival craft (lifeboats, inflatable liferafts, and inflatable buoyant apparatuses), and rescue boats, and add new harmonized rules addressing automatic disengaging devices;
- Incorporate the use of independent laboratories, under Coast Guard oversight, for Coast Guard approval procedures for launching appliances, lifeboats, rescue boats, and release mechanisms, and add such use of independent laboratories to new rules addressing automatic disengaging devices; and
- Revise the structure of certain subparts affected by this rulemaking, and make additional appliance-specific changes to these subparts not related to harmonization with international standards or use of independent laboratories. This revision includes updating, adding, or removing certain standards incorporated by reference and creating a new subpart in 46 CFR part 164 addressing fire-retardant resins used in the construction of lifeboats and rescue boats.

A complete discussion of these changes is available in the NPRM, published August 30, 2010. *See* 75 FR 53458, 53460.

A. Discussion of Changes From the NPRM

In the interim rule, the Coast Guard is making changes to the rule text as

inspection and regulation of vessels] in the most effective manner for (1) The design, construction, alteration, repair, and operation of those vessels [subject to inspection] * * * ; (2) lifesaving equipment and its use; (3) firefighting equipment, its use, and precautionary measures to guard against fire; (4) inspections and tests related to paragraphs (1), (2), and (3) of this subsection; and (5) the use of vessel stores and other supplies of a dangerous nature * * *.''

proposed in the NPRM (75 FR 53458 (August 30, 2010)). Some of the changes clarify the meaning of the proposed rule text, make requirements less restrictive than proposed, and many of these changes are in response to comments, as noted and discussed in this section. Other changes correct minor, inadvertent inaccuracies in the proposed rule text. While several of the changes are not related to or in response to a comment, the Coast Guard considers these changes to be a ''logical outgrowth'' of what was proposed in the NPRM, as discussed for each such change below, and that further notice and comment on them is not required.[5]

1. Officer-in-Charge, Marine Inspection (OCMI) Definition

The Coast Guard is changing the definition of OCMI in 46 CFR 160.115–3, 160.132–3, 160.133–3, 160.135–3, 160,151–3, 160.156–3, and 160.170–3 in the interim rule to more accurately align with existing definitions and delineation of OCMI responsibilities in Coast Guard regulations. The definition of OCMI in the proposed rule only addressed OCMIs assigned to Coast Guard Districts and inadvertently did not cover OCMIs assigned to Activities Europe. The interim rule defines OCMI by referring to 46 CFR 1.01–15(b), which details the responsibilities and duties of all OCMIs. If the Coast Guard makes any change to the responsibilities and duties of its OCMIs generally, it will make the changes in 46 CFR 1.01–15(b). By referring to 46 CFR 1.01–15(b), the definition of OCMI in subparts 160.115, 160.132, 160.133, 160.135, 160.151, 160.156, and 160.170 will always reflect the most current definition of an OCMI. The definition of OCMI in the proposed rule also defined the ''cognizant OCMI'' as ''the OCMI who has immediate jurisdiction over a vessel for the purpose of performing the duties previously described.'' The subparts affected by this rulemaking, however, address equipment, not vessels. As such, the Coast Guard is adding the phrase ''or geographic area'' to the sentence defining ''cognizant OCMI'' to make the definition more accurate. These changes are a logical outgrowth of the definition of OCMI in the proposed rule because the purpose of the proposed definition was to specify the Coast Guard personnel with responsibility under the proposed rule, and these changes clarify but do not otherwise affect that. The NPRM clearly specified the cognizant OCMI would be the responsible Coast Guard personnel, and intended the description of an OCMI to be consistent with the main definition of ''OCMI'' found in 46 CFR 1.01–15(b). The interim rule still specifies that OCMIs have responsibility under the interim rule and the interim rule definition of OCMI only more accurately describes OCMIs by aligning the definition with the Coast Guard's main regulation defining the duties and responsibility of its OCMIs and clarifying the definition of ''cognizant OCMI.''

2. Welder Certification

In response to a comment, the Coast Guard is expanding the certification requirement for welders in 46 CFR 160.115–7(b)(4), 160.132–7(b)(4), 160.133–7(b)(4), 160.135–7(b)(4), 160.156–7(b)(4), and 160.170–7(b)(4). The comment asked whether the reference to the American Bureau of Shipping would remain in the proposed rule requirement that welding must be performed by ''welders certified by the Commandant, American Bureau of Shipping, U.S. Navy, or an independent laboratory accepted by the Commandant.''

No. The Coast Guard has replaced, in the interim rule, the reference to American Bureau of Shipping with a phrase to encompass all Coast Guard-recognized classification societies, as well as revised the regulatory text to include other welder certifications to accommodate overseas manufacturing. The proposed rule would have required welders to be certified by the Commandant, American Bureau of Shipping, U.S. Navy, or an independent laboratory accepted by the Coast Guard. The proposed rule specifically mentioned the American Bureau of Shipping because historically it was the only classification society recognized by the Commandant. The proposed rule used the phrase ''independent laboratory accepted by the Coast Guard'' to cover welder certifications by other certifying bodies similar to American Bureau of Shipping, including other Coast Guard-recognized classification societies. The Coast Guard currently recognizes several classification societies in addition to the American Bureau of Shipping under the requirements of 46 CFR 8.220. Additionally, the Coast Guard is aware that, although American Bureau of Shipping-certified welders are readily available within the United States, this is not necessarily true overseas. The proposed rule's inclusion of ''independent laboratory accepted by the Coast Guard'' to cover welder certifications by other certifying bodies did not adequately cover welder certifications by other Coast Guard-recognized classification societies or other certifying bodies similar to Coast Guard-recognized classification societies.

The Coast Guard has revised the interim rule to appropriately reflect the Coast Guard's recognition of several classification societies and to cover welder certifications by other appropriate certifying bodies. Specifically, the revised regulatory text in the interim rule now states, ''welders certified by the Commandant, a classification society recognized by the Commandant in accordance with 46 CFR 8.220, the U.S. Navy, or the national body where the [lifesaving equipment] is constructed or the national body's designated recognized organization.'' The Coast Guard notes that the phrase ''classification society recognized by the Commandant in accordance with 46 CFR 8.220'' covers the American Bureau of Shipping for as long as it remains recognized in accordance with 46 CFR 8.220. These changes are a logical outgrowth of the NPRM because, although the proposed rule text did not adequately cover overseas welder certifications, the NPRM made clear that the proposed rule was designed in many instances to recognize that much of the lifesaving equipment covered by this rulemaking is manufactured overseas and to accommodate overseas manufacturing. See, for example, the discussion in the NPRM preamble in section VI. B. 75 FR 53463. It was inconsistent for the proposed rule to specifically expand the use of independent laboratories in the approval and inspection process to relieve manufacturers of certain burdens associated with this process, and then to also limit the use of welders for manufacturing to only those welders with U.S. certifications. Expanding the options for welder certifications to accommodate overseas manufacturing in the interim rule is a logical outgrowth of the NPRM's proposal to revise Coast Guard regulations to accommodate overseas manufacturing.

3. Launching Appliances for Fast Rescue Boats

The Coast Guard is correcting the reference to the LSA Code in the interim rule, § 160.115–7(a)(1), to ensure inclusion of the standards for launching appliances intended to be used with fast rescue boats. Proposed 160.115–7(a)(1) included LSA Code ''Chapter VI/6.1.1

[5] *See Int'l Union, United Mine Workers of Amer.* v. *Mine Safety and Health Admin.,* 626 F.3d 84, 95 (D.C. Cir. 2010) (''a final rule will be deemed to be the logical outgrowth of a proposed rule if a new round of notice and comment would not provide commenters with their first occasion to offer new and different criticisms which the agency might find convincing.'') (internal citations omitted).

and 6.1.2,'' for incorporation by reference. This citation to the LSA Code was too specific and erroneously omitted standards for launching appliances intended to be used with fast rescue boats included in provisions of LSA Code Chapter VI/6.1, which is the citation included in the interim rule. This change is a logical outgrowth because the proposed rule included the tests applicable to these launching appliances in § 160.115–7(b)(2) and highlighted the omission in proposed paragraph (a)(1) of the standards to which to test these launching appliances under proposed paragraph (b)(2).

4. Steel Grade Specification

In the interim rule, the Coast Guard is incorporating by reference three additional American Society for Testing Materials (ASTM) standards to correct a reference in the proposed rule to a stainless steel grade without the necessary standard reference. Proposed 46 CFR 160.133–7(b)(3), 160.135–7(b)(3), 160.156–7(b)(3), and 160.170–7(b)(3) stated ''Corrosion resistant steel must be a standard 302 stainless steel or have equal or superior corrosion resistant characteristics.'' While those familiar with 302 stainless steel would recognize it as an American Iron and Steel Institute (AISI) or ASTM designation, the proposed rule did not specify the designation. The Coast Guard is incorporating by reference ASTM A276–08a ''Standard Specification for Stainless Steel Bars and Shapes'', ASTM A313/A313M–08 ''Standard Specification for Stainless Steel Spring Wire'', and ASTM A314–08 ''Standard Specification for Stainless Steel Billets and Bars for Forging'' in each of the affected subparts, and each of the affected sections references these standards. The language in the interim rule reads: ''type 302 stainless steel per ASTM A276, A313 or A314.'' The interim rule retains the option for using another corrosion resistant steel of equal or superior corrosion resistant characteristics. This change is a logical outgrowth from the proposed rule because the omission of the specific standards organization designation in the proposed rule was clear from the text of the proposed rule. It would have been difficult to comply with the stainless steel requirement in the proposed rule without any reference to the specific designation, and the proposed rule provision providing the option to use other equal or superior steel was meaningless without appropriate designation of type 302 steel.

5. Clarifying Action of Independent Laboratories

In response to a comment, the Coast Guard is making a clarifying editorial change throughout the interim rule to reflect the fact that independent laboratories sometimes perform required tests and other times only witness the performance of required tests, depending on the circumstances. The comment suggested that the repeated NPRM preamble statement, ''The independent laboratory must perform or witness the inspections and tests under this section * * *'' is misleading because laboratories are otherwise only required by the proposed rule to witness tests, and not to perform them. The commenter suggested that the wording in the preamble should be changed to, ''The independent laboratory must witness the inspections and tests under this section * * *''

The Coast Guard clarifies that under the proposed and interim rules, independent laboratories both perform and witness required tests depending upon the circumstances. In order to ensure the interim rule accurately reflects these different, required actions of independent laboratories, and to ensure consistency of terminology between the affected subparts, the interim rule replaces instances of ''conduct or witness,'' ''conduct,'' and ''perform or witness'' with the phrase ''perform or witness, as appropriate,'' in 46 CFR 160.115–15, 160.132–15, 160.133–15, 160.135–11, 160.135–15, 160.156–11, 160.156–15 and 160.170–15, as necessary.

6. Adding an Additional, Optional Artificial Weathering Method for Resins

In response to a comment, the Coast Guard is adding an additional, optional method for artificially weathering resins in 46 CFR part 160, Table 164.120–7. In the proposed rule, this table was numbered as Table 164.017–7; see Section 7, Editorial Changes, below for more details on the renumbering. As proposed, Table 164.120–7(d)(5) (Table 164.017–7 in the NPRM) provided the option of weathering specimens by either 1 year per MIL–R–7575C, or 500-hour exposure per ASTM G154 Table X2.1 Cycle 3. The comment suggested adding as an alternative or changing to Cycle 1 in Table X2.1 of ASTM G154—UVA–340 exposure at Table 164.120–7 (UV test according to ASTM G154), stating that UVA exposure is seen as a more realistic comparison to natural weathering. The Coast Guard agrees that Cycle 1 is also an appropriate artificial weathering method, and has revised the regulatory text accordingly. In the interim rule, resin artificial weathering testing may be performed using Cycle 1 or Cycle 3 of ASTM G154.

7. Limiting Clear Resin Requirements for Lifeboats and Rescue Boats

In response to a comment, the Coast Guard is clarifying the meaning of proposed §§ 160.135–11(c)(2)(i)(A) and 160.156–11(c)(2)(i)(A). The commenter pointed out that in the proposed rule, §§ 160.135–11(c)(2)(i)(A) and 160. 156–11(c)(2)(i)(A) may be read to imply that every Fiber Reinforced Plastic (FRP) component of a prototype needs to be of clear resin, including the gel coat. The commenter suggested that this requirement be limited to the outer hull and FRP inner hull components which are bonded or bolted to the outer hull. The Coast Guard agrees the language of the proposed rule was unclear, and agrees with the commenter's suggestion, which was the intended meaning of the proposed rule's text. The Coast Guard has revised §§ 160.135–11(c)(2)(i)(A) and 160.156–11(c)(2)(i)(A) to clarify that only the outer hull and FRP inner hull components bonded or bolted to the outer hull must be constructed of clear resin.

8. Editorial Changes

The Coast Guard is making two clarifying editorial changes requested by commenters: (1) In § 160.115–7(b)(6)(vi)(B), the reference in the proposed rule to ''12 inches'' now reads in the interim rule as ''0.3m (12 in)'' for consistency throughout the rules in citing the metric measurement and noting the U.S. customary measurement in parentheses; and (2) in § 160.135–7(b)(12) the Coast Guard adds the word ''hull'' before ''drain plug'' in the paragraph heading to avoid confusion with engine oil pan drain plugs, or with other drain plugs.

Additionally, as suggested by a commenter, the Coast Guard is renumbering proposed 46 CFR part 164, subpart 164.017 as 46 CFR part 164, subpart 164.120. The commenter suggested that the choice of ''164.017'' for a new subpart number addressing fire retardant resins for lifeboats and rescue boats is possibly confusing because this designation might not be consistent with the currently applied numbering convention in 46 CFR. The current numbering convention used in 46 CFR correlates domestic-applicable—subparts 160.0XX—with SOLAS-applicable—subparts 160.1XX. This same numbering convention also applies to approval series. Under this convention, the correlating SOLAS-applicable approval series to proposed subpart 164.017 would be current

approval series 164.117, which is assigned to SOLAS Floor Coverings. The commenter recommended number ''164.050'' or higher as a suitable alternative. The Coast Guard has renumbered proposed 46 CFR part 164, subpart 164.017 to subpart 164.120 to resolve the conflict with the approval series assigned to floor coverings and to acknowledge that the proposed subpart is consistent with SOLAS requirements.

Finally, the Coast Guard is making additional non-substantive changes to the references to documents incorporated by reference and to correct a typo. The Coast Guard updated the citations to IMO documents incorporated by reference to make them easier to identify and to obtain copies. The Coast Guard has updated citations of other standards incorporated by reference by providing cites to edition and date, as applicable, to ensure proper identification of the standard and to conform to **Federal Register** requirements for incorporations by reference. None of the standards with updated citations have changed from the NPRM to the interim rule. The Coast Guard also removed two standards (ISO 2039–1:2001 and MIL P 17549D(SH)) that were erroneously proposed for incorporation by reference in part 164.120 because they were not proposed for use in part 164.120 in the NPRM and are not used in the interim rule. The NPRM proposed incorporation by reference of ISO 2039–1:2001 and ISO 2039–2:1987 in § 165.120–7, but that section only referenced ''ISO 2039'' as an equivalent, alternative to ASTM D 2583. Those familiar with these standards would recognize that ISO 2039–2:1987 is the equivalent, alternative to ASTM D 2583 for determining indentation hardness. The interim rule does not contain the unnecessary ISO standard and corrects the reference in § 165.120–7 to read ''ISO 2039–2.'' The NPRM proposed incorporate by reference of MIL P 17549D(SH) but the proposed rule and interim rule do not reference to this standard in part 164.120. The Coast Guard is also correcting a typo that appeared in the proposed definition of ''Independent Laboratory'' in proposed § 160.132–3. The proposed definition incorrectly referenced 46 CFR 169.001–3 instead of 46 CFR 159.001–3, which was correctly referenced in all other definitions of ''Independent Laboratory'' in the proposed rule.

B. Discussion of Comments on the NPRM

The Coast Guard received 29 comments in response to the NPRM published on August 31, 2010. *See* 75 FR 53458. Several comments proposed changes or made comments prompting changes in the interim rule, as discussed above in Section A, Discussion of Changes from the NPRM. The following paragraphs contain an analysis of the remaining comments received.

One commenter noted the two new resolutions recently adopted by IMO and asked whether the Coast Guard will require compliance with the amendments to the LSA Code and Recommendation on Testing that affect liferaft capacity requirements.

As discussed above in II, Regulatory History, the Coast Guard is publishing an SNPRM to propose changes to the interim rule to address these two new resolutions. The SNPRM is published separately in this issue of the **Federal Register** and the Coast Guard seeks comment on the proposed changes in the SNPRM.

One commenter noted that, under the Agreement between the United States and European Community on the mutual recognition of certification of conformity for marine equipment (US/EC MRA) and the agreement between the United States and the European Economic Area and European Free Trade Association countries on the Mutual Recognition for Conformity of Marine Equipment (US/EEA/EFTA MRA), a Notified Body [6] issues Coast Guard approval certificates, and asked whether the Coast Guard intends to modify this, based on the NPRM preamble statement: ''The Coast Guard would remain the sole issuer of certificates of approval for Coast Guard-approved lifesaving equipment.'' The commenter also stated that an independent laboratory publishes its approval certificates, and asked whether such publication would violate the proposed rule.

The Coast Guard clarifies that Notified Bodies, recognized under the US/EC MRA and the US/EEA/EFTA MRA, do not issue Coast Guard Certificates of Approval, but are permitted to issue a Coast Guard approval number for certain types of equipment and assign it to the Notified Body's certificate in accordance with the US/EC MRA and the US/EEA/EFTA MRA. For more information on the US/EC MRA and the US/EEA/EFTA MRA, please see Navigation and Inspection Circular 08–04 change 1 (available at: *http://www.uscg.mil/hq/cg5/nvic/pdf/2004/08–04change1.pdf*).

[6] A Notified Body is generally a testing or certification organization recognized by the European Union to evaluate certain equipment, similar to an independent laboratory accepted by the Commandant.

The Coast Guard notes that the only equipment affected by this rulemaking currently covered by the US/EC MRA and the US/EEA/EFTA MRA is liferaft automatic disengaging devices, which are addressed in 46 CFR part 160, subpart 160.170. Liferaft automatic release mechanisms may have a Certificate of Approval issued by the Coast Guard or a Coast Guard approval number issued by the appropriate Notified Body. The Coast Guard recognizes that an independent laboratory may also be a Notified Body, and clarifies that an independent laboratory publishing its approval certificates for equipment covered by the US/EC MRA and the US/EEA/EFTA MRA does not violate this rule, and in fact is required for Coast Guard approvals issued under the MRAs. The Coast Guard notes that, unless issued in accordance with one of the MRAs, an independent laboratory's approval certificate does not constitute Coast Guard approval. The Coast Guard further clarifies that for all other equipment it will remain the sole issuer of Certificates of Approval for Coast Guard-approved lifesaving equipment.

One commenter pointed out the discussion in the NPRM preamble regarding the Coast Guard's intention to relieve manufacturers of the burden of multiple design reviews, or prototype tests, by multiple nations with the expanded use of independent laboratories, and asked whether there will be Mutual Recognition Agreements (MRAs) with the other nations, or whether the Coast Guard will accept approvals done by an independent laboratory on behalf of other nations.

The Coast Guard is not currently pursuing MRAs with other nations, but will accept test reports from Coast Guard-accepted independent laboratories in support of approvals for other nations, provided the testing is conducted in accordance with this interim rule. While a foreign entity may qualify as an independent laboratory accepted under 46 CFR part 159, subpart 159.010, the entity will perform duties under the interim rule on behalf of the Coast Guard, and will apply and comply with Coast Guard requirements, not with the entities' own rules or guidelines.

One commenter noted the NPRM preamble statement, ''Manufacturers of liferafts would have to demonstrate that designs previously approved under the current regulations comply with the revised regulations prior to the expiration of their current approvals,'' and asked whether the rule will delegate the design review to a recognized laboratory.

No, the Coast Guard retains the responsibility for design review for liferafts under provisions in current 46 CFR part 160, subpart 160.151, and those provisions are not affected by this rulemaking.

One commenter noted that various steps of the approval process are split between the Coast Guard and an independent laboratory for some equipment. The commenter suggested it should be ensured that the same party is involved with all parts of the approval process.

The Coast Guard disagrees. As noted in the NPRM preamble, the Coast Guard retains authority for the phases of the approval process that involve decisions about the acceptability and approvability of lifesaving equipment design and performance, preapproval plan review and prototype testing. Additionally, the Coast Guard remains the sole issuer of Certificates of Approval (except where approval numbers are issued in accordance with the US/EC MRA or the US/EEA–EFTA MRA, as discussed above).

One commenter suggested that the use of independent laboratories for plan review and prototype inspection and tests be limited to manufacturers that already hold Coast Guard Certificates of Approval for the type of equipment under consideration, and independent laboratories already involved in inspection of the type of equipment involved.

The Coast Guard disagrees with the suggested blanket limitation because, as stated in the NPRM, the authority for independent laboratories to perform these functions will be defined in the course of acceptance of the independent laboratory in accordance with 46 CFR part 159, subpart 159.010. The commenter's suggestion may be considered, as appropriate, in the course of accepting specific independent laboratories for approval of specific types of equipment. The Coast Guard notes that an entity must already be involved in inspection of the type of equipment for which they apply in order to be an accepted independent laboratory under 46 CFR part 159, subpart 159.010.

One commenter asked whether the proposed rulemaking satisfies the court order of May 31, 1983, effectuating the decision in *U.S. Lifesaving Equipment Manufacturers Association* v. *Dole,* 567 F.Supp. 696, (May 4, 1983). Specifically, the court order prohibited the Coast Guard from requiring or authorizing ''any manufacturer or manufacturers of liferafts, lifeboats, or lifeboat equipment to have such equipment inspected or tested by an independent laboratory unless USCG shall have first (a) Published an appropriate notice of proposed rulemaking in the Federal Register advising interested persons of the scope and effect of and reasons for the proposed new requirement, (b) provided an opportunity for public comment thereon, (c) fully considered all such comments, and (d) included in the final regulation an adequate statement of the basis and purpose of the new requirements.''

Yes, the Coast Guard satisfies that court order with (a) Publication of the NPRM on August 30, 2010, (b) the public comment period that closed on November 29, 2010, (c) this discussion of comments evidencing Coast Guard's consideration of all comments, and (d) the discussion above under III, Basis and Purpose.

One commenter stated that they think the word ''advertise'' in § 159.010–3(a)(3)–(5) (requiring an independent laboratory not be owned or controlled by a manufacturer, vendor, or supplier of materials for the equipment or material to be inspected; not be dependent on acceptance as an independent laboratory to remain in business, and not advertise or promote equipment or materials that the independent laboratory inspects or tests), can be taken to mean that an independent laboratory cannot list the products it has approved or allow the use of its logos on such products.

The Coast Guard agrees that under longstanding Coast Guard policy, independent laboratories may, and commonly do, mark and list equipment they have tested. The Coast Guard emphasizes, however, that under the subparts affected by this rulemaking, independent laboratories do not approve equipment on behalf of the Coast Guard.

One commenter suggested that the proposed rule provisions for permitting the use of equivalent materials should require the independent laboratory to prepare the justification of equivalency for acceptance by the Commandant. The commenter suggested that Coast Guard staff should not have to do the research required to accept such equivalencies.

The Coast Guard concurs with the spirit of the comment to relieve Coast Guard staff of researching equivalencies. Under longstanding Coast Guard policy, it is the burden of the manufacturer to demonstrate equivalency when requesting such a determination. No regulatory text changes are necessary.

One commenter asked if the Coast Guard intends that a laboratory would be required to verify the quality assurance and quality control process in a given factory and monitor batch testing of resins, per the following NPRM preamble statement: ''The scope of proposed subpart 164.017 would state that the subpart contains performance requirements, acceptance tests, and production testing and inspection requirements for fire retardant resins used in the construction of lifeboats and rescue boats approved under proposed 46 CFR part 160, subparts 160.135 and 160.156. See proposed § 164.017–1.''

No, the intent of this rulemaking is not to require independent laboratories to verify the quality assurance and quality control process at a resin manufacturer. The Coast Guard notes that new 46 CFR part 164, subpart 164.120 (proposed in the NPRM as subpart 164.017) does not contain such a requirement. The Coast Guard accepts independent laboratories for the testing and inspections of specific equipment or materials. An independent laboratory accepted for resin may not be the same independent laboratory accepted for lifeboats or rescue boats.

One commenter suggested that Table 1, ''IMO Standards and Coast Guard Proposed Interpretations,'' in the NPRM preamble should be included in the final rule because of its usefulness in showing differences between IMO standards and Coast Guard interpretations of those standards.

While the Coast Guard included Table 1 in the NPRM preamble to aid readers in understanding the regulatory text, the regulatory text is the official legal language. Table 1, however, will remain available for reference as published in the NPRM.

One commenter expressed support for § 160.135–7(b)(2), describing operator visibility requirements which exceed the requirements of the IMO LSA Code.

The Coast Guard appreciates the support.

One commenter asked whether, per the preamble statement indicating that the Coast Guard will require the installation of navigation lights on lifeboats and rescue boats, consistent with the International Regulations for Preventing Collisions at Sea (COLREGS) requirements, the Coast Guard will present such a proposal to IMO for consideration.

No, the Coast Guard does not consider such a proposal necessary since neither SOLAS nor the LSA Code exempt lifeboats or rescue boats from navigational lights as required by the COLREGS for a vessel of the relevant size and speed.

One commenter asked that the Coast Guard make available the data used in the analysis of the proposed rule's effect on small entities.

The Coast Guard notes that the data has been available since publication of the NPRM. The data is disclosed in the NPRM's Regulatory Analysis, which continues to be available on the docket where indicated under **ADDRESSES**.

One commenter suggested adding MIL–R–21607E(SH), Resins, Polyester, Low Pressure Laminating, Fire-Retardant to the list of standards in § 160.135–5(f) without providing a reason.

The Coast Guard disagrees. This standard is incorporated by reference appropriately in 46 CFR part 164, proposed subpart 164.120 (proposed in the NPRM as subpart 164.017), which is the subpart addressing resins and required standards, and is only referred to, but not required, in 46 CFR part 160, subpart 160.135.

One commenter noted that proposed § 160.156–15(b)(3) refers to a guideline for rescue boat ''Running Lot Inspections,'' but that there are no other references to running lot inspections to be found. The commenter asked whether running lot inspections will be considered in the rulemaking.

The Coast Guard notes that the NPRM did not reference guidelines for rescue boat "'Running Lot Inspections,'' nor does this rulemaking address running lot inspections. Although past practice provided the option for the use of running lot inspections, the Coast Guard did not propose the use of running lot inspections in the NPRM because the Coast Guard determined it would be impractical for this type of equipment, which is produced and inspected on an individual, versus lot, basis. As such, under the interim rule, each production rescue boat must be tested in accordance with § 160.156–15.

One commenter asked if the Coast Guard was considering allowing extended service intervals for inflatable liferafts in light of movement toward extended service, applying vacuum packing and other methods.

The NPRM did not address extended service intervals for liferafts, and the Coast Guard is not addressing extended service intervals in this interim rule.

Two commenters suggested that the ''Incorporation by reference'' and ''Definitions'' sections and preemption language for each equipment type subpart should be combined into sections to apply to all of 46 CFR part 160 or all of 46 CFR subchapter Q. The commenters suggested this will eliminate the need to have these sections in each subpart.

The Coast Guard appreciates the potential gained efficiency in having combined sections; however, the standards incorporated by reference and the definitions contained in the subparts affected by this rulemaking do not apply to all of part 160. The Coast Guard also appreciates the suggestion regarding subchapter Q; however, it is beyond the scope of this rulemaking, which does not amend part 159 or affect all the subparts contained in subchapter Q. The incorporations by reference, definitions, and preemption language are appropriately placed for the purposes of this rulemaking. The Coast Guard, however, may consider the suggestion in a future rulemaking.

One commenter suggested that the Coast Guard remove from the CFR all existing language applicable to rigid buoyant apparatuses and life floats and add language indicating that all approvals of such equipment will be withdrawn under 46 CFR 2.75–50(a) on January 1, 2015, per Section 609 of the Coast Guard Authorization Act of 2010 (Pub. L. 111–281).

The Coast Guard plans to address Section 609 requirements in a future regulatory action, and not as part of this rulemaking.

One commenter asked whether the proposed rulemaking extends to those companies that service fire fighting and lifesaving equipment.

No, this is beyond the scope of this rulemaking.

One commenter noted that, although this rulemaking does not address installation testing, the Coast Guard's guidance on installation testing contained in the online version of the Marine Safety Manual (MSM), Volume II, section B.1.P.2 is incomplete and recommends that the missing sections be added to the Web site.

Although this comment is beyond the scope of this rulemaking, the Coast Guard appreciates the information and will take appropriate action to address it.

V. Incorporation by Reference

The Director of the Federal Register has approved the material in 46 CFR 160.010–1, 160.051–5, 160.115–5, 160.132–5, 160.133–5, 160.135–5, 160.151–5, 160.156–5, 160.170–5, and 164.120–5 for incorporation by reference under 5 U.S.C. 552 and 1 CFR part 51. You may inspect this material at U.S. Coast Guard Headquarters where indicated under **ADDRESSES**. Copies of the material are available from the sources listed in paragraph (b) in each of those sections.

VI. Regulatory Analyses

We developed this interim rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 15 of these statutes or executive orders.

A. Executive Order 12866 and Executive Order 13563

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review as supplemented by Executive Order 13563, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. OMB has not reviewed it under that Order.

Comments on the proposed rule are summarized in the ''Discussion of Comments and Changes'' section of this preamble. The Coast Guard received no comments that altered our assessment of impacts in the NPRM. We have found no additional data or information that changed our findings in the NPRM. We have adopted the assessment in the NPRM for this rule as final.

A ''Preliminary Regulatory Analysis and Initial Regulatory Flexibility Analysis'' is available in the docket where indicated under the ''Public Participation and Request for Comments'' section of this preamble. A summary of the analysis follows:

As previously discussed, the Coast Guard will amend 46 CFR part 160 to harmonize its regulations with IMO standards governing certain types of lifesaving equipment. The Coast Guard also will incorporate the use of independent laboratories for Coast Guard approval procedures for certain types of lifesaving equipment, including requiring the use of independent laboratories at certain stages of the approval procedures in lieu of Coast Guard personnel who currently perform these inspections and witness these tests.

We expect the changes to harmonize existing regulations with international standards to have no additional costs for manufacturers of lifesaving equipment. In order for their lifesaving equipment to be used on vessels for international voyages from any nation that is a SOLAS signatory, equipment manufacturers must currently comply with the international standards for lifesaving equipment established by SOLAS. We expect the rule reflects existing industry practices adopted in response to these international standards governing the performance of certain types of lifesaving equipment.

We expect the changes to require the use of independent laboratories instead of Coast Guard personnel will result in additional costs for manufacturers of certain types of lifesaving equipment.

Currently, the Coast Guard does not charge for its inspections (although

overseas manufacturing facilities reimburse the Coast Guard for travel and subsistence costs of Coast Guard inspectors). The use of independent laboratories required by this rule will create a new cost for manufacturers of lifesaving equipment. However, the costs of inspections by independent laboratories will be partially offset by an overall reduction in the number of inspections, made possible through the coordination of independent laboratories. Manufacturers will be able to schedule inspections and testing for independent laboratories acting on behalf of multiple nations, including the U.S., rather than requiring separate Coast Guard inspections and testing by Coast Guard inspectors. This coordinated use of independent laboratories will avoid multiple inspections and testing of the same equipment (see the ''Independent Laboratories'' section for more details).

Data obtained from the Coast Guard Maritime Information Exchange (CGMIX) indicates that the population affected by this rule includes eight U.S. manufacturers and 76 foreign manufacturers of lifesaving equipment. We estimate the annual costs to manufacturers for using independent laboratories are approximately $130,000 for U.S. firms and approximately $683,000 for foreign firms (undiscounted). Over a 10-year period of analysis, we estimate the total present value costs of the rulemaking are approximately $913,000 for U.S. firms and approximately $4.8 million for foreign firms, discounted at seven percent. We estimate the total present value cost of the rulemaking to be about $5.7 million over a 10-year period of analysis.

The other changes, not resulting from harmonization with internal standards or use of independent laboratories, update Coast Guard regulations to reflect current practice or newer versions of existing standards and have minimal costs. These include an amendment specifying the attachment point for sea anchors to liferafts, and the addition of a new subpart in 46 CFR part 164 addressing resins used in the construction of lifeboats and rescue boats and incorporating the use of equivalent international standards as an alternative to national consensus standards.

The benefits of the rule include compliance with U.S. obligations as a SOLAS signatory and the removal of inconsistencies between international standards and the Coast Guard's current regulations. The rule also provides possible savings for manufacturers from coordination efficiencies for inspections and increased efficiency for the Coast Guard from greater flexibility in assigning its human resources, particularly those stationed at overseas Coast Guard offices.

The ''Preliminary Regulatory Analysis and Initial Regulatory Flexibility Analysis'' available on the docket provides additional detail on the costs and benefits of this rulemaking.

B. Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), the Coast Guard has considered whether this rule will have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

A combined ''Preliminary Regulatory Analysis and Initial Regulatory Flexibility Analysis'' discussing the impact of this rule on small entities is available in the docket where indicated under the ''Public Participation and Request for Comments'' section of this preamble.

In the NPRM, the Coast Guard certified under 5 U.S.C. 605(b) that the rule would not have a significant economic impact on a substantial number of small entities. We received no comments on this certification and have made no changes that would alter our assessment of the impacts in the NPRM.

We determined that six of the eight U.S. firms manufacturing lifesaving equipment are classified as small entities under the Small Business Administration size standards. We estimate the annual costs to use independent laboratories is less than 0.5 percent of revenue for five of the six small entities and less than 1.25 percent of revenue for one of the six small entities. However, these estimates do not include adjustments for manufacturer savings from the coordinated use of independent laboratories that will avoid multiple inspections and testing of the same equipment (see the ''Independent Laboratories'' section for more details).

Based on this information, the Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

C. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), the Coast Guard wants to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule will affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please consult Mr. George Grills, P.E., Commercial Regulation and Standard Directorate, Office of Design and Engineering Standards, Lifesaving and Fire Safety Division (CG–5214), Coast Guard, telephone 202–372–1385, or e-mail *George.G.Grills@uscg.mil.* The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

D. Collection of Information

This rule will call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The information collected under the rule is addressed in the existing collection of information, OMB control number 1625–0035, title 46 subchapter Q: Lifesaving, Electrical, and Engineering Equipment, Construction and Materials & Marine Sanitation Devices (33 CFR part 159), which was reviewed by OMB on May 27, 2009 and will expire after the 3-year approval period ending on May 31, 2012, unless renewed. The rule's requirement for the use of inspectors from independent laboratories will increase the total annual collection burden of the existing collection of information by 1.2 percent. The current authorized annual burden is 103,289 hours and the rule will increase the annual burden by approximately 1,221 hours.

The increase in the annual burden is not considered material or substantive. To confirm this, the Coast Guard has submitted a change worksheet (OMB Form 83–C) to OIRA noting the change in the annual burden. The change worksheet is available in the docket where indicated under the ''Public

Participation and Request for Comments'' section of this preamble.

E. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and will either preempt State law or impose a substantial direct cost of compliance on them.

The U.S. Supreme Court has long recognized the field preemptive impact of the Federal regulatory regime for inspected vessels. *See, e.g., Kelly* v. *Washington ex rel Foss,* 302 U.S. 1 (1937) and the consolidated cases of *United States* v. *Locke and Intertanko* v. *Locke,* 529 U.S. 89, 113–116 (2000). Therefore, the Coast Guard's view is that regulations issued under the authority of 46 U.S.C. 3306 in the areas of design, construction, alteration, repair, operation, superstructures, hulls, fittings, equipment, appliances, propulsion machinery, auxiliary machinery, boilers, unfired pressure vessels, piping, electric installations, accommodations for passengers and crew, sailing school instructors, sailing school students, lifesaving equipment and its use, firefighting equipment, its use and precautionary measures to guard against fire, inspections and tests related to these areas and the use of vessel stores and other supplies of a dangerous nature have preemptive effect over State regulation in these fields, regardless of whether the Coast Guard has issued regulations on the subject or not, and regardless of the existence of conflict between the state and Coast Guard regulation.

While it is well settled that States may not regulate in categories in which Congress intended the Coast Guard to be the sole source of a vessel's obligations, as these categories are within a field foreclosed from regulation by the States (see *U.S.* v. *Locke,* above), the Coast Guard recognizes the key role state and local governments may have in making regulatory determinations. Additionally, Sections 4 and 6 of Executive Order 13132 require that for any rules with preemptive effect, the Coast Guard shall provide elected officials of affected state and local governments and their representative national organizations the notice and opportunity for appropriate participation in any rulemaking proceedings, and to consult with such officials early in the rulemaking process. Therefore, we invited affected state and local governments and their representative national organizations to indicate their desire for participation and consultation in this rulemaking. We received no such indications.

F. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, the Coast Guard does discuss the effects of this rule elsewhere in this preamble.

G. Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

H. Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

I. Protection of Children

The Coast Guard has analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and will not create an environmental risk to health or risk to safety that might disproportionately affect children.

J. Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

K. Energy Effects

The Coast Guard has analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. The Coast Guard has determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

L. International Trade Impacts

Under the Trade Agreement Act of 1979 (codified at 19 U.S.C. 2501 *et seq.),* agencies are prohibited from promulgating any standards or engaging in related activities that create unnecessary obstacles to foreign commerce. Because the rule will have an effect on foreign firms, we have also examined the costs and regulatory action to determine if it will constitute an unnecessary obstacle to trade. Because the overall costs are minimal, the requirement for third-party inspections and testing is uniform across product classes, and the requirement for independent third-party testing applies to both domestic and overseas manufacturers, this rule does not constitute an obstacle to trade or a non-tariff barrier to trade.

M. Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through OMB, with an explanation of why using these standards will be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule uses the following voluntary consensus standards:

- ASTM A 36/A 36M–08, Standard Specification for Carbon Structural Steel, (approved May 15, 2008);
- ASTM A 216/A 216M–08, Standard Specification for Steel Castings, Carbon, Suitable for Fusion Welding for High-Temperature Service, (approved November 1, 2008);
- ASTM A 276–08a, Standard Specification for Stainless Steel Bars and Shapes, (approved October 1, 2008);
- ASTM A 313/A313M—08, Standard Specification for Stainless Steel Spring Wire, (approved October 1, 2008);
- ASTM A 314–08, Standard Specification for Stainless Steel Billets and Bars for Forging, (approved October 1, 2008);
- ASTM A 653/A 653M–08, Standard Specification for Steel Sheet, Zinc-Coated (Galvanized) or Zinc-Iron Alloy-Coated (Galvannealed) by the Hot-Dip Process, (approved July 15, 2008);

• ASTM B 127–05 (Reapproved 2009), Standard Specification for Nickel-Copper Alloy (UNS N04400) Plate, Sheet, and Strip, (approved October 1, 2009);

• ASTM B 209–07, Standard Specification for Aluminum and Aluminum-Alloy Sheet and Plate, (approved August 1, 2007);

• ASTM D 543–06, Standard Practices for Evaluating the Resistance of Plastics to Chemical Reagents, (approved April 1, 2006);

• ASTM D 570–98 (Reapproved 2005), Standard Test Method for Water Absorption of Plastics, (approved November 1, 2005);

• ASTM D 638–08, Standard Test Method for Tensile Properties of Plastics, (approved April 1, 2008);

• ASTM D 695–08, Standard Test Method for Compressive Properties of Rigid Plastics, (approved August 1, 2008);

• ASTM D 790–07e1, Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials, (approved September 1, 2007);

• ASTM D 792–08, Standard Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement, (approved June 15, 2008);

• ASTM D 1045–08, Standard Test Methods of Sampling and Testing Plasticizers used in Plastics, (approved August 1, 2008);

• ASTM D 1824–95 (Reapproved 2002), Standard Test Method for Apparent Viscosity of Plastisols and Organosols at Low Shear Rates, (approved March 15, 1995);

• ASTM D 2471–99, Standard Test Method for Gel Time and Peak Exothermic Temperature of Reacting Thermosetting Resins, (approved November 10, 1999);

• ASTM D 2583–07, Standard Test Method for Indentation Hardness of Rigid Plastics by Means of a Barcol Impressor, (approved March 1, 2007);

• ASTM D 2584–08, Standard Test Method of Ignition Loss for Cured Reinforced Resins, (approved May 1, 2008);

• ASTM D 4029–09, Standard Specification for Finished Woven Glass Fabrics, (approved January 15, 2009);

• ASTM F 1014–02 (Reapproved 2007), Standard Specification for Flashlights on Vessels, (approved May 1, 2007);

• ASTM F 1166–07, Standard Practice for Human Engineering Design for Marine Systems, Equipment, and Facilities, (approved January 1, 2007);

• ASTM G 154–06, Standard Practice for Operating Fluorescent Light Apparatus for UV Exposure of Nonmetallic Materials, (approved June 5, 2006);

• IMO Resolution A.657(16), Instructions for Action in Survival Craft, (adopted October 19, 1989);

• IMO Resolution A.658(16), Use and Fitting of Retro-Reflective Materials on Life-Saving Appliances, (adopted October 19, 1989);

• IMO Resolution A.760(18), Symbols Related to Life-Saving Appliances and Arrangements, (adopted November 4, 1993);

• Life-Saving Appliances, including LSA Code, 2010 Edition, (2010);

• MSC/Circular 980, Standardized Life-saving Appliance Evaluation and Test Report Forms (February 13, 2001);

• MSC/Circular 1006, Guidelines On Fire Test Procedures For Acceptance Of Fire-Retardant Materials For The Construction Of Lifeboats, (June 18, 2001);

• MSC.1/Circular 1205, Guidelines for Developing Operation and Maintenance Manuals for Lifeboat Systems, (May 26, 2006);

• ISO 62:2008(E), Plastics—Determination of water absorption, Third Edition (February 15, 2008);

• ISO 175:1999(E), Plastics—Methods of test for the determination of the effects of immersion in liquid chemicals, Second Edition (May 1, 1999);

• ISO 527–1:1993(E), Plastics—Determination of tensile properties, Part 1: General Principles, First Edition (June 15, 1993);

• ISO 604:2002(E), Plastics—Determination of compressive properties, Third Edition (March 1, 2002);

• ISO 1172:1996(E), Textile-glass-reinforced plastics—Prepregs, moulding compounds and laminates—Determination of the textile-glass and mineral-filler content—Calcination methods, Second Edition (December 15, 1996);

• ISO 1183–1:2004(E), Plastics,—Methods for determining the density of non-cellular plastics—Part 1: Immersion method, liquid pyknometer method and titration method, First Edition (February 1, 2004);

• ISO 1675–1985(E), Plastics—Liquid resins—Determination of density by the pyknometer method, Second Edition (August 15, 1985);

• ISO 2039–2:1987(E), Plastics—Determination of hardness—Part 2: Rockwell hardness, Second Edition (July 15, 1987);

• ISO 2114:2000(E), Plastics (polyester resins) and paints and varnishes (binders)—Determination of partial acid value and total acid value, Third Edition (August 1, 2000);

• ISO 2535:2001(E), Plastics—Unsaturated-polyester resins—Measurement of gel time at ambient temperature, Third Edition (July 15, 2001);

• ISO 2555:1989(E), Plastics—Resins in the liquid state or as emulsions or dispersions—Determination of apparent viscosity by the Brookfield test method, Second Edition (February 1, 1989, corrected and reprinted February 1, 1999);

• ISO 14125:1998(E), Fibre-reinforced plastic composites—Determination of flexural properties, First Edition (March 1, 1998);

• ISO 15372:2000(E), Ships and marine technology—Inflatable rescue boats—Coated fabrics for inflatable chambers, First Edition (December 1, 2000);

• ISO 15738:2002(E), Ships and marine technology—Gas Inflation systems for inflatable life-saving appliances, First Edition (February 1, 2002);

• ISO 17339:2002(E), Ships and marine technology—Sea anchors for survival craft and rescue boats, First Edition (November 15, 2002);

• ISO 18813:2006(E), Ships and marine technology—Survival equipment for survival craft and rescue boats, First Edition (April 1, 2006);

• SAE J1527–93 (Revised JAN93), Marine Fuel Hoses, (February 5, 1993);

• UL 1102, Standard for Nonintegral Marine Fuel Tanks, Fifth Edition (February 4, 1999); and

• UL 1185, Standard for Portable Marine Fuel Tanks, Fourth Edition (September 26, 1996).

The sections that reference these standards and the locations where these standards are available are listed in 46 CFR 160.010–1, 160. 051–5, 160.115–5, 160.132–5, 160.133–5, 160.135–5, 160.151–5, 160.156–5, 160.170–5, and 164.120–5.

This rule also uses technical standards other than voluntary consensus standards. The Coast Guard will use the below-listed standards issued by the Department of Defense and the General Services Administration because the Coast Guard did not find voluntary consensus standards that fulfill the purpose of these standards as applicable to the rule:

• A–A–55308, Commercial Item Description, Cloth And Strip, Laminated Or Coated, Vinyl Nylon Or Polyester, High Strength, Flexible, (May 13, 1997);

• Federal Standard 595C, Colors Used in Government Procurement, (January 16, 2008);

• MIL–C–17415F, Military Specification, Cloth, Coated, and

Webbing, Inflatable Boat and Miscellaneous Use, (May 31, 1989);

- MIL–C–19663D, Military Specification, Cloth, Woven Roving, For Plastic Laminate, (August 4, 1988);
- MIL–P–17549D(SH), Military Specification, Plastic Laminates, Fibrous Glass Reinforced, Marine Structural, (August 31, 1981);
- MIL–P–19644C, Military Specification, Plastic Molding Material (Polystyrene Foam, Expanded Bead), (July 10, 1970);
- MIL–P–21929B, Military Specification, Plastic Material, Cellular Polyurethane, Foam-In-Place, Rigid (2 and 4 Pounds per Cubic Foot), (August 11, 1969);
- MIL–P–40619A, Military Specification, Plastic Material, Cellular, Polystyrene (For Buoyancy Applications) (December 9, 1968);
- MIL–R–7575C, Military Specification, Resin, Polyester, Low-Pressure Laminating, (June 29, 1966);
- MIL–R–21607E(SH), Military Specification, Resins, Polyester, Low Pressure Laminating, Fire-Retardant, (May 25, 1990); and
- MIL–R–24719(SH), Military Specification, Resins, Vinyl Ester, Low Pressure Laminating, (May 4, 1989).

N. Coast Guard Authorization Act Sec. 608 (46 U.S.C. 2118(a))

Section 608 of the Coast Guard Authorization Act of 2010 (Pub. L. 111–281) adds new section 2118 to 46 U.S.C. subtitle II (Vessels and Seamen), chapter 21 (General). New section 2118(a) sets forth requirements for standards established for approved equipment required on vessels subject to 46 U.S.C. subtitle II (Vessels and Seamen), Part B (Inspection and Regulation of Vessels). Those standards must be ''(1) Based on performance using the best available technology that is economically achievable; and (2) operationally practical.'' *See* 46 U.S.C. 2118(a). This rulemaking addresses lifesaving equipment for Coast Guard approval that is required on vessels subject to 46 U.S.C. subtitle II, part B, and the Coast Guard has ensured this rule satisfies the requirements of 46 U.S.C. 2118(a), as necessary.

O. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded under section 2.B.2, figure 2–1, paragraph (34)(a) and (d) of the Instruction and under section 6(a) of the ''Appendix to National Environmental Policy Act: Coast Guard Procedures for Categorical Exclusions, Notice of Final Agency Policy'' (67 FR 48243, July 23, 2002). This rule involves regulations which are editorial or procedural; regulations concerning equipping of vessels, and regulations concerning vessel operation safety standards. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under **ADDRESSES.**

List of Subjects

46 CFR Part 108

Fire prevention, Marine safety, Occupational safety and health, Oil and gas exploration, Vessels.

46 CFR Part 117

Marine safety, Passenger vessels.

46 CFR Part 133

Cargo vessels, Marine safety, Reporting and recordkeeping requirements.

46 CFR Part 160

Marine safety, Incorporation by reference, Reporting and recordkeeping requirements.

46 CFR Part 164

Fire prevention, Incorporation by reference, Marine safety, Reporting and recordkeeping requirements.

46 CFR Part 180

Marine safety, Passenger vessels.

46 CFR Part 199

Cargo vessels, Marine safety, Oil and gas exploration, Passenger vessels, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, the Coast Guard amends 46 CFR parts 108, 117, 133, 160, 164, 180, and 199 as follows:

PART 108—DESIGN AND EQUIPMENT

■ 1. The authority citation for part 108 continues to read as follows:

Authority: 43 U.S.C. 1333; 46 U.S.C. 3102, 3306; Department of Homeland Security Delegation No. 0170.1.

■ 2. Revise § 108.550(a) to read as follows:

§ 108.550 Survival craft launching and recovery arrangements: General.

(a)(1) Each launching appliance must be a davit approved under 46 CFR part 160, subpart 160.132 for use with the intended craft, with a winch approved under 46 CFR part 160, subpart 160.115 for use with the intended craft.

(2) Each launching appliance for a davit-launched liferaft must include an automatic disengaging apparatus approved under 46 CFR part 160, subpart 160.170 and be either—

(i) A launching appliance described in paragraph (a)(1) of this section; or

(ii) A launching appliance approved on or before November 10, 2011 under approval series 160.163.

* * * * *

PART 117—LIFESAVING EQUIPMENT AND ARRANGEMENTS

■ 3. The authority citation for part 117 continues to read as follows:

Authority: 46 U.S.C. 2103, 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

■ 4. In § 117.150, revise paragraph (a) and add paragraph (c) to read as follows:

§ 117.150 Survival craft embarkation arrangements.

(a) A launching appliance described in paragraph (c) of this section, or a marine evacuation system approved under approval series 160.175, must be provided for each inflatable liferaft and inflatable buoyant apparatus when either—

* * * * *

(c) Each launching appliance for a davit-launched liferaft must include an automatic disengaging apparatus approved under 46 CFR part 160, subpart 160.170 and be either—

(1) A davit approved under 46 CFR part 160, subpart 160.132 for use with a liferaft, with a winch approved under 46 CFR part 160, subpart 160.115 for use with a liferaft; or

(2) A launching appliance approved on or before November 10, 2011 under approval series 160.163.

PART 133—LIFESAVING SYSTEMS

■ 5. The authority citation for part 133 continues to read as follows:

Authority: 46 U.S.C. 3306, 3307; Department of Homeland Security Delegation No. 0170.1.

■ 6. Revise § 133.150(b) to read as follows:

§ 133.150 Survival craft launching and recovery arrangements: General.

* * * * *

(b)(1) Each launching appliance must be a davit approved under 46 CFR part 160, subpart 160.132 for use with the intended craft, with a winch approved under 46 CFR part 160, subpart 160.115 for use with the intended craft.

(2) Each launching appliance for a davit-launched liferaft must include an automatic disengaging apparatus approved under 46 CFR part 160, subpart 160.170 and be either—

(i) A launching appliance described in paragraph (b)(1) of this section; or

(ii) A launching appliance approved on or before November 10, 2011 under approval series 160.163.

* * * * *

PART 160—LIFESAVING EQUIPMENT

■ 7. The authority citation for part 160 continues to read as follows:

Authority: 46 U.S.C. 2103, 3306, 3703 and 4302; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; 49 CFR 1.46.

Subpart 160.010—Buoyant Apparatus for Merchant Vessels

■ 8. Revise § 160.010–1 to read as follows:

§ 160.010–1 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Coast Guard must publish notice of change in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at Commandant (CG–5214), U.S. Coast Guard, 2100 Second Street, SW., Stop 7126, Washington, DC 20593–7126. You may also inspect this material 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.* You may obtain copies of the material from the sources specified in the following paragraphs.

(b) General Services Administration, Federal Acquisition Service, Office of the FAS Commissioner, 2200 Crystal Drive, 11th Floor, Arlington, VA 22202, 703–605–5400.

(1) Federal Standard 595C, Colors Used in Government Procurement, (January 16, 2008), IBR approved for § 160.010–4 (''FED–STD–595C'').

(2) [Reserved].

(c) International Maritime Organization (IMO), Publications Section, 4 Albert Embankment, London SE1 7SR, United Kingdom, +44 (0)20 7735 7611, *http://www.imo.org/.*

(1) Life-Saving Appliances, including LSA Code, 2010 Edition, (2010), pages 7–71 (''IMO LSA Code''), IBR approved for § 160.010–3.

(2) Life-Saving Appliances, including LSA Code, 2010 Edition, (2010), Revised recommendation on testing of live-saving appliances, pages 79–254 (''IMO Revised recommendation on testing''), IBR approved for § 160.010–3.

(d) Military Specifications and Standards, Standardization Documents Order Desk, Building 4D, 700 Robbins Avenue, Philadelphia, PA 19111–5094, *https://assist.daps.dla.mil/quicksearch/.*

(1) MIL–P–19644C, Military Specification, Plastic Molding Material (Polystyrene Foam, Expanded Bead), (July 10, 1970), IBR approved for § 160.010–5 (''MIL–P–19644C'').

(2) MIL–P–21929B, Military Specification, Plastic Material, Cellular Polyurethane, Foam-In-Place, Rigid (2 and 4 Pounds per Cubic Foot), (August 11, 1969), IBR approved for § 160.010–5 (''MIL–P–21929B'').

(3) MIL–P–40619A, Military Specification, Plastic Material, Cellular, Polystyrene (For Buoyancy Applications), (December 9, 1968), IBR approved for § 160.010–5 (''MIL–P–40619A'').

(4) MIL–R–21607E(SH), Military Specification, Resins, Polyester, Low Pressure Laminating, Fire-Retardant, (May 25, 1990), IBR approved for § 160.010–5 (''MIL–R–21607E(SH)'').

■ 9. In § 160.010–2, revise the definition for ''Commandant'' to read as follows:

§ 160.010–2 Definitions.

* * * * *

Commandant means the Commandant (CG–5214), U.S. Coast Guard, 2100 Second Street, SW., Stop 7126, Washington, DC 20593–7126.

* * * * *

■ 10. Amend § 160.010–3 as follows:

■ a. In paragraph (a)(1), remove the words ''(SOLAS chapter III, regulation 38, paragraph 1.5 (III/38.1.5))'' and add, in their place, the words ''(IMO LSA Code, Chapter IV/4.1.1.5 (incorporated by reference, see § 160.010–1 of this subpart))'';

■ b. In paragraph (a)(2), remove the words ''(Regulation III/38.2.1)'' and add, in their place, the words ''(IMO LSA Code, chapter IV/4.1.2.1)'';

■ c. In paragraph (a)(3), remove the words ''(Regulation III/39.2.2)'' and add, in their place, the words ''(IMO LSA Code, chapter IV/4.2.2.2)'';

■ d. In paragraph (a)(4), remove the words ''(Regulation III/39.5.1)'' and add, in their place, the words ''IMO LSA Code, chapter IV/4.2.5.4'';

■ e. In paragraph (a)(5), remove the words ''(Regulation III/39.5.2)'' and add, in their place, the words ''(IMO LSA Code, chapter IV/4.2.5.2)'';

■ f. In paragraph (a)(9) introductory text, remove the words ''(Regulation III/39.4.1)'' and add, in their place, the words ''(IMO LSA Code, chapter IV/4.2.4.1)'';

■ g. In paragraph (a)(10) introductory text, remove the words ''(Regulation III/39.4.2)'' and add, in their place, the words ''(IMO LSA Code, chapter IV/4.2.4.2)'';

■ h. In paragraph (a)(11) introductory text, remove the symbol ''§ '' and add, in its place, the words ''46 CFR''; and remove the words ''of this subchapter'';

■ i. In paragraph (a)(12), in the introductory text after the word ''Equipment'', remove the words ''(Regulation III/38.5.1)''; and in the last sentence in the introductory text, remove the words ''Regulation III/38.5.1'' and add, in their places, the words ''IMO LSA Code, Chapter IV/4.1.5'';

■ j. In paragraph (a)(13), remove the words ''(Regulations III/39.7.3.4, III/39.7.3.5, and III/39.8.6)''; after the words ''requirements of § 160.151–33'', add the words '', as well as IMO LSA Code, chapter IV/4.2.6.3 and 4.2.7.1.6''; and remove the words ''regulation III/39.8.6'' and add, in their place, the words ''IMO LSA Code, chapter IV/4.2.7.1.6'';

■ k. In paragraph (a)(14), remove the words ''IMO Resolution A.689(17)'' and add, in their place, the words ''IMO Revised recommendation on testing (incorporated by reference, see § 160.010–1 of this subpart)'';

■ l. In paragraphs (a)(15) and (a)(16), remove the words ''IMO Resolution A.689(17)'' and add, in their place, the words ''IMO Revised recommendation on testing'';

■ m. In paragraph (e) introductory text, remove the words ''under the IMO International Code of Safety for High-Speed Craft (HSC Code)''; and remove the words ''Annex 10 to the HSC Code'' and add, in their places, the words ''Annex 11 to IMO Res. MSC.97(73)''; and

■ n. Add paragraph (e)(9) to read as follows:

§ 160.010–3 Inflatable buoyant apparatus.

* * * * *

(e) * * *

(9) *Stability.* It must be fitted with stability pockets, in accordance with IMO LSA Code Chapter IV/4.2.5.4.

§ 160.010–4 [Amended]

■ 11. Amend § 160.010–4 as follows:

■ a. In paragraph (g), remove the word ''(1/4in.)'' and add, in its place, the words ''(1/4 in.)''; and

■ b. In paragraph (n), remove the words ''sections 13 and 14 of the ''Color Names Dictionary'''' and add, in their place, the words ''sections 13 and 14 of FED–STD–595C (incorporated by reference, see § 160.010–1 of this subpart)''.

■ 12. Amend § 160.010–5 as follows:

■ a. In paragraph (b) introductory text, remove the text ''(CG–521)'' and add, in its place, the text ''(CG–5214)'';

■ b. Revise paragraph (b)(2) to read as set forth below;

■ c. Revise paragraph (b)(3) to read as set forth below;

■ d. Revise paragraph (b)(4) to read as set forth below'';

■ e. In paragraph (c)(1), remove the text ''MIL–P–21607'' and add, in its place, the text ''MIL–P–21607E(SH) (incorporated by reference, see § 160.010–1 of this subpart)''; and remove the text ''(G–MSE)'' and add, in its place, the text ''(CG–5214)''; and

■ f. In paragraphs (c)(2) and (c)(3), remove the text ''(CG–521)'' and add, in its place, the text ''(CG–5214)''.

§ 160.010–5 Buoyant apparatus with plastic foam buoyancy.

* * * * *

(b) * * *

(2) MIL–P–19644C (incorporated by reference, see § 160.010–1 of this subpart).

(3) MIL–P–21929B (incorporated by reference, see § 160.010–1 of this subpart).

(4) MIL–P–40619A (incorporated by reference, see § 160.010–1 of this subpart).

* * * * *

§ 160.010–7 [Amended]

■ 13. In § 160.010–7(a), remove the text ''CG–521'' and add, in its place, the text ''CG–5214''.

Subpart 160.015 [Removed and Reserved]

■ 14. Remove and reserve subpart 160.015.

Subpart 160.032 [Removed and Reserved]

■ 15. Remove and reserve subpart 160.032.

Subpart 160.033 [Removed and Reserved]

■ 16. Remove and reserve subpart 160.033.

Subpart 160.035 [Removed and Reserved]

■ 17. Remove and reserve subpart 160.035.

Subpart 160.051—Inflatable Liferafts for Domestic Service

■ 18. Revise § 160.051–1 to read as follows:

§ 160.051–1 Scope.

(a) This subpart prescribes requirements for approval by the Coast Guard of A, B, and Coastal Service inflatable liferafts for use only in domestic service. These liferafts must comply with all of the requirements for SOLAS A and SOLAS B liferafts in subpart 160.151 except as specified in this subpart.

(b) This subpart does not apply to any A, B, and Coastal Service inflatable liferaft for use only in domestic service that has been approved by the Coast Guard before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION OF INTERIM RULE], so long as the liferaft satisfies the annual servicing requirements set forth in 46 CFR 160.151–57.

■ 19. In § 160.051–3, add the definition for ''Commandant'', in alphabetical order, to read as follows:

§ 160.051–3 Definitions.

* * * * *

Commandant means the Commandant (CG–5214), U.S. Coast Guard, 2100 Second Street, SW., Stop 7126, Washington, DC 20593–7126.

§§ 160.051–5 through 160.051–9 [Redesignated as §§ 160.051–7 through 160.051–11]

■ 20. Redesignate §§ 160.051–5, 160.051–7, and 160.051–9 as §§ 160.051–7, 160.051–9, and 160.051–11, respectively.

■ 21. Add new § 160.051–5 to read as follows:

§ 160.051–5 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Coast Guard must publish notice of change in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at Commandant (CG–5214), U.S. Coast Guard, 2100 Second Street, SW., Stop 7126, Washington, DC 20593–7126. You may also inspect this material 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.* You may obtain copies of the material from the sources specified in the following paragraphs.

(b) International Maritime Organization (IMO) Publications Section, 4 Albert Embankment, London SE1 7SR, United Kingdom, +44 (0)20 7735 7611, *http://www.imo.org/.*

(1) Life-Saving Appliances, including LSA Code, 2010 Edition, (2010), pages 7–71 (''IMO LSA Code''), IBR approved for §§ 160.051–7 and 160.051–9.

(2) Life-Saving Appliances, including LSA Code, 2010 Edition, (2010), Revised recommendation on testing of live-saving appliances, pages 79–254 (''IMO Revised recommendation on testing''), IBR approved for §§ 160.051–7 and 160.051–11.

§ 160.051–7 [Amended]

■ 22. Amend newly redesignated § 160.051–7 as follows:

■ a. In paragraph (a) introductory text, remove the words ''Regulation III/38.1.5'' and add, in their place, the words ''IMO LSA Code chapter IV/4.1.1.5, (incorporated by reference, see § 160.051–5 of this subpart)'';

■ b. In paragraph (b), remove the first instance of the words ''Regulation III/38.1.5.5'' and add, in their place, the words ''IMO LSA Code, chapter IV/4.1.1.5.5''; and after the words ''the viewing port'', remove the words ''described in Regulation III/38.1.5.5'';

■ c. In paragraph (c), remove the first instance of the words ''Regulation III/38.1.5.6'' and add, in their place, the words ''IMO LSA Code, chapter IV/4.1.1.5.6''; and after the words ''means of rainwater collection'', remove the words ''described in Regulation III/38.1.5.6'';

■ d. In paragraph (d), remove the words ''Regulation III/38.2.1'' and add, in their place, the words ''IMO LSA Code, chapter IV/4.1.2.1'';

■ e. In paragraph (e), remove the words ''Regulation III/39.2.2'' and add, in their place, the words ''IMO LSA Code, chapter IV/4.2.2.2'';

■ f. In paragraph (f), remove the words ''Regulation III/39.4.1'' and add, in their place, the words ''IMO LSA Code, chapter IV/4.2.4.1'';

■ g. In paragraph (g), remove the words ''Regulation III/39.5.1'' and add, in their place, the words ''IMO LSA Code, chapter IV/4.2.5'';

■ h. In paragraph (h), remove the first instance of the words ''Regulation III/39.6.3'' and add, in their place, the words ''IMO LSA Code, chapter IV/4.1.3.4''; and after the words ''controlled

interior lamp'', remove the words ''described in Regulation III/39.6.3'';

■ i. In paragraph (i), remove the words ''Regulations III/39.7.3.4 and III/39.7.3.5'' and add, in their place, the words ''IMO LSA Code, chapter IV/4.2.3.6'';

■ j. In paragraph (j), remove the words ''IMO Resolution A.689(17)'' and add, in their place, the words ''IMO Revised recommendation on testing (incorporated by reference, see § 160.051–5 of this subpart)''; and

■ k. In paragraphs (k) and (l), remove the words ''IMO Resolution A.689(17)'' and add, in their place, the words ''IMO Revised recommendation on testing''.

§ 160.051–9 [Amended]

■ 23. Amend newly redesignated § 160.051–9 as follows:

■ a. In paragraph (a), remove the words ''Regulation III/38.2.1'' and add, in their place, the words ''IMO LSA Code chapter IV/4.1.2.1''; and

■ b. In paragraph (b), remove the words ''Regulations III/39.7.3.4 and III/39.7.3.5'' and add, in their place, the words ''IMO LSA Code, chapter IV/4.2.6.3''.

§ 160.051–11 [Amended]

■ 24. In newly redesignated § 160.051–11, paragraph (f), remove the words ''IMO Resolution A.689(17)'' and add, in their place, the words ''IMO Revised recommendation on testing (incorporated by reference, see § 160.051–5 of this subpart)''.

■ 25. Add subpart 160.115 to read as follows:

Subpart 160.115—Launching Appliances—Winches

Sec.

160.115–1 Scope.
160.115–3 Definitions.
160.115–5 Incorporation by reference.
160.115–7 Design, construction, and performance of winches.
160.115–9 Preapproval review.
160.115–11 [Reserved]
160.115–13 Approval inspections and tests for prototype winches.
160.115–15 Production inspections, tests, quality control, and conformance of winches.
160.115–17 Marking and labeling.
160.115–19 Operating instructions and information for the ship's training manual.
160.115–21 Operation and maintenance instructions.
160.115–23 Procedure for approval of design or material change.
Subpart 160.115—Launching Appliances—Winches

§ 160.115–1 Scope.

This subpart prescribes standards, tests, and procedures for seeking Coast Guard approval of a winch used in conjunction with a davit approved under subpart 160.132 of this part for lifeboats approved under subpart 160.135 of this part, liferafts approved under subparts 160.051 or 160.151 of this part, and rescue boats approved under subparts 160.056 or 160.156 of this part.

§ 160.115–3 Definitions.

In addition to the definitions in the IMO LSA Code (incorporated by reference, see § 160.115–5 of this subpart), in this subpart, the term:

Commandant means the Commandant (CG–5214), U.S. Coast Guard, 2100 Second Street, SW., Stop 7126, Washington, DC 20593–7126.

Independent laboratory has the same meaning as 46 CFR 159.001–3. A list of accepted independent laboratories is available from the Commandant and online at *http://cgmix.uscg.mil.*

Officer in Charge, Marine Inspection (OCMI) means an officer of the Coast Guard designated as such by the Commandant and who fulfills the duties described in 46 CFR 1.01–15(b). The ''cognizant OCMI'' is the OCMI who has immediate jurisdiction over a vessel or geographic area for the purpose of performing the duties previously described.

SOLAS means the International Convention for the Safety of Life at Sea, 1974, as amended.

§ 160.115–5 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Coast Guard must publish notice of change in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at Commandant (CG–5214), U.S. Coast Guard, 2100 Second Street, SW., Stop 7126, Washington, DC 20593–7126. You may also inspect this material 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.* You may obtain copies of the material from the sources specified in the following paragraphs.

(b) International Maritime Organization (IMO) Publications Section, 4 Albert Embankment, London SE1 7SR, United Kingdom, +44 (0)20 7735 7611, *http://www.imo.org/.*

(1) IMO Resolution A.760(18), Symbols Related to Life-Saving Appliances and Arrangements, (adopted November 4, 1993), IBR approved for § 160.115–19 (''IMO Res. A.760(18)'').

(2) Life-Saving Appliances, including LSA Code, 2010 Edition, (2010), pages 7–71 (''IMO LSA Code''), IBR approved for § 160.115–7.

(3) Life-Saving Appliances, including LSA Code, 2010 Edition, (2010), Revised recommendation on testing of live-saving appliances, pages 79–254 (''IMO Revised recommendation on testing''), IBR approved for §§ 160.115–7, 160.115–13, and 160.115–15.

(4) MSC/Circular 980, Standardized Life-saving Appliance Evaluation and Test Report Forms, (February 13, 2001), IBR approved for § 160.115–13 (''IMO MSC Circ. 980'').

(5) MSC.1/Circular 1205, Guidelines for Developing Operation and Maintenance Manuals for Lifeboat Systems, (May 26, 2006), IBR approved for § 160.115–21 (''IMO MSC.1 Circ. 1205'').

§ 160.115–7 Design, construction, and performance of winches.

(a) To seek Coast Guard approval of a winch, a manufacturer must comply with, and each winch must meet, the requirements of the following—

(1) IMO LSA Code, chapter I/1.2.2 and chapter VI/6.1. (incorporated by reference, see § 160.115–5 of this subpart) applicable to the design and intended service of the winch;

(2) IMO Revised recommendation on testing, Part 1/8.1 (incorporated by reference, see § 160.115–5 of this subpart) applicable to the winch;

(3) 46 CFR part 159; and

(4) This subpart.

(b) Each winch must meet each of the following requirements:

(1) *Materials.* (i) All gears must be machine cut and made of steel, bronze, or other suitable materials properly keyed to shafts. The use of cast iron is not permitted for these parts.

(ii) Metals in contact with each other must be either galvanically compatible or insulated with suitable non-porous materials. Provisions must also be made to prevent loosening or tightening resulting from differences of thermal expansion, freezing, buckling of parts, galvanic corrosion, or other incompatibilities.

(iii) Screws, nuts, bolts, pins, keys, and other similar hardware, securing moving parts must be fitted with suitable lock washers, cotter pins, or locks to prevent them from coming adrift.

(2) *Bearings and gears.* (i) Positive means of lubrication must be provided for all bearings.

(ii) When worm gears are used, the worm wheel must operate in an oil bath.

Means to easily check the oil level in the gear case must be provided.

(iii) The manufacturer must furnish a lubrication chart and a plate attached to the winch indicating the lubricant recommended for extremes in temperature.

(3) *Guards.* All moving parts must have suitable guards.

(4) *Welding.* Welding must be performed by welders certified by the Commandant, a classification society recognized by the Commandant in accordance with 46 CFR 8.220, the U.S. Navy, or the national body where the winch is constructed or the national body's designated recognized organization. Only electrodes intended for use with the material being welded may be used. All welds must be checked using appropriate non-destructive tests.

(5) *Winch drums.* (i) A winch must have grooved drums unless otherwise approved by the Commandant.

(ii) The diameter of the drums must be at least 16 times the diameter of the falls.

(iii) Drums must be so arranged as to keep the falls separate, and to pay out the falls at the same rate. Clutches between drums are not permitted unless bolted locking devices are used.

(6) *Winch motors.* For a winch powered by electric or hydraulic motors, or portable power units such as air or electric drills—

(i) Positive means must be provided for controlling the power to the winch, arranged so that the operator must hold the master switch or controller in the ''on'' or ''hoist'' position for hoisting, and when released, will immediately shut off the power;

(ii) A clutch must be fitted to disengage the power installation during the lowering operation;

(iii) A means must be provided to disconnect power to the winch before a hand crank can be engaged with the winch operating shaft, and this interruption of power must be maintained while the hand crank is so engaged;

(iv) The air or electric power outlet for a portable power unit must be located adjacent to the winch where the unit is to be coupled, and the outlet must be interconnected with, and protected by, the same system of safety devices as required for a winch with built-in-motors;

(v) A main line emergency disconnect switch, the opening of which disconnects all electrical potential to the winch, must be provided. This switch must be located in a position accessible to the person in charge of the boat stowage and must be in a position from which the movement of both davit arms can be observed as they approach the final stowed position;

(vi) Limit switches, one for each davit arm, must be provided to limit the travel of the davit arms as they approach the final stowed position. These switches must—

(A) Be so arranged that the opening of either switch will disconnect all electrical potential of the circuit in which the switches are connected;

(B) Be arranged to stop the travel of the davit arms not less than 0.3m (12 in) from their final stowed position; and

(C) Remain open until the davit arms move outboard beyond the tripping position of the switches;

(vii) Motor clutches, when used, must be of either frictional or positive engaging type. When one motor is used for two winches, the clutch must be so arranged that only one winch may be engaged at any one time. The clutch operating lever must be capable of remaining in any position when subject to vibration and must be so arranged that when in neutral position both lifeboats may be lowered simultaneously;

(viii) Motors, switches, controls, and cables must be waterproof if installed on an open deck. Controls may be of the drip-proof type if installed in a deck house or under deck;

(ix) Hydraulic systems must be in accordance with 46 CFR part 58, subpart 58.30; and

(x) Electrical installations must comply with 46 CFR 111.01–9, 111.01–11, 111.01–19, 111.25, 111.55, 111.70, and 111.95.

(7) *Quick return.* For a winch used to launch an inflatable liferaft means must be provided for rapidly retrieving the falls by hand power.

(c) Determinations of equivalence of design, construction, and materials will be made by the Commandant only.

§ 160.115–9 Preapproval review.

(a) Except as provided in paragraph (c) of this section, the Commandant must conduct the preapproval review required by this section, in accordance with 46 CFR 159.005–5.

(b) *Manufacturer requirements.* To seek Coast Guard approval of a winch, the manufacturer must submit an application to the Commandant meeting the requirements of 46 CFR 159.005–5 for preapproval review. To meet the requirements of 46 CFR 159.005–5(a)(2), the manufacturer must submit in triplicate—

(1) A list of drawings, specifications, manuals, and any other documentation submitted, with each document identified by number, title, revision number, and issue date;

(2) General arrangement and assembly drawings, including principal dimensions;

(3) Stress calculations for all load carrying parts;

(4) An operation, maintenance, and training manual as described in §§ 160.115–19 and 160.115–21 of this subpart;

(5) A description of the quality control procedures and recordkeeping that will apply to the production of the winch, which must include, but is not limited to—

(i) The system for checking material certifications received from suppliers;

(ii) The method for controlling the inventory of materials;

(iii) The method for checking quality of fabrication and joints, including welding inspection procedures; and

(iv) The inspection checklists used during various stages of fabrication to assure that the approved winch complies with the approved plans and the requirements of this subpart;

(6) Any other drawing(s) necessary to show that the winch complies with the requirements of this subpart;

(7) The location or address of all manufacturing sites, including the name and address of any subcontractors, where the winch will be constructed; and

(8) The name of the independent laboratory that will perform the duties prescribed in § 160.115–15 of this subpart.

(c) At the request of the manufacturer and discretion of the Commandant, an independent laboratory may conduct preapproval review required by this section; so long as the preapproval review is conducted in accordance with the procedures agreed upon between the independent laboratory and Commandant under 46 CFR part 159, subpart 159.010.

(d) *Plan quality.* All plans and specifications submitted to the Commandant under this section must—

(1) Be provided in English, including all notes, inscriptions, and designations for configuration control;

(2) Address each of the applicable items in paragraph (b) of this section in sufficient detail to show that the winch meets the construction requirements of this subpart;

(3) Accurately depict the proposed winch;

(4) Be internally consistent;

(5) Be legible; and

(6) If reviewed by an independent laboratory under paragraph (c) of this section, include the independent laboratory's attestation that the plans meet the quality requirements of this section.

(e) *Alternatives.* Alternatives in materials, parts, or construction, and each item replaced by an alternative, must be clearly indicated as such in the plans and specifications submitted to the Commandant under this section.

(f) *Coast Guard review.* If the plans or specifications do not comply with the requirements of this section, Coast Guard review may be suspended, and the applicant notified accordingly.

§ 160.115–11 [Reserved]

§ 160.115–13 Approval inspections and tests for prototype winches.

(a) If the manufacturer is notified that the information submitted in accordance with § 160.115–9 of this subpart is satisfactory to the Commandant, the manufacturer may proceed with fabrication of the prototype winch and the approval inspections and tests required under this section.

(b) Except as provided in paragraph (f) of this section, the Coast Guard must conduct the approval inspections and witness the approval tests required under this section.

(c) *Manufacturer requirements.* To proceed with approval inspections and tests required by this section, the manufacturer must—

(1) Notify the Commandant and cognizant Officer in Charge, Marine Inspection (OCMI) of where the approval inspections and tests required under this section will take place, and such notifications must be in sufficient time to allow making travel arrangements;

(2) Arrange a testing schedule that allows for a Coast Guard inspector to travel to the site where the testing is to be performed;

(3) Admit the Coast Guard inspector to any place where work or testing is performed on winches or their component parts and materials for the purpose of—

(i) Conducting inspections as necessary to determine that the prototype—

(A) Conforms with the plans reviewed under § 160.115–9 of this subpart;

(B) Is constructed by the methods and with the materials specified in the plans reviewed under § 160.115–9 of this subpart; and

(C) When welding is part of the construction process, is constructed by the welding procedure and materials as per the plans reviewed under § 160.115–9 of this subpart and the welders are appropriately qualified;

(ii) Assuring that the quality-assurance program of the manufacturer is satisfactory;

(iii) Witnessing tests; and

(iv) Taking samples of parts or materials for additional inspections or tests; and

(4) Make available to the Coast Guard inspector the affidavits or invoices from the suppliers of all essential materials used in the production of winches, together with records identifying the lot or serial numbers of the winches in which such materials were used.

(d) *Tests.* (1) *IMO Revised recommendation on testing.* Each prototype winch of each design must pass each of the tests described in IMO Revised recommendation on testing, part 1, paragraph 8.1 (incorporated by reference, see § 160.115–5 of this subpart) applicable to winches.

(2) *Visual inspection.* Each winch must be visually inspected to confirm—

(i) Compliance with this subpart;

(ii) Conformance with the examined plans; and

(iii) Ease of operation and maintenance.

(3) *Hydraulic controls.* If the winch motor includes a fluid power and control system, a test of the hydraulic controls must be conducted in accordance with 46 CFR 58.30–35.

(e) *Test waiver.* The Commandant may waive certain tests for a winch similar in construction to a winch that has successfully completed the tests.

(f) At the request of the manufacturer and discretion of the Commandant, an independent laboratory may perform approval inspections and witness approval tests required by this section so long as the inspections and tests are performed and witnessed in accordance with the procedures agreed upon between the independent laboratory and Commandant under 46 CFR part 159, subpart 159.010.

(g) After completion of approval inspections and tests required by this section, the manufacturer must comply with the requirements of 46 CFR 159.005–9(a)(5) by preparing and submitting to the Commandant for review—

(1) The prototype approval test report containing the same information recommended by IMO MSC Circ. 980 (incorporated by reference, see § 160.115–5). The report must include a signed statement by the Coast Guard inspector (or independent laboratory as permitted under paragraph (f) of this section) who witnessed the testing, indicating that the report accurately describes the testing and its results; and

(2) The final version of the plans required under § 160.115–9 of this subpart in triplicate.

(h) The Commandant will review the report and plans submitted under paragraph (g) of this section, and if satisfactory to the Commandant, will approve the plans under 46 CFR 159.005–13.

§ 160.115–15 Production inspections, tests, quality control, and conformance of winches.

(a) Unless the Commandant directs otherwise, an independent laboratory must perform or witness, as appropriate, inspections, tests, and oversight required by this section. Production inspections and tests of a winch must be carried out in accordance with the procedures for independent laboratory inspection in 46 CFR part 159, subpart 159.007 and in this section, unless the Commandant authorizes alternative tests and inspections. The Commandant may prescribe additional production tests and inspections necessary to maintain quality control and to monitor compliance with the requirements of this subpart.

(b) *Manufacturer's responsibility.* The manufacturer must—

(1) Institute a quality control procedure to ensure that all production winches are produced to the same standard, and in the same manner, as the prototype winch approved by the Commandant. The manufacturer's quality control personnel must not work directly under the department or person responsible for either production or sales;

(2) Schedule and coordinate with the independent laboratory (or Coast Guard inspector if required under paragraph (a) of this section) to ensure that all tests are performed as described in this section;

(3) Submit to the Commandant a yearly report that contains the following—

(i) Serial number and date of final assembly of each winch constructed;

(ii) The name of the representative of the independent laboratory (or Coast Guard inspector if required under paragraph (a) of this section); and

(iii) Name of the vessel and company receiving the winch, if known;

(4) Ensure that the arrangement and materials entering into the construction of the winch are in accordance with plans approved under § 160.115–13(h) of this subpart;

(5) Allow an independent laboratory (or Coast Guard inspector if required under paragraph (a) of this section) access to any place where materials are stored for the winch, work or testing is performed on winches or their component parts and materials, or records are retained to meet the requirements of paragraph (c) of this section, below, for the purpose of—

(i) Assuring that the quality control program of the manufacturer is satisfactory;

(ii) Witnessing tests; or

(iii) Taking samples of parts or materials for additional inspections or tests; and

(6) Ensure that the independent laboratory (or Coast Guard inspector if required under paragraph (a) of this section) conducts the inspections and witnesses the tests required by paragraph (e) of this section, and further conducts a visual inspection to verify that the winches are being made in accordance with the plans approved under § 160.115–13(h) of this subpart and the requirements of this subpart.

(c) *Recordkeeping.* The manufacturer must maintain records in accordance with 46 CFR 159.007–13. The manufacturer must keep records of all items listed in this section for at least 5 years from the date of termination of approval of each winch. The records must include—

(1) A copy of this subpart, other CFR sections referenced in this subpart, and each document listed in § 160.115–5 of this subpart;

(2) A copy of the approved plans, documentation, and certifications;

(3) A current certificate of approval for each approved winch;

(4) Affidavits, certificates, or invoices from the suppliers identifying all essential materials used in the production of approved winches, together with records identifying the serial numbers of the winches in which such materials were used;

(5) Records of all structural welding and name of operator(s);

(6) Records of welder certificates, training, and qualifications;

(7) Date and results of calibration of test equipment and the name and address of the company or agency that performed the calibration;

(8) The serial number of each production winch, along with records of its inspections and tests carried out under this section; and

(9) The original purchaser of each winch and the vessel on which it was installed, if known.

(d) *Independent laboratory responsibility.* The independent laboratory must perform or witness, as appropriate, the inspections and tests under this section for each Coast Guard-approved winch to be installed on a U.S. flag vessel. If the manufacturer also produces winches for approval by other maritime safety administrations, the inspections may be coordinated with inspection visits for those administrations.

(e) *Production inspections and tests.*

(1) Each approved winch must be inspected and tested in accordance with the procedures in 46 CFR part 159, subpart 159.007 and the brake test described in IMO Revised recommendation on testing, part 2, paragraph 6.1.1 (incorporated by reference, see § 160.115–5 of this subpart).

(2) The lowering tests described in IMO Revised recommendation on testing, Part 2, paragraph 6.1 may be performed if the installation height is known. If these tests are performed, the results must be in accordance with 46 CFR 199.153(h) through (j).

§ 160.115–17 Marking and labeling.

(a) Each winch must be marked with a plate or label permanently affixed in a conspicuous place readily accessible for inspection and sufficiently durable to withstand continuous exposure to environmental conditions at sea for the life of the winch.

(b) The plate or label must be in English, but may also be in other languages.

(c) The plate or label must contain the—

(1) Name and address of the manufacturer;

(2) Manufacturer's model identification;

(3) Name of the independent laboratory that witnessed the prototype or production tests;

(4) Serial number of the winch;

(5) U.S. Coast Guard approval number;

(6) Month and year of manufacture;

(7) Safe working load of the winch; and

(8) Word ''SOLAS''.

§ 160.115–19 Operating instructions and information for the ship's training manual.

(a) Each winch must have instructions and information for the ship's training manual that use the symbols from IMO Res. A.760(18) (incorporated by reference, see § 160.115–5 of this subpart) to describe the location and operation of the winch.

(b) The instructions and information required by paragraph (a) of this section may be combined with similar material for survival craft and rescue boats, and their complete launching systems.

(c) The winch manufacturer must make operating instructions and information required by paragraph (a) of this section available in English to the purchaser of a winch approved by the Coast Guard.

§ 160.115–21 Operation and maintenance instructions.

(a) Each winch must have operation and maintenance instructions that—

(1) Follows the general format and content specified in IMO MSC.1 Circ. 1205 (incorporated by reference, see § 160.115–5 of this subpart); and

(2) Includes a checklist for use in monthly, external visual inspections of the winch.

(b) The winch manufacturer must make the manual required by paragraph (a) of this section available in English to the purchaser of a winch approved by the Coast Guard.

(c) The operation and maintenance instructions required by paragraph (a) of this section may be combined with similar material for survival craft and rescue boats, and their complete launching systems.

§ 160.115–23 Procedure for approval of design or material change.

(a) Each change in design, material, or construction from the plans approved under 46 CFR 159.005–13 and § 160.115–13(h) of this subpart must be approved by the Commandant before being used in any production winch. The manufacturer must submit any such change following the procedures in § 160.115–9 of this subpart, but documentation on items that are unchanged from the plans approved under 46 CFR 159.005–13 and § 160.115–13(h) of this subpart need not be resubmitted.

(b) Unless determined by the Commandant to be unnecessary, a prototype winch with each change described in paragraph (a) of this section must be made and tested according to the procedures for new approvals in §§ 160.115–9 through 160.115–13 of this subpart.

(c) Determinations of equivalence of design, construction, and materials will be made by the Commandant only.

■ 26. Add subpart 160.132 to read as follows:

Subpart 160.132—Launching Appliances—Davits

Sec.

160.132–1 Scope.
160.132–3 Definitions.
160.132–5 Incorporation by reference.
160.132–7 Design, construction, and performance of davits.
160.132–9 Preapproval review.
160.132–11 [Reserved]
160.132–13 Approval inspections and tests for prototype davits.
160.132–15 Production inspections, tests, quality control, and conformance of davits.
160.132–17 Marking and labeling.
160.132–19 Operating instructions and information for the ship's training manual.
160.132–21 Operation and maintenance instructions.

160.132–23 Procedure for approval of design or material change.

Subpart 160.132—Launching Appliances—Davits

§ 160.132–1 Scope.

This subpart prescribes standards, tests, and procedures for seeking Coast Guard approval of a davit used in conjunction with a winch approved under subpart 160.115 of this part for lifeboats approved under subpart 160.135 of this part, liferafts approved under subparts 160.051 or 160.151 of this part, and rescue boats approved under subparts 160.056 or 160.156 of this part.

§ 160.132–3 Definitions.

In addition to the definitions in the IMO LSA Code (incorporated by reference, see § 160.132–5 of this subpart), in this subpart, the term:

Commandant means the Commandant (CG–5214), U. S. Coast Guard, 2100 Second Street SW., Stop 7126, Washington, DC 20593–7126.

Independent laboratory has the same meaning as 46 CFR 159.001–3. A list of accepted independent laboratories is available from the Commandant and online at *http://cgmix.uscg.mil.*

Officer in Charge, Marine Inspection (OCMI) means an officer of the Coast Guard designated as such by the Commandant and who fulfills the duties described in 46 CFR 1.01–15(b). The ''cognizant OCMI'' is the OCMI who has immediate jurisdiction over a vessel or geographic area for the purpose of performing the duties previously described.

SOLAS means the International Convention for the Safety of Life at Sea, 1974, as amended.

§ 160.132–5 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Coast Guard must publish notice of change in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at Commandant (CG–5214), U.S. Coast Guard, 2100 Second Street, SW., Stop 7126, Washington, DC 20593–7126. You may also inspect this material 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.* You may obtain copies of the material from the sources specified in the following paragraphs

(b) American Society for Testing and Materials (ASTM), 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA, 19428–2959.

(1) ASTM A 36/A 36M–08, Standard Specification for Carbon Structural Steel, (approved May 15, 2008), IBR approved for § 160.132–7 (''ASTM A 36'').

(2) ASTM A 216/A 216M–08, Standard Specification for Steel Castings, Carbon, Suitable for Fusion Welding, for High-Temperature Service, (approved November 1, 2008), IBR approved for § 160.132–7 (''ASTM A 216'').

(c) International Maritime Organization (IMO) Publications Section, 4 Albert Embankment, London SE1 7SR, United Kingdom, +44 (0)20 7735 7611, *http://www.imo.org/.*

(1) IMO Resolution A.760(18), Symbols Related to Life-Saving Appliances and Arrangements, (adopted November 4, 1993), IBR approved for § 160.132–19 (''IMO Res. A.760(18)'').

(2) International Life-Saving Appliances, including LSA Code, 2010 Edition, (2010), pages 7–71 (''IMO LSA Code''), IBR approved for §§ 160.132–3 and 160.132–7.

(3) Life-Saving Appliances, including LSA Code, 2010 Edition, (2010), Revised recommendation on testing of live-saving appliances, pages 79–254 (''IMO Revised recommendation on testing''), IBR approved for §§ 160.132–7, 160.132–13, and 160.132–15.

(4) MSC/Circular 980, Standardized Life-Saving Appliance Evaluation and Test Report Forms, (February 13, 2001), IBR approved for § 160.132–13 (''IMO MSC Circ. 980'').

(5) MSC.1/Circular 1205, Guidelines for Developing Operation and Maintenance Manuals for Lifeboat Systems, (May 26, 2006), IBR approved for § 160.132–21 (''IMO MSC.1 Circ. 1205'').

§ 160.132–7 Design, construction, and performance of davits.

(a) To seek Coast Guard approval of a davit, a manufacturer must comply with, and each davit must meet, the requirements of following—

(1) IMO LSA Code chapter I/1.2.2 and Chapter VI/6.1 (incorporated by reference, see § 160.132–5 of this subpart) applicable to the design and intended service of the davit;

(2) IMO Revised recommendation on testing, part 1/8.1 (incorporated by reference, see § 160.132–5 of this subpart) applicable to the design and intended service of the davit;

(3) 46 CFR part 159; and

(4) This subpart.

(b) Each davit must meet the following requirements—

(1) *Materials.* Each major structural component of each davit must be constructed of steel. Other materials may be used if accepted by the Commandant as equivalent or superior—

(i) Structural steel made by the open-hearth or electric furnace process must be in accordance with ASTM A 36 (incorporated by reference, see § 160.132–5 of this subpart);

(ii) Steel castings not intended for fusion welding must be in accordance with ASTM A 36, Grades U–60–30, 60–30, 65–30, 65–35, and 70–36;

(iii) Steel castings intended to be fabricated by fusion welding must be in accordance with ASTM A 216 (incorporated by reference, see § 160.132–5 of this subpart), Grades WCA and WCB;

(iv) Cast iron must not be used in the construction of a davit; and

(v) Metals in contact with each other must be either galvanically compatible or insulated with suitable non-porous materials. Provisions must also be made to prevent loosening or tightening resulting from differences of thermal expansion, freezing, buckling of parts, galvanic corrosion, or other incompatibilities;

(2) *Bearings.* (i) Bearings must be of non-ferrous metal, or must be of the roller or ball-bearing type;

(ii) Positive means of lubrication must be provided; and

(iii) The manufacturer must furnish a lubrication chart for each davit together with a plate attached to the davit indicating the lubricants recommended for extremes in temperature;

(3) *Guards.* All moving parts must have guards;

(4) *Welding.* Welding must be performed by welders certified by the Commandant, a classification society recognized by the Commandant in accordance with 46 CFR 8.220, the U.S. Navy, or the national body where the davit is constructed or the national body's designated recognized organization. Only electrodes intended for use with the material being welded may be used. All welds must be checked using appropriate non-destructive tests; and

(5) *Hydraulic systems,* if installed, must be in accordance with 46 CFR part 58, subpart 58.30.

(c) Determinations of equivalence of design, construction, and materials will be made by the Commandant only.

§ 160.132–9 Preapproval review.

(a) Except as provided in paragraph (c) of this section, the Commandant

must conduct the preapproval review required by this section, in accordance with 46 CFR 159.005–5.

(b) *Manufacturer requirements.* To seek Coast Guard approval of a davit, the manufacturer must submit an application to the Commandant meeting the requirements of 46 CFR 159.005–5 for preapproval review. To meet the requirements of 46 CFR 159.005–5(a)(2), the manufacturer must submit in triplicate—

(1) A list of drawings, specifications, manuals, and any other documentation submitted, with each document identified by number, title, revision issue, and date;

(2) General arrangement and assembly drawings, including principal dimensions;

(3) Stress calculations for all load carrying parts;

(4) An operation, maintenance, and training manual as described in §§ 160.132–19 and 160.132–21 of this subpart;

(5) A description of the quality control procedures and recordkeeping that will apply to the production of the davit, which must include, but is not limited to—

(i) The system for checking material certifications received from suppliers;

(ii) The method for controlling the inventory of materials;

(iii) The method for checking quality of fabrication and joints, including welding inspection procedures; and

(iv) The inspection checklists used during various stages of fabrication to assure that the approved release mechanism complies with the approved plans and the requirements of this subpart;

(6) Any other drawing(s) necessary to show that the davit complies with the requirements of this subpart;

(7) The location or address of all manufacturing sites, including the name and address of any subcontractors, where the davit will be constructed; and

(8) The name of the independent laboratory that will perform the duties prescribed in § 160.132–15 of this subpart.

(c) At the request of the manufacturer and discretion of the Commandant, an independent laboratory may conduct preapproval review required by this section; so long as the preapproval review is conducted in accordance with the procedures agreed upon between the independent laboratory and Commandant under 46 CFR subpart 159.010.

(d) *Plan quality.* All plans and specifications submitted to the Commandant under this section must—

(1) Be provided in English, including all notes, inscriptions, and designations for configuration control;

(2) Address each of the applicable items in paragraph (b) of this section in sufficient detail to show that the davit meets the construction requirements of this subpart;

(3) Accurately depict the proposed davit;

(4) Be internally consistent;

(5) Be legible; and

(6) If reviewed by an independent laboratory under paragraph (c) of this section, include the independent laboratory's attestation that the plans meet the quality requirements of this section.

(e) *Alternatives.* Alternatives in materials, parts, or construction, and each item replaced by an alternative, must be clearly indicated as such in the plans and specifications submitted to the Commandant under this section.

(f) *Coast Guard review.* If the plans or specifications do not comply with the requirements of this section, Coast Guard review may be suspended, and the applicant notified accordingly.

§ 160.132–11 [Reserved]

§ 160.132–13 Approval inspections and tests for prototype davits.

(a) If the manufacturer is notified that the information submitted in accordance with § 160.132–9 of this subpart is satisfactory to the Commandant, the manufacturer may proceed with fabrication of the prototype davit, and the approval inspections and tests required under this section.

(b) Except as provided in paragraph (f) of this section, the Coast Guard must conduct the approval inspections and witness the approval tests required under this section.

(c) *Manufacturer requirements.* To proceed with approval inspections and tests required by this section, the manufacturer must—

(1) Notify the Commandant and cognizant Officer in Charge, Marine Inspection (OCMI) of where the approval inspections and tests required under this section will take place, and such notifications must be in sufficient time to allow making travel arrangements;

(2) Arrange a testing schedule with the cognizant OCMI that allows for a Coast Guard inspector to travel to the site where the testing is to be performed;

(3) Admit the Coast Guard inspector to any place where work or testing is performed on davits or their component parts and materials for the purpose of—

(i) Conducting inspections as necessary to determine that the prototype—

(A) Conforms with the plans reviewed under § 160.132–9 of this subpart;

(B) Is constructed by the methods and with the materials specified in the plans reviewed under § 160.132–9 of this subpart; and

(C) When welding is part of the construction process, is constructed by the welding procedure and materials as per the plans reviewed under § 160.132–9 of this subpart and the welders are appropriately qualified;

(ii) Assuring that the quality-assurance program of the manufacturer is satisfactory;

(iii) Witnessing tests; and

(iv) Taking samples of parts or materials for additional inspections or tests; and

(4) Make available to the Coast Guard inspector the affidavits or invoices from the suppliers of all essential materials used in the production of davits, together with records identifying the lot or serial numbers of the davits in which such materials were used.

(d) *Tests.* (1) *IMO Revised recommendation on testing.* Each prototype davit of each design must pass each of the tests described in IMO Revised recommendation on testing, part 1, paragraph 8.1 (incorporated by reference, see § 160.132–5 of this subpart) applicable to the design and service of the davit.

(2) *Visual inspection.* Each davit must be visually inspected to confirm—

(i) Compliance with this subpart;

(ii) Conformance with the examined plans; and

(iii) Ease of operation and maintenance.

(3) *Hydraulic controls.* If the davit design includes a fluid power and control system, a test of the hydraulic controls must be conducted in accordance with 46 CFR 58.30–35.

(e) *Test waiver.* The Commandant may waive certain tests for a davit similar in construction to a davit that has successfully completed the tests.

(f) At the request of the manufacturer and discretion of the Commandant, an independent laboratory may perform approval inspections and witness approval tests required by this section so long as the inspections and tests are performed and witnessed in accordance with the procedures agreed upon between the independent laboratory and Commandant under 46 CFR part 159, subpart 159.010.

(g) After completion of approval inspections and tests required by this section, the manufacturer must comply with the requirements of 46 CFR

159.005–9(a)(5) by preparing and submitting to the Commandant for review—

(1) The prototype approval test report containing the same information recommended by IMO MSC Circ. 980 (incorporated by reference, see § 160.132–5 of this subpart). The report must include a signed statement by the Coast Guard inspector (or independent laboratory as permitted by paragraph (f) of this section) who witnessed the testing, indicating that the report accurately describes the testing and its results; and

(2) The final version of the plans required under § 160.132–9 of this subpart in triplicate.

(h) The Commandant will review the report and plans submitted under paragraph (g) of this section, and if satisfactory to the Commandant, will approve the plans under 46 CFR 159.005–13.

§ 160.132–15 Production inspections, tests, quality control, and conformance of davits.

(a) Unless the Commandant directs otherwise, an independent laboratory must perform or witness, as appropriate, inspections, tests, and oversight required by this section. Production inspections and tests of davits must be carried out in accordance with the procedures for independent laboratory inspection in 46 CFR part 159, subpart 159.007 and in this section, unless the Commandant authorizes alternative tests and inspections. The Commandant may prescribe additional production tests and inspections necessary to maintain quality control and to monitor compliance with the requirements of this subpart.

(b) *Manufacturer's responsibility.* The manufacturer must—

(1) Institute a quality control procedure to ensure that all production davits are produced to the same standard, and in the same manner, as the prototype davit approved by the Commandant. The manufacturer's quality control personnel must not work directly under the department or person responsible for either production or sales;

(2) Schedule and coordinate with the independent laboratory (or Coast Guard inspector if required under paragraph (a) of this section), to ensure that all tests are performed as described in this section;

(3) Submit to the Commandant a yearly report that contains the following—

(i) Serial number and date of final assembly of each davit constructed;

(ii) The name of the representative of the independent laboratory (or Coast Guard inspector if required under paragraph (a) of this section); and

(iii) Name of the vessel and company receiving the davit, if known;

(4) Ensure that the arrangement and materials entering into the construction of the davit are in accordance with plans approved under § 160.132–13(h) of this subpart;

(5) Allow an independent laboratory (or Coast Guard inspector if required under paragraph (a) of this section) access to any place where materials are stored for the davit, work or testing is performed on davits or their component parts and materials, or records are retained to meet the requirements of paragraph (c) of this section, below, for the purpose of—

(i) Assuring that the quality control program of the manufacturer is satisfactory;

(ii) Witnessing tests; or

(iii) Taking samples of parts or materials for additional inspections or tests; and

(6) Ensure that the independent laboratory (or Coast Guard inspector if required under paragraph (a) of this section) conducts the inspections and witnesses the tests required by paragraph (e) of this section, and further conducts a visual inspection to verify that the davits are being made in accordance with the plans approved under § 160.132–13(h) of this subpart and the requirements of this subpart.

(c) *Recordkeeping.* The manufacturer must maintain records in accordance with 46 CFR 159.007–13. The manufacturer must keep records of all items listed in this section for at least 5 years from the date of termination of approval of each davit. The records must include—

(1) A copy of this subpart, other CFR sections referenced in this subpart, and each document listed in § 160.132–5 of this subpart;

(2) A copy of the approved plans, documentation, and certifications;

(3) A current certificate of approval for each approved davit;

(4) Affidavits, certificates, or invoices from the suppliers identifying all essential materials used in the production of approved davits, together with records identifying the serial numbers of davits in which such materials were used;

(5) Records of all structural welding and name of operator(s);

(6) Records of welder certificates, training, and qualifications;

(7) Date and results of calibration of test equipment and the name and address of the company or agency that performed the calibration;

(8) The serial number of each production davit, along with records of its inspections and tests carried out under this section; and

(9) The original purchaser of each davit and the vessel on which it was installed, if known.

(d) *Independent laboratory responsibility.* The independent laboratory must perform or witness, as appropriate, the inspections and tests under this section for each Coast Guard-approved davit to be installed on a U.S.-flagged vessel. If the manufacturer also produces davits for approval by other maritime safety administrations, the inspections may be coordinated with inspection visits for those administrations.

(e) *Production inspections and tests.* Each approved davit must be inspected and tested in accordance with the procedures in 46 CFR part 159, subpart 159.007 and the load test described in IMO Revised recommendation on testing, Part 2, paragraph 6.1.1 (incorporated by reference, see § 160.132–5 of this subpart).

§ 160.132–17 Marking and labeling.

(a) Each davit must be marked with a plate or label permanently affixed in a conspicuous place readily for inspection and sufficiently durable to withstand continuous exposure to environmental conditions at sea for the life of the davit.

(b) The plate or label must be in English, but may also be in other languages.

(c) The plate or label must contain the—

(1) Name and address of the manufacturer;

(2) Manufacturer's model identification;

(3) Name of the independent laboratory that witnessed the prototype or production tests;

(4) Serial number of the davit;

(5) U.S. Coast Guard approval number;

(6) Month and year of manufacture;

(7) Safe working load of the davit; and

(8) Word ''SOLAS''.

§ 160.132–19 Operating instructions and information for the ship's training manual.

(a) Each davit must have instructions and information for the ship's training manual that use the symbols from IMO Res. A.760(18) (incorporated by reference, see § 160.132–5 of this subpart) to describe the location and operation of the davit.

(b) The instructions and information required by paragraph (a) of this section may be combined with similar material

for survival craft and rescue boats, and their complete launching systems.

(c) The davit manufacturer must make operating instructions and information required by paragraph (a) of this section available in English to the purchaser of a davit approved by the Coast Guard.

§ 160.132–21 Operation and maintenance instructions.

(a) Each davit must have operation and maintenance instructions that—

(1) Follows the general format and content specified in IMO MSC.1 Circ. 1205 (incorporated by reference, see § 160.132–5 of this subpart); and

(2) Includes a checklist for use in monthly, external visual inspections of the davit.

(b) The davit manufacturer must make the manual required by paragraph (a) of this section available in English to the purchaser of a davit approved by the Coast Guard.

(c) The operation and maintenance instructions required by paragraph (a) of this section may be combined with similar material for survival craft and rescue boats, and their complete launching systems.

§ 160.132–23 Procedure for approval of design or material change.

(a) Each change in design, material, or construction from the plans approved under 46 CFR 159.005–13 and § 160.132–13(h) of this subpart must be approved by the Commandant before being used in any production davit. The manufacturer must submit any such change following the procedures in § 160.132–9 of this subpart, but documentation on items that are unchanged from the plans approved under 46 CFR 159.005–13 and § 160.115–13(h) of this subpart need not be resubmitted.

(b) Unless determined by the Commandant to be unnecessary, a prototype davit with each change described in paragraph (a) of this section must be made and tested according to the procedures for new approvals in §§ 160.132–9 through 160.132–13 of this subpart.

(c) Determinations of equivalence of design, construction, and materials will be made by the Commandant only.

■ 27. Add subpart 160.133 to read as follows:

Subpart 160.133—Release Mechanisms for Lifeboats and Rescue Boats (SOLAS)

Sec.

160.133–1 Scope.
160.133–3 Definitions.
160.133–5 Incorporation by reference.
160.133–7 Design, construction, and performance of release mechanisms.
160.133–9 Preapproval review.
160.133–11 [Reserved]
160.133–13 Approval inspections and tests for prototype release mechanisms.
160.133–15 Production inspections, tests, quality control, and conformance of release mechanisms.
160.133–17 Marking and labeling.
160.133–19 Operating instructions and information for the ship's training manual.
160.133–21 Operation and maintenance instructions.
160.133–23 Procedure for approval of design or material change.

Subpart 160.133—Release Mechanisms for Lifeboats and Rescue Boats (SOLAS)

§ 160.133–1 Scope.

This subpart prescribes standards, tests, and procedures for seeking Coast Guard approval of a release mechanism used for davit-launched and free-fall lifeboats approved under subpart 160.135 of this part, and rescue boats approved under subpart 160.156 of this part.

§ 160.133–3 Definitions.

In addition to the definitions in the IMO LSA Code (incorporated by reference, see § 160.133–5 of this subpart), in this subpart, the term:

Commandant means the Commandant (CG–5214), U.S. Coast Guard, 2100 Second Street, SW., Stop 7126, Washington, DC 20593–7126.

Full load means the weight of the complete lifeboat or rescue boat including all required equipment, provisions, fuel, and the number of persons for which it is approved. This is also known as the ''condition B'' weight.

Independent laboratory has the same meaning as 46 CFR 159.001–3. A list of accepted independent laboratories is available from the Commandant and online at *http://cgmix.uscg.mil.*

Light load means the weight of the complete lifeboat or rescue boat empty and does not include fuel, required equipment, or the equivalent weight of persons. This is also known as the ''condition A'' weight.

Officer in Charge, Marine Inspection (OCMI) means an officer of the Coast Guard designated as such by the Commandant and who fulfills the duties described in 46 CFR 1.01–15(b). The ''cognizant OCMI'' is the OCMI who has immediate jurisdiction over a vessel or geographic area for the purpose of performing the duties previously described.

SOLAS means the International Convention for the Safety of Life at Sea, 1974, as amended.

§ 160.133–5 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Coast Guard must publish notice of change in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at Commandant (CG–5214), U.S. Coast Guard, 2100 Second Street, SW., Stop 7126, Washington, DC 20593–7126. You may also inspect this material 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.* You may obtain copies of the material from the sources specified in the following paragraphs.

(b) American Society for Testing and Materials (ASTM), 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA, 19428–2959.

(1) ASTM A 36/A 36M–08, Standard Specification for Carbon Structural Steel, (approved May 15, 2008), IBR approved for § 160.133–7 (''ASTM A 36'').

(2) ASTM A 276–08a, Standard Specification for Stainless Steel Bars and Shapes, (approved October 1, 2008), IBR approved for § 160.133–7 (''ASTM A 276'').

(3) ASTM A 313/A 313M -08, Standard Specification for Stainless Steel Spring Wire, (approved October 1, 2008), IBR approved for § 160.133–7 (''ASTM A 313'').

(4) ASTM A 314–08, Standard Specification for Stainless Steel Billets and Bars for Forging, (approved October 1, 2008), IBR approved for § 160.133–7 (''ASTM A 314'').

(5) ASTM A 653/A 653M–08, Standard Specification for Steel Sheet, Zinc-Coated (Galvanized) or Zinc-Iron Alloy-Coated (Galvannealed) by the Hot-Dip Process, (approved July 15, 2008), IBR approved for §§ 160.133–7, 160.133–13, and 160.133–15. (''ASTM A 653'').

(6) ASTM F 1166–07, Standard Practice for Human Engineering Design for Marine Systems, Equipment, and Facilities, (approved January 1, 2007), IBR approved for § 160.133–7 (''ASTM F 1166'').

(c) International Maritime Organization (IMO), Publications Section, 4 Albert Embankment, London, SE1 7SR, United Kingdom, +44 (0)20 7735 7611, *http://www.imo.org/.*

(1) IMO Resolution A.760(18), Symbols Related to Life-Saving

Appliances and Arrangements, (adopted November 4, 1993), IBR approved for § 160.133–19 (''IMO Res. A.760(18)'').

(2) Life-Saving Appliances, including LSA Code, 2010 Edition, (2010), pages 7–71 (''IMO LSA Code''), IBR approved for § § 160.133–3 and 160.133–7.

(3) Life-Saving Appliances, including LSA Code, 2010 Edition, (2010), Revised recommendation on testing of live-saving appliances, pages 79–254 (''IMO Revised recommendation on testing''), IBR approved for §§ 160.133–7 and 160.133–13 (''IMO Revised recommendation on testing'').

(4) MSC/Circular 980, Standardized Life-saving Appliance Evaluation and Test Report Forms, (February 13, 2001), IBR approved for § 160.133–13 (''IMO MSC Circ. 980'').

(5) MSC.1/Circular 1205, Guidelines for Developing Operation and Maintenance Manuals for Lifeboat Systems, (May 26, 2006), IBR approved for § 160.133–21 (''IMO MSC.1 Circ. 1205'').

§ 160.133–7 Design, construction, and performance of release mechanisms.

(a) To seek Coast Guard approval of a release mechanism, a manufacturer must comply with, and each release mechanism must meet, the requirements of the following—

(1) IMO LSA Code, chapter IV/4.4.7.6 (incorporated by reference, see § 160.133–5 of this subpart), and a release mechanism for free-fall lifeboats must also meet the applicable provisions of chapter VI/6.1.4;

(2) IMO Revised recommendation on testing, Part ⅙.9 (incorporated by reference, see § 160.133–5 of this subpart);

(3) 46 CFR part 159; and

(4) This subpart.

(b) Each release mechanism must meet the following requirements—

(1) *Design.* All functions of the release mechanism, including removal of interlocks, operation of the release handle, resetting the hooks, and reattaching the falls to the hooks, must be designed to be operable by persons wearing immersion suits;

(2) Each release mechanism should be designed following standard human engineering practices described in ASTM F 1166 (incorporated by reference, see § 160.133–5 of this subpart). Design limits should be based on a range from the fifth percentile female to the ninety-fifth percentile male values for critical body dimensions and functional capabilities as described in ASTM F 1166. The dimensions for a person wearing an immersion suit correspond to the arctic clothed dimensions of ASTM F 1166;

(3) *Steel.* Each major structural component of each release mechanism must be constructed of steel. Other materials may be used if accepted by the Commandant as equivalent or superior. Sheet steel and plate must be low-carbon, commercial quality, either corrosion resistant or galvanized as per ASTM A 653 (incorporated by reference, see § 160.133–5 of this subpart), coating designation G115. Structural steel plates and shapes must be carbon steel as per ASTM A 36 (incorporated by reference, see § 160.133–5 of this subpart). All steel products, except corrosion resistant steel, must be galvanized to provide high-quality zinc coatings suitable for the intended service life in a marine environment. Each fabricated part must be galvanized after fabrication. Corrosion resistant steel must be a type 302 stainless steel per ASTM A 276, ASTM A 313 or ASTM A 314 (incorporated by reference, see § 160.133–5 of this subpart) or another corrosion resistant stainless steel of equal or superior corrosion resistant characteristics;

(4) *Welding.* Welding must be performed by welders certified by the Commandant, a classification society recognized by the Commandant in accordance with 46 CFR 8.220, the U.S. Navy, or the national body where the release mechanism is constructed or the national body's designated recognized organization. Only electrodes intended for use with the material being welded may be used. All welds must be checked using appropriate non-destructive tests;

(5) Metals in contact with each other must be either galvanically compatible or insulated with suitable non-porous materials. Provisions must also be made to prevent loosening or tightening resulting from differences of thermal expansion, freezing, buckling of parts, galvanic corrosion, or other incompatibilities;

(6) Screws, nuts, bolts, pins, keys, and other similar hardware, securing moving parts must be fitted with suitable lock washers, cotter pins, or locks to prevent them from coming adrift;

(7) The on-load operation of the release mechanism must require two separate, deliberate actions by the operator;

(8) The mechanical protection required by LSA Code Chapter IV/4.4.7.6.2.2 must only be able to be engaged when the release mechanism is properly and completely reset. Proper engagement of the mechanical protection must be visually indicated;

(9) The release and recovery procedures required by LSA Code Chapter IV/4.4.7.6.5 must be included as an illustrated operation instruction plate or placard. The plate or placard must be corrosion resistant and weatherproof and must be marked with the word ''Danger''. The illustrations must correspond exactly to those used in the instruction and maintenance manual provided by the manufacturer;

(10) The release lever or control must be red in color, and the area immediately surrounding the control must be a sharply contrasting light color;

(11) The release lever and its connection to the release mechanism must be of sufficient strength so that there is no deformation of the release lever or the release control assembly during on-load release;

(12) Positive means of lubrication must be provided for each bearing which is not permanently lubricated. Points of lubrication must be so located that they are clearly visible and accessible in the installed position in the boat;

(13) A hydraulic system, if used to activate the release mechanism, must be in accordance with 46 CFR part 58, subpart 58.30, with hose and fittings in accordance with 46 CFR part 56, subpart 56.60, except that—

(i) Push-on type fittings such as Aeroquip 1525–X, 25156–X, and FC332–X are not permitted;

(ii) The length of nonmetallic flexible hose is limited to 760 mm (30 in); and

(iii) If a hand pump is provided, adequate space must be provided for the hand pump or hand operation;

(14) Each release mechanism designed to launch a boat by free-fall must not be able to carry any weight until the release mechanism is properly reset, and each of the two independent activation systems required to be operated from inside the boat must require at least two independent actions from different locations inside the boat to release the hook; and

(15) Each release mechanism must have mechanical protection against accidental or premature release that can only be engaged when the release mechanism is properly and completely reset. Proper engagement of the mechanical protection must be visually indicated.

(c) Determinations of equivalence of design, construction, and materials will be made by the Commandant only.

§ 160.133–9 Preapproval review.

(a) Except as provided in paragraph (c) of this section, the Commandant must conduct the preapproval review, required by this section, in accordance with 46 CFR 159.005–5.

(b) *Manufacturer requirements.* To seek Coast Guard approval of a release

mechanism, the manufacturer must submit an application to the Commandant meeting the requirements of 46 CFR 159.005–5 for preapproval review. To meet the requirements of 46 CFR 159.005–5(a)(2), the manufacturer must submit in triplicate—

(1) A list of drawings, specifications, manuals, and any other documentation submitted, with each document identified by number, title, revision issue, and date;

(2) General arrangement and assembly drawings, including principal dimensions;

(3) Stress calculations for all load carrying parts, including the release hooks, release mechanisms, and connections;

(4) Hydraulic systems drawings and specifications, if installed;

(5) Drawings of all signs and placards showing actual inscription, format, color, and size;

(6) An operation, maintenance, and training manual as described in §§ 160.133–19 and 160.133–21 of this subpart;

(7) A description of the quality control procedures and recordkeeping that will apply to the production of the release mechanism, which must include but is not limited to—

(i) The system for checking material certifications received from suppliers;

(ii) The method for controlling the inventory of materials;

(iii) The method for checking quality of fabrication and joints, including welding inspection procedures; and

(iv) The inspection checklists used during various stages of fabrication to assure that the approved release mechanism complies with the approved plans and the requirements of this subpart;

(8) Full details of any other unique capability;

(9) Any other drawing(s) necessary to show that the release mechanism complies with the requirements of this subpart;

(10) The location or address of all manufacturing sites, including the name and address of any subcontractors, where the release mechanism will be constructed; and

(11) The name of the independent laboratory that will perform the duties prescribed in § 160.133–15 of this subpart.

(c) At the request of the manufacturer and discretion of the Commandant, an independent laboratory may conduct preapproval review required by this section, so long as the preapproval review is conducted in accordance with the procedures agreed upon between the independent laboratory and Commandant under 46 CFR part 159, subpart 159.010.

(d) *Plan quality.* The plans and specifications submitted to the Commandant under this section must—

(1) Be provided in English, including all notes, inscriptions, and designations for configuration control;

(2) Address each of the applicable items in paragraph (b) of this section in sufficient detail to show that the release mechanism meets the construction requirements of this subpart;

(3) Accurately depict the proposed release mechanism;

(4) Be internally consistent;

(5) Be legible; and

(6) If reviewed by an independent laboratory under paragraph (c) of this section, include the independent laboratory's attestation that the plans meet the quality requirements of this section.

(e) *Alternatives.* Alternatives in materials, parts, or construction, and each item replaced by an alternative, must be clearly indicated as such in the plans and specifications submitted to the Commandant under this section.

(f) *Coast Guard review.* If the plans or specifications do not comply with the requirements of this section, Coast Guard review may be suspended, and the applicant notified accordingly.

§ 160.133–11 [Reserved]

§ 160.133–13 Approval inspections and tests for prototype release mechanisms.

(a) If the manufacturer is notified that the information submitted in accordance with § 160.133–9 of this subpart is satisfactory to the Commandant, the manufacturer may proceed with fabrication of the prototype release mechanism, and the approval inspections and tests required under this section.

(b) Except as provided in paragraph (f) of this section, the Coast Guard must conduct the approval inspections and witness the approval tests required under this section.

(c) *Manufacturer requirements.* To proceed with approval inspections and tests required by this section, the manufacturer must—

(1) Notify the Commandant and cognizant Officer in Charge, Marine Inspection (OCMI) of where the approval inspections and tests required under this section will take place, and such notification must be in sufficient time to allow making travel arrangements;

(2) Arrange a testing schedule that allows for a Coast Guard inspector to travel to the site where the testing is to be performed;

(3) Admit the Coast Guard inspector to any place where work or testing is performed on release mechanisms or their component parts and materials for the purpose of—

(i) Conducting inspections as necessary to determine that the prototype—

(A) Conforms with the plans reviewed under § 160.133–9 of this subpart;

(B) Is constructed by the methods and with the materials specified in the plans reviewed under § 160.133–9 of this subpart; and

(C) When welding is part of the construction process, is constructed by the welding procedure and materials as per the plans reviewed under § 160.133–9 of this subpart and the welders are appropriately qualified;

(ii) Assuring that the quality-assurance program of the manufacturer is satisfactory;

(iii) Witnessing tests; and

(iv) Taking samples of parts or materials for additional inspections or tests; and

(4) Make available to the Coast Guard inspector the affidavits or invoices from the suppliers of all essential materials used in the production of release mechanisms, together with records identifying the lot or serial numbers of the release mechanisms in which such materials were used.

(d) *Tests.* (1) *Prototype release mechanism readiness.* All tests must be conducted on a complete release mechanism.

(2) *IMO Revised recommendation on testing.* Each prototype release mechanism of each design must pass each of the tests described in IMO Revised recommendation on testing, part 1, paragraph 6.9 (incorporated by reference, see § 160.133–5 of this subpart) applicable to davit-launched or free-fall lifeboats. Tests must be conducted in accordance with these paragraphs of IMO Revised recommendation on testing, Part 1, with the following modifications—

(i) *Visual inspection.* Each release mechanism must be visually inspected to confirm—

(A) Compliance with this subpart;

(B) Conformance with the examined plans; and

(C) Ease of operation and maintenance;

(ii) *Operation.* Operation of the off-load control, for a davit-launched boat, must be tested to confirm that the release lever cannot be shifted to release the boat in either the full load or light load condition. For a free-fall boat, the operation of the hook release must be demonstrated using both activation

systems and may be tested without launching the boat;

(iii) *Materials.* Steel meeting ASTM A 653 (incorporated by reference, see § 160.133–5 of this subpart) must meet the coating mass and bend tests requirement specified under ASTM A 653 after galvanizing or other anti-corrosion treatment has been applied. This compliance can be ascertained through a supplier's certification or by conducting actual tests;

(iv) *Tensile tests.* The release mechanism hook assembly and supporting structure must be tensile tested in a jig built to load the hook assembly in the same way it would be loaded when installed in a boat. The hook assembly will be approved for a maximum of one-sixth of the highest load applied without failure;

(v) *Universal joints.* This test is required if the release mechanism employs universal joints to transmit the release power from the control to the hook release. One of each type and size of universal joint must be set up in a jig with the angles of leads set at 0 (zero), 30, and 60 degrees, respectively. A torque of 540 Nm (400 ft lb) must be applied. This torque must be applied with the connecting rod secured beyond the universal and with the lever arm in the horizontal position. There must be no permanent set, or undue stress, as a result of this test; and

(vi) *Hydraulic controls.* If the release mechanism includes a fluid power and control system, a test of the hydraulic controls must be conducted in accordance with 46 CFR 58.30–35.

(e) *Test waiver.* The Commandant may waive certain tests for a release mechanism identical in construction to smaller and larger release mechanisms that have successfully completed the tests. However, stress calculations in accordance with § 160.133–9(b)(3) of this subpart must still be submitted. Tests associated with release mechanism components that have already been accepted by the Commandant are not required to be repeated.

(f) At the request of the manufacturer and discretion of the Commandant, an independent laboratory may perform approval inspections and witness approval tests required by this section so long as the inspections and tests are performed and witnessed in accordance with the procedures agreed upon between the independent laboratory and Commandant under 46 CFR part 159, subpart 159.010.

(g) After completion of approval inspections and tests required by this section, the manufacturer must comply with the requirements of 46 CFR 159.005–9(a)(5) by preparing and submitting to the Commandant for review—

(1) The prototype approval test report containing the same information recommended by IMO MSC Circ. 980 (incorporated by reference, see § 160.133–5 of this subpart). The report must include a signed statement by the Coast Guard inspector (or independent laboratory as permitted under paragraph (f) of this section) who witnessed the testing, indicating that the report accurately describes the testing and its results; and

(2) The final plans of the release mechanism as built, in triplicate. The plans must include the instructions for training and maintenance described in §§ 160.133–19 and 160.133–21 of this subpart, respectively.

(h) The Commandant will review the report and plans submitted under paragraph (g) of this section, and if satisfactory to the Commandant, will approve the plans under 46 CFR 159.005–13.

§ 160.133–15 Production inspections, tests, quality control, and conformance of release mechanisms.

(a) Unless the Commandant directs otherwise, an independent laboratory must perform or witness, as appropriate, inspections, tests, and oversight required by this section. Production inspections and tests of release mechanisms must be carried out in accordance with the procedures for independent laboratory inspection in 46 CFR part 159, subpart 159.007 and in this section, unless the Commandant authorizes alternative tests and inspections. The Commandant may prescribe additional production tests and inspections necessary to maintain quality control and to monitor compliance with the requirements of this subpart.

(b) *Manufacturer's responsibility.* The manufacturer must—

(1) Institute a quality control procedure to ensure that all production release mechanisms are produced to the same standard, and in the same manner, as the prototype release mechanism approved by the Commandant. The manufacturer's quality control personnel must not work directly under the department or person responsible for either production or sales;

(2) Schedule and coordinate with the independent laboratory (or Coast Guard inspector if required under paragraph (a) of this section) to ensure that all tests are performed as described in this section;

(3) Submit to the Commandant, a yearly report that contains the following—

(i) Serial number and date of final assembly of each release mechanism constructed;

(ii) The name of the representative of the independent laboratory (or Coast Guard inspector if required under paragraph (a) of this section); and

(iii) Serial number and model of the lifeboat or rescue boat in which the release mechanism is installed, if known;

(4) Ensure that the arrangement and materials entering into the construction of the release mechanism are in accordance with plans approved under § 160.133–13(h) of this subpart;

(5) Allow an independent laboratory (or Coast Guard inspector if required under paragraph (a) of this section) access to any place where materials are stored for the release mechanism, work or testing is performed on release mechanism or their component parts and materials, or records are retained to meet the requirements of paragraph (c) of this section, for the purpose of—

(i) Assuring that the quality control program of the manufacturer is satisfactory;

(ii) Witnessing tests; or

(iii) Taking samples of parts or materials for additional inspections or tests; and

(6) Ensure that the independent laboratory (or Coast Guard inspector if required under paragraph (a) of this section) conducts the inspections and witnesses the tests required by paragraph (e) of this section, and further conducts a visual inspection to verify that the release mechanisms are being made in accordance with the approved plans approved under § 160.133–13(h) of this subpart and the requirements of this subpart.

(c) *Recordkeeping.* The manufacturer must maintain records in accordance with 46 CFR 159.007–13. The manufacturer must keep records of all items listed in this section for at least 5 years from the date of termination of approval of each release mechanism. The records must include—

(1) A copy of this subpart, other CFR sections referenced in this subpart, and each document listed in § 160.133–5 of this subpart;

(2) A copy of the approved plans, documentation, and certifications;

(3) A current certificate of approval for each approved release mechanism;

(4) Affidavits, certificates, or invoices from the suppliers identifying all essential materials used in the production of approved release mechanisms, together with records

identifying the serial numbers of the release mechanisms in which such materials were used;

(5) Records of all structural welding and name of operator(s);

(6) Records of welder certificates, training, and qualifications;

(7) Date and results of calibration of test equipment and the name and address of the company or agency that performed the calibration;

(8) The serial number of each production release mechanism, along with records of its inspections and tests carried out under this section; and

(9) The original purchaser of each release mechanism and the vessel on which it was installed, if known.

(d) *Independent laboratory responsibility.* The independent laboratory must perform or witness, as appropriate, the inspections and tests under paragraph (e) of this section for each Coast Guard-approved release mechanism to be installed on a U.S.-flagged vessel. If the manufacturer also produces release mechanisms for approval by other maritime safety administrations, the inspections may be coordinated with inspection visits for those administrations.

(e) *Production inspections and tests.* Each finished release mechanism must be visually inspected. The manufacturer must develop and maintain a visual inspection checklist designed to ensure that all applicable requirements have been met. Each approved release mechanism constructed with non-corrosion resistant steel must be confirmed to have met the coating mass and bend tests requirement specified under ASTM A 653 (incorporated by reference, see § 160.133–5 of this subpart) after galvanizing or other anti-corrosion treatment has been applied. This compliance can be ascertained through a supplier's certification papers or through conducting actual tests.

§ 160.133–17 Marking and labeling.

(a) Each hook body of a release mechanism must be marked with a plate or label permanently affixed in a conspicuous place readily accessible for inspection and sufficiently durable to withstand continuous exposure to environmental conditions at sea for the life of the release mechanism.

(b) The plate or label must be in English, but may also be in other languages.

(c) The plate or label must contain the—

(1) Manufacturer's name and model identification;

(2) Name of the independent laboratory that witnessed the prototype or production tests;

(3) Serial number of the release mechanism;

(4) U.S. Coast Guard approval number;

(5) Month and year of manufacture;

(6) Safe working load of the release mechanism; and

(7) Word ''SOLAS.''

§ 160.133–19 Operating instructions and information for the ship's training manual.

(a) Each release mechanism must have instructions and information for the ship's training manual that use the symbols from IMO Res. A.760(18) (incorporated by reference, see § 160.133–5 of this subpart) to describe the location and operation of the release mechanism.

(b) The instructions and information required by paragraph (a) of this section may be combined with similar material for survival craft and rescue boats, and their launching systems.

(c) The release mechanism manufacturer must make the instructions and information required by paragraph (a) of this section available—

(1) In English to purchasers of release mechanisms approved by the Coast Guard; and

(2) In the form of an instruction placard providing simple procedures and illustrations for operation of the release mechanism. The placard must be not greater than 36 cm (14 in) by 51 cm (20 in), and must be made of durable material and suitable for display inside a lifeboat and rescue boat and/or near launching appliances on vessels.

§ 160.133–21 Operation and maintenance instructions.

(a) Each release mechanism must have operation and maintenance instructions that—

(1) Follows the general format and content specified in IMO MSC.1 Circ. 1205 (incorporated by reference, see § 160.133–5 of this subpart); and

(2) Includes a checklist for use in monthly, external visual inspections of the release mechanism.

(b) The release mechanism manufacturer must make the manual required by paragraph (a) of this section available in English to purchasers of a release mechanism approved by the Coast Guard.

(c) The operation and maintenance instructions required by paragraph (a) of this section may be combined with similar material for survival craft and rescue boats, and their launching systems.

§ 160.133–23 Procedure for approval of design, material, or construction change.

(a) Each change in design, material, or construction from the plans approved under 46 CFR 159.005–13 and § 160.133–13(h) of this subpart must be approved by the Commandant before being used in any production release mechanism. The manufacturer must submit any such change following the procedures set forth in § 160.133–9 of this subpart, but documentation on items that are unchanged from the plans approved under 46 CFR 159.005–13 and § 160.133–13(h) of this subpart need not be resubmitted.

(b) Unless determined by the Commandant to be unnecessary, a prototype release mechanism with each change described in paragraph (a) of this section must be made and tested according to the procedures for new approvals in §§ 160.133–9 through 160.133–13 of this subpart.

(c) Determinations of equivalence of design, material, or construction will be made by the Commandant only.

■ 28. Add subpart 160.135 to read as follows:

Subpart 160.135—Lifeboats (SOLAS)

Sec.

160.135–1 Scope.
160.135–3 Definitions.
160.135–5 Incorporation by reference.
160.135–7 Design, construction, and performance of lifeboats.
160.135–9 Preapproval review.
160.135–11 Fabrication of prototype lifeboats for approval.
160.135–13 Approval inspections and tests for prototype lifeboats.
160.135–15 Production inspections, tests, quality control, and conformance of lifeboats.
160.135–17 Marking and labeling.
160.135–19 Operating instructions and information for the ship's training manual.
160.135–21 Operation and maintenance instructions.
160.135–23 Procedure for approval of design or material change.

Subpart 160.135—Lifeboats (SOLAS)

§ 160.135–1 Scope.

This subpart prescribes standards, tests, and procedures for seeking Coast Guard approval of a lifeboat.

§ 160.135–3 Definitions.

In addition to the definitions in the IMO LSA Code (incorporated by reference, see § 160.135–5 of this subpart), in this subpart, the term:

Commandant means the Commandant (CG–5214), U.S. Coast Guard, 2100 Second Street SW., Stop 7126, Washington, DC 20593–7126.

Fiberglass Reinforced Plastic (FRP) means a composite structural material formed by electrical-grade glass fibers in Coast Guard accepted catalyst activated resin.

Full load means the weight of the complete lifeboat including all required equipment, provisions, fuel, and the number of persons for which it is approved. This is also known as the ''condition B'' weight.

Independent laboratory has the same meaning as 46 CFR 159.001–3. A list of accepted independent laboratories is available from the Commandant and online at *http://cgmix.uscg.mil.*

Light load means the weight of the complete lifeboat empty and does not include fuel, required equipment, or the equivalent weight of persons. This is also known as the ''condition A'' weight.

Officer in Charge, Marine Inspection (OCMI) means an officer of the Coast Guard designated as such by the Commandant and who fulfills the duties described in 46 CFR 1.01–15(b). The ''cognizant OCMI'' is the OCMI who has immediate jurisdiction over a vessel or geographic area for the purpose of performing the duties previously described.

Positive Stability means the condition of a lifeboat such that when it is displaced a small amount in any direction from upright, it returns on its own to the position before displacement.

SOLAS means the International Convention for the Safety of Life at Sea, 1974, as amended.

§ 160.135–5 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Coast Guard must publish notice of change in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at Commandant (CG–5214), U.S. Coast Guard, 2100 Second Street, SW., Stop 7126, Washington, DC 20593–7126. You may also inspect this material 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.* You may obtain copies of the material from the sources specified in the following paragraphs.

(b) American Society for Testing and Materials (ASTM), 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA, 19428–2959.

(1) ASTM A 36/A 36M–08, Standard Specification for Carbon Structural Steel, (approved May 15, 2008), IBR approved for §§ 160.135–7 and 160.135–15 (''ASTM A 36'').

(2) ASTM A 276–08a, Standard Specification for Stainless Steel Bars and Shapes, (approved October 1, 2008), IBR approved for § 160.135–7 (''ASTM A 276'').

(3) ASTM A 313/A 313M –08, Standard Specification for Stainless Steel Spring Wire, (approved October 1, 2008), IBR approved for § 160.135–7 (''ASTM A 313'').

(4) ASTM A 314–08, Standard Specification for Stainless Steel Billets and Bars for Forging, (approved October 1, 2008), IBR approved for § 160.135–7 (''ASTM A 314'').

(5) ASTM A 653/A 653M–08, Standard Specification for Steel Sheet, Zinc-Coated (Galvanized) or Zinc-Iron Alloy-Coated (Galvannealed) by the Hot-Dip Process, (approved July 15, 2008), IBR approved for §§ 160.135–7, 160.135–11, and 160.135–15 (''ASTM A 653'').

(6) ASTM B 127–05 (Reapproved 2009), Standard Specification for Nickel-Copper Alloy (UNS N04400) Plate, Sheet, and Strip, (approved October 1, 2009), IBR approved for § 160.135–7 (''ASTM B 127'').

(7) ASTM B 209–07, Standard Specification for Aluminum and Aluminum-Alloy Sheet and Plate, (approved August 1, 2007), IBR approved for § 160.135–7 (''ASTM B 209'').

(8) ASTM D 638–08, Standard Test Method for Tensile Properties of Plastics, (approved April 1, 2008), IBR approved for § 160.135–11 (''ASTM D 638'').

(9) ASTM D 790–07e1, Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials, (approved September 1, 2007), IBR approved for § 160.135–11 (''ASTM D 970'').

(10) ASTM D 2584–08, Standard Test Method of Ignition Loss for Cured Reinforced Resins, (approved May 1, 2008), IBR approved for §§ 160.135–11 and 160.135–15 (''ASTM D 2584'').

(11) ASTM D 4029–09, Standard Specification for Finished Woven Glass Fabrics, (approved January 15, 2009), IBR approved for § 160.135–7 (''ASTM D 4029'').

(12) ASTM F 1166–07, Standard Practice for Human Engineering Design for Marine Systems, Equipment, and Facilities, (approved January 1, 2007), IBR approved for §§ 160.135–7 and 160.135–13 (''ASTM F 1166'').

(c) General Services Administration, Federal Acquisition Service, Office of the FAS Commissioner, 2200 Crystal Drive, 11th Floor, Arlington, VA 22202, 703–605–5400.

(1) Federal Standard 595C, Colors Used in Government Procurement, (January 16, 2008), IBR approved for § 160.135–7 (''FED–STD–595C'').

(2) [Reserved].

(d) International Maritime Organization (IMO), Publications Section, 4 Albert Embankment, London SE1 7SR, United Kingdom, +44 (0)20 7735 7611, *http://www.imo.org/.*

(1) IMO Resolution A.658(16), Use and Fitting of Retro-Reflective Materials on Life-Saving Appliances, (adopted October 19, 1989), IBR approved for § 160.135–7 (''IMO Res. 658(16)'').

(2) IMO Resolution A.760(18), Symbols Related to Life-Saving Appliances and Arrangements, (adopted November 4, 1993), IBR approved for §§ 160.135–7 and 160.135–19 (''IMO Res. A.760(18)'').

(3) Life-Saving Appliances, including LSA Code, 2010 Edition, (2010), pages 7–71 (''IMO LSA Code''), IBR approved for §§ 160.135–3, 160.135–7, and 160.135–13.

(4) Life-Saving Appliances, including LSA Code, 2010 Edition, (2010), Revised recommendation on testing of life-saving appliances, pages 79–254 (''IMO Revised recommendation on testing''), IBR approved for §§ 160.135–7 and 160.135–13.

(5) MSC/Circular 980, Standardized life-saving Appliance Evaluation and Test Report Forms, (February 13, 2001), IBR approved for §§ 160.135–7 and 160.135–13 (''IMO MSC Circ. 980'').

(6) MSC.1/Circular 1205, Guidelines for Developing Operation and Maintenance Manuals for Lifeboat Systems, (May 26, 2006), IBR approved for § 160.135–21 (''IMO MSC.1 Circ. 1205'').

(e) International Organization for Standardization (ISO): ISO Central Secretariat [ISO Copyright Office], Case Postale 56, CH–1211 Geneve 20, Switzerland.

(1) ISO 527–1:1993(E), Plastics—Determination of tensile properties, part 1: General Principles, First Edition (June 15, 1993), IBR approved for § 160.135–11 (''ISO 527'').

(2) ISO 1172:1996(E), Textile-glass-reinforced plastics—Prepregs, moulding compounds and laminates—Determination of the textile-glass and mineral-filler content—Calcination methods, Second Edition (December 15, 1996), IBR approved for §§ 160.135–11 and 160.135–15 (''ISO 1172'').

(3) ISO 14125:1998(E), Fibre-reinforced plastic composites—Determination of flexural properties, First Edition (March 1, 1998), IBR approved for § 160.135–11 (''ISO 14125'').

(f) Military Specifications and Standards, Standardization Documents Order Desk, Building 4D, 700 Robbins Avenue, Philadelphia, PA 19111–5094, *https://assist.daps.dla.mil/quicksearch/.*

(1) A–A–55308, Commercial Item Description, Cloth And Strip, Laminated Or Coated, Vinyl Nylon Or Polyester, High Strength, Flexible, (May 13, 1997), IBR approved for §§ 160.135–7 and 160.135–15. (''A–A–55308'').

(2) MIL–C–19663D, Military Specification, Cloth, Woven Roving, For Plastic Laminate, (August 4, 1988), IBR approved for § 160.135–7 (''MIL–C–19663D'').

(3) MIL–P–17549D(SH), Military Specification, Plastic Laminates, Fibrous Glass Reinforced, Marine Structural, (August 31, 1981), IBR approved for § 160.135–11 (''MIL–P–17549D(SH)'').

(4) MIL–R–21607E(SH), Military Specification, Resins, Polyester, Low Pressure Laminating, Fire-Retardant, (May 25, 1990), IBR approved for § 160.135–11,

§ 160.135–7 Design, construction, and performance of lifeboats.

(a) To seek Coast Guard approval of a lifeboat, a manufacturer must comply with, and each lifeboat must meet, the requirements of the following—

(1) IMO LSA Code, Chapter IV (incorporated by reference, see § 160.135–5 of this subpart) applicable to the type of lifeboat;

(2) IMO Revised recommendation on testing, Part ⅙ (incorporated by reference, see § 160.135–5 of this subpart) applicable to the type of lifeboat;

(3) 46 CFR part 159; and

(4) This subpart.

(b) Each lifeboat must meet the following requirements:

(1) *Design.* (i) Each lifeboat, other than a totally enclosed lifeboat, must be designed to be operable by persons wearing immersion suits.

(ii) Each lifeboat should be designed following standard human engineering practices described in ASTM F 1166 (incorporated by reference, see § 160.135–5 of this subpart). Design limits should be based on a range from the fifth percentile female to the ninety-fifth percentile male values for critical body dimensions and functional capabilities as described in ASTM F 1166. The dimensions for a person wearing an immersion suit correspond to the arctic clothed dimensions of ASTM F 1166.

(2) *Visibility from operator's station.* (i) The operator's station must be designed such that the operator, when seated at the control station, has visibility 360 degrees around the lifeboat, with any areas obstructed by the lifeboat structure or its fittings visible by moving the operator's head and torso.

(ii) The operator, while still being able to steer and control the speed of the lifeboat, must be able to see the water—

(A) Over a 90 degree arc within 3 m (9 ft, 10 in) of each side of the lifeboat;

(B) Over a 30 degree arc within 1 m (3 ft, 3 in) of each side of the lifeboat; and

(C) Within 0.5 m (1 ft, 8 in) of the entrances designated for recovering persons from the water.

(iii) In order to see a person in the water during recovery or docking operations, a hatch must be provided so that the operator can stand with his or her head outside the lifeboat for increased visibility, provided the operator can still steer and control the speed of the lifeboat.

(3) *Construction.* Each major rigid structural component of each lifeboat must be constructed of steel, aluminum, Fiber Reinforced Plastic (FRP), or materials accepted by the Commandant as equivalent or superior.

(i) *General.* Metals in contact with each other must be either galvanically compatible or insulated with suitable non-porous materials. Provisions must also be made to prevent loosening or tightening resulting from differences of thermal expansion, freezing, buckling of parts, galvanic corrosion, or other incompatibilities.

(ii) *Steel.* Sheet steel and plate must be low carbon, commercial quality, either corrosion resistant or galvanized as per ASTM A 653, coating designation G90 (incorporated by reference, see § 160.135–5 of this subpart). Structural steel plates and shapes must be carbon steel as per ASTM A 36 (incorporated by reference, see § 160.135–5 of this subpart), or an equivalent or superior steel accepted by the Commandant. All steel products, except corrosion resistant steel, must be galvanized to provide high quality zinc coatings suitable for the intended service life in a marine environment. Corrosion resistant steel must be a type 302 stainless steel per ASTM A 276, ASTM A 313 or ASTM A 314 (incorporated by reference, see § 160.135–5 of this subpart) or another corrosion resistant stainless steel of equal or superior corrosion resistant characteristics.

(iii) *Aluminum.* Aluminum and aluminum alloys must conform to ASTM B 209 (incorporated by reference, see § 160.135–5 of this subpart) and be high purity for good marine corrosion resistance, free of iron, and containing not more than 0.6 percent copper.

(iv) *Fiber Reinforced Plastic.*

(A) *Resin.* Any resin used for the hull, canopy, hatches, rigid covers, and enclosures for the engine, transmission, and engine accessories, must be fire retardant and accepted by the Commandant in accordance with 46 CFR part 164, subpart 164.120.

(B) *Glass reinforcement.* Any glass reinforcement used must have good laminated wet strength retention and must meet the appropriate specification in this paragraph. Glass cloth must be a finished fabric woven from ''E'' electrical glass fiber yarns meeting ASTM D 4029 commercial style designation 1564 (incorporated by reference, see § 160.135–5 of this subpart). Woven roving must conform to MIL–C–19663D (incorporated by reference, see § 160.135–5 of this subpart). Other glass materials equivalent or superior in strength, design, wet out, and efficiency will be given consideration on specific request to the Commandant.

(C) *Laminate.* All exposed surfaces of any finished laminate must present a smooth finish, and there must be no protruding surface fibers, open voids, pits, cracks, bubbles, or blisters. The laminate must be essentially free from resin-starved or overimpregnated areas, and no foreign matter must remain in the finished laminate. The entire laminate must be fully cured and free of tackiness, and must show no tendency to delaminate, peel, or craze in any overlay. The laminate must not be released from the mold until a Barcol hardness reading of not less than 40–55 is obtained from at least 10 places on the non-gel coated surface, including all interior inner and outer hull surfaces and built-in lockers. The mechanical properties of the laminate must meet the requirements for a Grade 3 laminate as specified in Table I of MIL–P–17549D(SH) (incorporated by reference, see § 160.135–5 of this subpart). Other grades will be given consideration on specific request to the Commandant.

(4) *Welding.* Welding must be performed by welders certified by the Commandant, a classification society recognized by the Commandant in accordance with 46 CFR 8.220, the U.S. Navy, or the national body where the lifeboat is constructed or the national body's designated recognized organization. Only electrodes intended for use with the material being welded

may be used. All welds must be checked using appropriate non-destructive tests.

(5) *Lifeboat buoyancy.* (i) The buoyancy material must be accepted by the Commandant as meeting the performance requirements of the IMO Revised recommendation on testing, part 1, 6.2.2 to 6.2.7, with a density of 32 ± 8 kg/m^3 (2 ± 0.5 lb/ft^3). The buoyancy foam or lifeboat manufacturer must certify the results of the testing to IMO Revised recommendation on testing, part 1, 6.2.2 to 6.2.7 and submit those results to the Commandant. A list of accepted buoyancy foams may be obtained from the Commandant upon request and online at *http://cgmix.uscg.mil.*

(ii) All voids in the hull and canopy required to provide buoyancy for positive stability and self righting must be completely filled with Coast Guard accepted buoyancy material.

(6) *Engines.* (i) In order to be accepted by the Commandant, any compression ignition engine fitted to an approved lifeboat must meet the U.S. Environmental Protection Agency emission requirements in 40 CFR part 89, part 94, or part 1042, as applicable, and have reports containing the same information as recommended by MSC Circ. 980 (incorporated by reference, see § 160.135–5 of this subpart) certified and witnessed by a U.S. Coast Guard inspector or an independent laboratory.

(ii) A hydraulic system, if used to start the engine, must be in accordance with 46 CFR part 58, subpart 58.30, with hose and fittings in accordance with 46 CFR part 56, subpart 56.60, except that—

(A) Push-on type fittings such as Aeroquip 1525–X, 25156–X, and FC332–X are not permitted; and

(B) The length of nonmetallic flexible hose is limited to 760 mm (30 in). Longer, nonmetallic flexible hoses may be allowed in emergency steering systems at the discretion of the Commandant.

(iii) If a hand pump is provided, or if the engine has a manual starting system, adequate space must be provided for the hand pump or hand start operation.

(7) *Fuel system.* (i) The fuel system must meet 46 CFR 56.50–75(b) and, except as specified in this paragraph, the fuel tank must meet 46 CFR 58.50–10.

(ii) Tanks constructed with—

(A) *Aluminum* must be at least 5 mm (0.20 in) thick of ASTM B 209 or 5086 alloy;

(B) *Nickel-copper* must be at least 0.9 mm (0.0375 in) thick of ASTM B 127 hot-rolled sheet or plate;

(C) *Steel or iron* must be at least 1.9 mm (0.0747 in) thick. Diesel tanks of steel or iron must not have interior galvanizing;

(D) *Fiberglass reinforced plastic* must be at least 5 mm (0.187 in) thick; be sealed against porosity by at least one ply of chopped strand mat; be reinforced in the way of tank openings; be fitted with corrosion-resistant fittings; have each joint at the top of the tank; and have each joint bonded and through-bolted; or

(E) *Roto-molded plastic* must be at least 5 mm thick; must meet the requirements of 33 CFR 183.510 (a), (b), and (e) regardless of tank capacity; must be able to pass all static pressure tests as required in 33 CFR 183.510 at a minimum pressure of 5 psi; and be fitted with corrosion-resistant fittings.

(iii) Each fuel tank over 0.75 m (30 in) long must be baffled at intervals not exceeding 0.45 m (18 in).

(iv) A fuel level indicator must be provided for each fuel tank.

(v) Any fuel tank vent piping must be at least 6 mm (0.25 in) outside diameter tubing.

(vi) A shut-off valve must be provided at the fuel tank and must not be provided at the fuel pump. The valve must be clearly labeled. The position of the valve must be clearly indicated by a permanent marking inside the lifeboat. The marking must be an arrow pointing in the direction of the valve, and the words ''Fuel Shut-Off Valve'' must be in a color that contrasts with their background. The marking must be legible to a person within the vicinity of the engine.

(8) *Starting system batteries.* Any battery fitted in a totally enclosed lifeboat must be stored in a sealed compartment with exterior venting. If the lifeboat has more than one engine, then only one starting battery is required per engine.

(9) *Exhaust.* Engine exhaust must be routed away from bilge and potential oil drips. Any paint used on engines, manifolds, or exhaust must not give off fumes when heated. All exhaust lagging must be non-absorbent.

(10) *Propeller guard.* Each propeller on a lifeboat must be fitted with a propeller guard with a maximum opening of 76 mm (3 in) on all sides on which a person is likely to be exposed.

(11) *Control and steering station.* The operator's control and steering station must have complete lifeboat lowering and launching, hook release, engine throttle, steering controls, and if applicable, an air system and water spray system.

(i) The throttle must be a continuous manual control and must be able to be set and locked at any position.

(ii) The control and steering station must be designed and laid out in accordance with ASTM F 1166 sections 9 and 10, so that controls and displays are unambiguous, accessible, and easy to reach and use from the operator's normal seated position, while wearing an immersion suit or a lifejacket.

(iii) Each control, gauge, or display must be identified by a marking posted on, above, or adjacent to the respective item. Each control must operate in a logical manner and be marked with an arrow to show direction of movement of control which will cause an increased response. Each gauge must be marked with the normal operating range and indicate danger or abnormal conditions. Each marking must be permanent and weatherproof.

(iv) Gauges, and audio and visual alarms must be provided to monitor at least the following parameters—

(A) Coolant temperature, for a liquid cooled engine;

(B) Oil pressure, for an engine with an oil pump;

(C) Tachometer, for an engine not provided with over-speed protection; and

(D) State of charge, or rate of charge, for each rechargeable engine starting power source.

(12) *Hull drain plug.* The position of each drain plug must be clearly indicated by a permanent marking inside the lifeboat. The marking must be an arrow pointing in the direction of the plug, and the words ''Drain Plug'' must be 76 mm (3 in) high and have letters of a color that contrast with their background. The marking must be clearly visible to a person within the vicinity of the drain plug.

(13) *Remote steering.* The procedure to change over from remote to local steering must be simple, not require the use of tools, and be clearly posted. There must be sufficient clear space to install, operate, remove, and stow the removable tiller arm. The tiller arm and its connection to the rudder stock must be of sufficient strength so that there is no slippage or bending of the tiller arm. Rudder stops or other means must be provided to prevent the rudder from turning too far on either side.

(14) *Lifelines.* Buoyant lifelines must be of ultraviolet resistant material.

(15) *Rails provided as handholds.* Rails provided as handholds to cling when the lifeboat is overturned must extend for half the length of the lifeboat on both sides of the hull, and the clearance between the rail and hull must also be at least 38 mm (1.5 in). The rails must be attached to the hull below the chine or turn of the bilge, must be faired to prevent any fouling, and not

project beyond the widest part of the lifeboat.

(16) *Storage compartments and collection and storage of rainwater.* (i) Each storage compartment must be supported and secured against movement. It must have adequate hand access for removing and storing the required equipment, provisions, or water, and for cleaning the inside of the compartment.

(ii) The rain water collecting device may be incorporated into the design of the canopy or may be a separate unit to be mounted outside the lifeboat. The device must have a projected horizontal area of at least 1 m^2 (10.7 ft^2) collection area and be designed to function unattended.

(iii) Provision must be made to continue to collect water in the storage compartment while drawing water to fill a cup. The compartment must have a means of drainage and adequate access to allow filling the graduated drinking cup required to be carried as part of the lifeboat equipment.

(17) *Release mechanism.* Each release mechanism must be identified at the application for approval of the prototype lifeboat and must be approved under 46 CFR part 160, subpart 160.133. The release lever or control in the lifeboat must be red in color, and the area immediately surrounding the control must be a sharply contrasting light color. An illustrated operating instruction plate or placard showing the correct off-load and emergency on-load release procedure and recovery procedure must be posted so that it is visible and legible from the helmsman's normal operating position. The plate or placard must be corrosion resistant and weatherproof and must be marked with the word ''Danger''.

(18) *Painter release.* Any painter release must be located such that the lifeboat operator can readily release the painter from the operator's control and steering station.

(19) *Canopy lamp.* Any exterior lifeboat position-indicating light must be approved by the Commandant under approval series 161.101.

(20) *Manually-controlled interior light.* Any interior light must be approved by the Commandant under approval series 161.101.

(21) *Lifeboat equipment.* Each lifeboat must be designed to accommodate and carry the equipment as specified in 46 CFR 199.175.

(22) *Oars.* Oars are not required on a lifeboat with more than one engine, provided one engine can be operated while the other is disabled.

(23) *Bilge pump.* Each lifeboat that is not automatically self-bailing, must be fitted with a manual bilge pump approved under 46 CFR part 160, subpart 160.044. Each such lifeboat with a capacity of 100 persons or more must carry an additional approved manual bilge pump or an engine-powered bilge pump.

(24) *Exterior color.* The primary color of the exterior of the canopy and interior of partially enclosed lifeboats visible from the air must be a highly visible color equivalent to vivid reddish orange color number 12197 of FED–STD–595C (incorporated by reference, see § 160.135–5 of this subpart), or a durable fluorescent color of a similar hue.

(25) *Self-contained air supply system and fire protection system operating instructions.* Each compressed gas air cylinder must meet the requirements in 46 CFR 147.60. The cylinders must be accessible for removal and charging in place. Water-resistant instructions for starting the water spray and air supply, if fitted, must be provided and mounted in a conspicuous place near the system controls.

(26) *Navigating lights.* Each lifeboat must have navigation lights that are in compliance with the applicable sections of the International and Inland Navigation Rules and meet 46 CFR 111.75–17.

(27) *Retroreflective material.* The exterior of each lifeboat and its canopy must be marked with Type II retroreflective material approved under 46 CFR part 164, subpart 164.018. The arrangement of the retroreflective material must comply with IMO Res. A.658(16) (incorporated by reference, see § 160.135–5 of this subpart).

(28) *Permanently attached foldable canopy.* For a partially enclosed lifeboat, the foldable canopy cloth material must meet the specifications for Type II, Class 1 requirements of A–A–55308 (incorporated by reference, see § 160.135–5 of this subpart), or be accepted by the Commandant as equivalent or superior.

(29) *Labels and notices.* Any labels, caution and danger notices, and operating, maintenance, or general instructions, must be in accordance with ASTM F 1166, Section 15, in terms of format, content, lettering size and spacing, color, and posted location. They must be illustrated with symbols in accordance with IMO Res. A.760(18) (incorporated by reference, see § 160.135–5 of this subpart), as applicable. Information and instruction plates, not specifically mentioned in this section, must not be posted in the vicinity of the control and steering station without prior approval from the Commandant. Identification label plates, if required, must be posted on or above the component or equipment to be identified.

(c) Determinations of equivalence of design, construction, and materials will be made by the Commandant only.

§ 160.135–9 Preapproval review.

(a) Except as provided in paragraph (c) of this section, the Commandant must conduct the preapproval review, required by this section, in accordance with 46 CFR 159.005–5.

(b) *Manufacturer requirements.* To seek Coast Guard approval of a lifeboat, the manufacturer must submit an application to the Commandant meeting the requirements of 46 CFR 159.005–5 for preapproval review. To meet the requirements of 46 CFR 159.005–5(a)(2), the manufacturer must submit in triplicate—

(1) A list of drawings, specifications, manuals, and any other documentation submitted, with each document identified by number, title, revision issue, and date;

(2) General arrangement and assembly drawings, including principal dimensions;

(3) Seating arrangement plan, including a dimensioned seat form to scale;

(4) A complete material list, with each material referenced to a U.S. national standard or, if a copy is provided in English, an equivalent international standard;

(5) Plans for carriage and, in detail, stowage of equipment;

(6) Hull, canopy, and critical parts lay-up schedule for a Fiber Reinforced Plastic (FRP) lifeboat;

(7) Hull and canopy construction drawings, including particulars of joints, welds, seams, and other fabricating details;

(8) Weights and thickness of each major FRP structural component, including the hull, canopy, and inner liners, before outfitting;

(9) Specification and identification of materials such as steel, aluminum, resin, foam, fiberglass, cloth, and plastic used in the lifeboat's manufacture;

(10) Fabrication details for each major structural component, including details of each welded joint;

(11) Lines plans;

(12) Propulsion system specifications and arrangement and installation drawings;

(13) Steering system drawings and specifications;

(14) Release mechanism installation drawings and the mechanism's Coast Guard approval number;

(15) Air and water spray systems drawings and specifications, if installed;

(16) Plans for critical subassemblies;

(17) Hydraulic systems drawings and specifications, if installed;

(18) Electrical system schematics and specifications;

(19) Stability data, including righting arm curves in the light and loaded condition for both intact and flooded stability;

(20) Drawings of all signs and placards, showing actual inscription, format, color, size, and location on the lifeboat;

(21) Complete data pertinent to the installation and use of the proposed lifeboat, including the light load (condition A) and full load (condition B) weights;

(22) Specifications for the required launching ramp length and angle, and the height of free-fall lifeboat installation above the water;

(23) An operation, maintenance, and training manual as described in §§ 160.135–19 and 160.135–21 of this subpart;

(24) A description of the quality control procedures and record keeping that will apply to the production of the lifeboat, which must include but is not limited to—

(i) The system for checking material certifications received from suppliers;

(ii) The method for controlling the inventory of materials;

(iii) The method for checking quality of fabrication, seams, and joints, including welding inspection procedures; and

(iv) The inspection checklists used during various stages of fabrication to assure that the approved lifeboat complies with the approved plans and the requirements of this subpart;

(25) Full details of any other unique capability;

(26) Any other drawing(s) necessary to show that the lifeboat complies with the requirements of this subpart;

(27) The location or address of all manufacturing sites, including the name and address of any subcontractors, where the lifeboat will be constructed; and

(28) The name of the independent laboratory that will perform the duties prescribed in §§ 160.135–11 and 160.135–15 of this subpart.

(c) At the request of the manufacturer and discretion of the Commandant, an independent laboratory may conduct preapproval review required by this section so long as the preapproval review is conducted in accordance with the procedures agreed upon between the independent laboratory and Commandant under 46 CFR part 159, subpart 159.010.

(d) *Plan quality.* The plans and specifications submitted to the Commandant under this section must—

(1) Be provided in English, including all notes, inscriptions, and designations for configuration control;

(2) Address each of the applicable items in paragraph (b) of this section in sufficient detail to show that the lifeboat meets the construction requirements of this subpart;

(3) Accurately depict the proposed lifeboat;

(4) Be internally consistent;

(5) Be legible; and

(6) If reviewed by an independent laboratory under paragraph (c) of this section, include the independent laboratory's attestation that the plans meet the quality requirements of this section.

(e) *Alternatives.* Alternatives in materials, parts, or construction, and each item replaced by an alternative, must be clearly indicated as such in the plans and specifications submitted to the Commandant under this section.

(f) *Coast Guard review.* If the plans or specifications do not comply with the requirements of this section, Coast Guard review may be suspended, and the applicant notified accordingly.

§ 160.135–11 Fabrication of prototype lifeboats for approval.

(a) If the manufacturer is notified that the information submitted in accordance with § 160.135–9 of this subpart is satisfactory to the Commandant, the manufacturer may proceed with fabrication of the prototype lifeboat as set forth in this section.

(b) Unless the Commandant directs otherwise, an independent laboratory must perform or witness, as appropriate, inspections, tests, and oversight required by this section. Prototype inspections and tests of a lifeboat must be carried out in accordance with the procedures for independent laboratory inspection in 46 CFR part 159, subpart 159.007 and in this section, unless the Commandant authorizes alternative tests and inspections. The Commandant may prescribe additional prototype tests and inspections necessary to maintain quality control and to monitor compliance with the requirements of this subpart.

(c) Fabrication of a lifeboat must proceed in the following sequence:

(1) The manufacturer must arrange for an independent laboratory (or Coast Guard inspector if required under paragraph (b) of this section) to inspect, test, and oversee the lifeboat during its fabrication and prepare an inspection and test report meeting the requirements of 46 CFR 159.005–11.

(2) The independent laboratory must make such inspections as are necessary to determine that the prototype is constructed by the methods and with the materials specified in the plans reviewed under § 160.135–9 of this subpart. By conducting at least one inspection during its construction, the independent laboratory must determine the prototype lifeboat conforms with those plans by inspecting—

(i) *Fiber Reinforced Plastic (FRP) Construction.*

(A) FRP components of each prototype lifeboat outer hull and any FRP inner hull or liner components that are bonded or bolted to the outer hull must have a layup made of unpigmented clear resins so that details of construction are visible for inspection. Test panels representative of each prototype layup must be tested in accordance with MIL–P–17549D(SH) (incorporated by reference, see § 160.135–5 of this subpart). If an accepted MIL–R–21607E(SH) (incorporated by reference, see § 160.135–5 of this subpart) Grade B resin is used for the prototype lifeboat, additives for fire retardancy must not be used so that the laminate is translucent for inspection purposes. Any prototype test lifeboat with Grade B resins will not be marked in accordance with § 160.135–17 of this subpart for use as a production lifeboat regardless of the outcome of the performance tests. Whichever accepted resin the manufacturer decides to use for the prototype lifeboat, the same resin must be used in the production lifeboats.

(B) The hull, canopy, and major structural laminates of each prototype FRP lifeboat must be tested for resin content, ultimate flexural strength, and tensile strength. The test samples must be cut out from the prototype lifeboat, or be laid up at the same time, using the same procedures and by the same operators as the laminate used in the lifeboat. The number of samples used for each test, and the conditions and test methods used, must be as per the applicable test specified in this paragraph. The resin content must be determined as per ASTM D 2584 or ISO 1172 (incorporated by reference, see § 160.135–5 of this subpart). The flexural ultimate strength must be determined by ASTM D 790 method I (test condition ''A'', flatwise, dry) or the corresponding ISO 14125 test method (incorporated by reference, see § 160.135–5 of this subpart). The tensile strength, lengthwise, must be determined as per ASTM D 638 or ISO 527 (incorporated by reference, see § 160.135–5 of this subpart).

(C) Each major FRP component, such as the hull, canopy, and inner liner(s), of each prototype FRP lifeboat must be examined and weighed after it is completed but before it is assembled. If the lifeboat is constructed by the spray lay-up technique, the hull and canopy thicknesses must be measured using ultrasonic or equivalent techniques;

(ii) *Steel construction.* Steel sheet and plate used for the hull, floors, and other structural components of a prototype steel lifeboat must meet the bend tests requirement specified under ASTM A 653 (incorporated by reference, see § 160.135–5 of this subpart) after galvanizing or other anti-corrosion treatment has been applied. This may be demonstrated through a supplier's certification papers or through witnessing actual tests;

(iii) *Coated cloth for partially enclosed lifeboats.* Cloth material used in the construction of each prototype lifeboat must be confirmed to have met the requirements specified under § 160.135–7(b)(28) of this subpart. This may be demonstrated through a supplier's certification papers or through witnessing actual tests;

(iv) *Welding.* Structural components of each prototype lifeboat joined by welding must be welded by the welding procedures and materials as per the plans reviewed under § 160.135–9 of this subpart and by welders appropriately qualified;

(v) *Buoyancy foam.* Each major subassembly of a prototype lifeboat, such as the hull with liner and canopy with liner, must be weighed after the buoyancy foam is installed and before it is further assembled;

(vi) Installation of the propulsion system;

(vii) Installation of the steering system; and

(viii) Installation of the water spray fire-protection and air support system(s), if fitted.

(3) The independent laboratory must submit the inspection report to the Commandant.

§ 160.135–13 Approval inspections and tests for prototype lifeboats.

(a) After the Commandant notifies the manufacturer that the prototype lifeboat is in compliance with the requirements of § 160.135–11 of this subpart, the manufacturer may proceed with the prototype approval inspections and tests required under this section. The prototype lifeboat, the construction of which was witnessed under § 160.135–11 of this subpart, must be used for the tests in this section.

(b) Except as provided in paragraph (f) of this section, the Coast Guard must conduct the approval inspections and witness the approval tests required under this section.

(c) *Manufacturer requirements.* To proceed with approval inspections and tests required by this section, the manufacturer must—

(1) Notify the Commandant and cognizant Officer in Charge, Marine Inspection (OCMI) of where the approval inspections and tests required under this section will take place, and such notification must be in sufficient time to allow making travel arrangements;

(2) Arrange a testing schedule that allows for a Coast Guard inspector to travel to the site where the testing is to be performed;

(3) Admit the Coast Guard inspector to any place where work or testing is performed on lifeboats or their component parts and materials for the purpose of—

(i) Conducting inspections as necessary to determine that the prototype is constructed by the methods and with the materials specified in the plans reviewed under § 160.135–9 of this subpart and the inspection report under § 160.135–11 of this subpart;

(ii) Assuring that the quality assurance program of the manufacturer is satisfactory;

(iii) Witnessing tests; and

(iv) Taking samples of parts or materials for additional inspections or test; and

(4) Make available to the Coast Guard inspector the affidavits or invoices from the suppliers of all essential materials used in the production of lifeboats, together with records identifying the lot or serial numbers of the lifeboats in which such materials were used.

(d) *Tests.* (1) *Prototype lifeboat readiness.* All tests must be conducted on a completely outfitted lifeboat, including fixed equipment such as compass, searchlight, and navigating lights. Loose equipment may be substituted by weights.

(2) *Fiber Reinforced Plastic (FRP) prototype lifeboat lay-up.* For the prototype of each design of an FRP lifeboat, the lay-up must be made of unpigmented resins and clear gel coat.

(3) *Fuel tank.* Each non-portable fuel tank must be tested by a static head above the tank top of 3 m (10 ft) of water without showing any leaks or signs of permanent distortion.

(4) *IMO Revised recommendation on testing.* Each prototype lifeboat of each design must pass each of the tests for davit-launched or free-fall lifeboats, as applicable, described in the IMO Revised recommendation on testing, part 1, paragraphs 6.1 through 6.17 (incorporated by reference, see § 160.135–5 of this subpart). Tests must be conducted in accordance with these paragraphs of IMO Revised recommendation on testing, Part 1, with the following modifications:

(i) *Fire retardancy/release mechanism and engine tests* (Paragraphs 1/6.2, 6.9, 6.10, 6.14). The tests in the following IMO Revised recommendation on testing paragraphs may be accomplished independent of the lifeboat, and may be considered completed and need not be repeated if the tests have been previously shown to meet the necessary requirements—

(A) Paragraph 6.2;

(B) Paragraphs 6.9.3 through 6.9.6;

(C) Paragraph 6.10.2 through 6.10.6; and

(D) Paragraphs 6.14.6 through 6.14.8.

(ii) *Lifeboat overload test* (Paragraph 1/6.3). For a davit launched lifeboat, the overload test must be conducted with the lifeboat suspended from the lifting hooks. During this test, the canopy of a free-fall lifeboat must not deform so as to harm any potential occupants.

(iii) *Impact test* (Paragraph 1/6.4). The rigid vertical surface must not be displaced or deformed as a result of the test.

(iv) *Lifeboat seating space test* (Paragraph 1/6.7). The average mass of persons used to test the lifeboat seating space must be determined by weighing as a group or individually. Each person must wear an inherently buoyant SOLAS lifejacket with at least 150 N of buoyancy or a Coast Guard-approved lifejacket approved under approval series 160.155. For other than a totally enclosed lifeboat, the operator(s) must demonstrate that the lifeboat can be operated while wearing a Coast Guard approved, insulated-buoyant immersion suit approved under approval series 160.171. The Commandant will give consideration to requests to test at, and designate lifeboats for, a heavier occupant weight than that stated in the IMO LSA Code, Chapter IV (incorporated by reference, § 160.135–5 of this subpart).

(v) *Flooded stability test* (Paragraph 1/6.8). Any materials used to raise the test weights representing the lifeboat occupants above the seat pan must be at least as dense as fresh water.

(vi) *Lifeboat operational test, Operation of engine* (Paragraph 1/6.10.1). For the 4-hour lifeboat maneuvering period, the lifeboat must not (except for a short period to measure towing force and to demonstrate towing fixture durability) be secured, and must be run through its full range of speeds and full range of all controls throughout the period.

(vii) *Survival recovery test* (Paragraph 1/6.10.8). The recovery demonstration must show that no more than two crewmembers are required to recover a helpless person of ninety-fifth percentile by weight described in ASTM F 1166 (incorporated by reference, see § 160.135–5 of this subpart) while the crewmembers and helpless person are each wearing a lifejacket.

(viii) *Flooded capsizing test* (Paragraph 1/6.14.3-.5). For any lifeboat also approved as a rescue lifeboat, the lifeboat must return to an upright position and, without undue delay, the crew must be able to use the lifeboat again as a lifeboat.

(ix) *Fire test* (Paragraph 1/6.16.4). The locations where temperatures are measured along with the rationale for the proposed locations must be provided to the Commandant for approval prior to the testing.

(x) *Water spray tests* (Paragraph 1/6.16.9). The delivery rate of water, or the sprayed water film thickness over the lifeboat, must be at least equivalent to that used to achieve passing results for the fire test. Full coverage must be obtained without the need to rock the lifeboat or induce wetting by wiping or applying any agent.

(xi) *Measuring and evaluating acceleration forces* (Paragraph 1/6.17.5). For free-fall lifeboats, the selection, placement, and mounting of the accelerometers along with the rationale for the proposed selection, placement, and mounting must be provided to the Commandant for approval prior to the testing.

(xii) *Evaluation acceleration forces with the dynamic response model* (Paragraph 1/6.17.9). For free-fall lifeboats only, sections 6.17.9 thru 6.17.12 must be used along with the displacement limits for lifeboats in Table 2 under ''Evaluation with the dynamic response model''.

(5) *Visual inspection.* Each lifeboat must be visually inspected to confirm—

(i) Compliance with this subpart;

(ii) Conformance with plans reviewed under § 160.135–9 of this subpart; and

(iii) Ease of operation and maintenance.

(e) *Test waiver.* The Commandant may waive certain tests for a lifeboat identical in construction to smaller and larger lifeboats that have successfully completed the tests. Tests associated with lifeboat components that have already been approved by the Commandant are not required to be repeated.

(f) At the request of the manufacturer and discretion of the Commandant, an independent laboratory may perform approval inspections and witness approval tests required by this section so long as the inspections and tests are performed and witnessed in accordance with the procedures agreed upon between the independent laboratory and Commandant under 46 CFR part 159, subpart 159.010.

(g) After completion of approval inspections and tests required by this section, the manufacturer must comply with the requirements of 46 CFR 159.005–9(a)(5) by preparing and submitting to the Commandant for review—

(1) The prototype approval test report containing the same information recommended by IMO MSC Circ. 980 (incorporated by reference, see § 160.135–5 of this subpart). The report must include a signed statement by the Coast Guard inspector (or independent laboratory as permitted by paragraph (f) of this section) who witnessed the testing, indicating that the report accurately describes the testing and its results; and

(2) The final plans of the lifeboat as built. The plans must include, in triplicate—

(i) The instructions for training and maintenance described in §§ 160.135–19 and 160.135–21 of this subpart; and

(ii) The final version of the plans required under § 160.135–9 of this subpart.

(h) The Commandant will review the report and plans submitted under paragraph (g) of this section, and if satisfactory to the Commandant, will approve the plans under 46 CFR 159.005–13.

§ 160.135–15 Production inspections, tests, quality control, and conformance of lifeboats.

(a) Unless the Commandant directs otherwise, an independent laboratory must perform or witness, as appropriate, inspections, tests, and oversight required by this section. Production inspections and tests of lifeboats must be carried out in accordance with the procedures for independent laboratory inspection in 46 CFR part 159, subpart 159.007 and in this section, unless the Commandant authorizes alternative tests and inspections. The Commandant may prescribe additional production tests and inspections necessary to maintain quality control and to monitor compliance with the requirements of this subpart.

(b) *Manufacturer's responsibility.* The manufacturer must—

(1) Institute a quality control procedure to ensure that all production lifeboats are produced to the same standard, and in the same manner, as the prototype lifeboat approved by the Commandant. The manufacturer's quality control personnel must not work directly under the department or person responsible for either production or sales;

(2) Schedule and coordinate with the independent laboratory (or Coast Guard inspector if required under paragraph (a) of this section) to ensure that all tests are performed as described in this section;

(3) Submit to the Commandant, a yearly report that contains the following—

(i) Serial number and date of final assembly of each lifeboat constructed;

(ii) Name of the representative of the independent laboratory (or Coast Guard inspector if required under paragraph (a) of this section); and

(iii) Name of the vessel and company receiving the lifeboat, if known; and

(4) Ensure that the arrangement and materials entering into the construction of the lifeboat are in accordance with plans approved under § 160.135–13(h) of this subpart;

(5) Allow an independent laboratory (or Coast Guard inspector if required under paragraph (a) of this section) access to any place where materials are stored for the lifeboat, work or testing is performed on lifeboats or their component parts and materials, or records are retained to meet the requirements of paragraph (c) of this section, for the purpose of—

(i) Assuring that the quality control program of the manufacturer is satisfactory;

(ii) Witnessing tests; or

(iii) Taking samples of parts or materials for additional inspections or tests; and

(6) Ensure that the independent laboratory (or Coast Guard inspector if required under paragraph (a) of this section) conducts the inspections and witnesses the tests required by paragraph (e)(2) of this section, and further conducts a visual inspection to verify that the lifeboats are being made in accordance with the plans approved under § 160.135–13(h) of this subpart and the requirements of this subpart.

(c) *Recordkeeping.* The manufacturer must maintain records in accordance with 46 CFR 159.007–13. The manufacturer must keep records of all items listed in this section for at least 5 years from the date of termination of approval of each lifeboat. The records must include—

(1) A copy of this subpart, other CFR sections referenced in this subpart, and each applicable document listed in § 160.135–5 of this subpart;

(2) A copy of approved plans, documentation, and certifications;

(3) A current certificate of approval for each approved lifeboat;

(4) Affidavits, certificates, or invoices from the suppliers identifying all essential materials used in the production of approved lifeboats, together with records identifying the serial numbers of the lifeboats in which such materials were used;

(5) Start and finish date and time of the lay-up of each major Fiber Reinforced Plastic (FRP) component such as the hull, canopy, and inner liner and the names of the operator(s);

(6) Start and finish date and time of pouring of foam-in-place rigid buoyancy foam, and name of operator(s);

(7) Records of all structural welding and name of operator(s);

(8) Records of welder certificates, training and qualifications;

(9) Date and results of calibration of test equipment and the name and address of the company or agency that performed the calibration;

(10) The serial number of each production lifeboat, along with records of its inspections and tests carried out under this section; and

(11) The original purchaser of each lifeboat and the vessel on which it was installed, if known.

(d) *Independent laboratory responsibility.* The independent laboratory must perform or witness, as appropriate, the inspections and tests under paragraph (e)(2) of this section for each Coast Guard-approved lifeboat to be installed on a U.S.-flagged vessel. If the manufacturer also produces lifeboats for approval by other maritime safety administrations, the inspections may be coordinated with inspection visits for those administrations.

(e) *Production inspections and tests.* Each approved lifeboat must be inspected and tested in accordance with each of the following procedures:

(1) *In-process inspections and tests.* Each production lifeboat must be examined during lay-up of the hull to verify that the lay-up conforms to the approved drawings. Each FRP major component, such as the hull, canopy, and inner liner, must be examined and weighed after it is completed but before assembled. If the lifeboat is constructed by the spray lay-up technique, the hull and canopy thicknesses must be measured using ultrasonic or equivalent techniques. Laboratory tests of laminates must be conducted at this time. Test samples must be cut out from the lifeboat itself or be laid up at the same time, using the same procedures and by the same operators as the laminate used in the lifeboat. The number of samples used for each test, and the conditions and test methods used, must be as described in the applicable test specified in this paragraph.

(i) *Weight.* The weight of each FRP section, such as hull, canopy, and inner liner, must be within 10 percent of similar sections of the prototype lifeboat. These weights must be the bare laminate weights. Backing plates that are molded into the laminate may be included.

(ii) *Thickness.* The average thickness of each section of sprayed-up laminate must be within 20 percent of the corresponding sections of the prototype.

(iii) *Resin content.* Laminate samples from the hull, canopy, and inner liners must be tested in accordance with ASTM D 2584 or ISO 1172 (incorporated by reference, see § 160.135–5 of this subpart). The resin content must be within 8 percentage points of the prototype results. If the resin content does not comply, flexural ultimate strength and tensile tests in paragraph (e)(1)(iv) of this section must be conducted.

(iv) *Flexural ultimate strength and tensile tests.* Each laminate sample from each major component, such as hull and liner, that does not comply with the resin content requirement in paragraph (e)(1)(iii) of this section, and from each component of every fifth production lifeboat, must be subjected to the flexural ultimate strength and tensile strength tests as described in § 160.135–13(c)(2)(i)(B) of this subpart. The values must be at least 90 percent of the prototype results.

(v) *Buoyancy material.* If block foam buoyancy material is used, each piece must be weighed after it is cut and shaped to make sure that the correct amount of foam is installed. If foamed-in-place buoyancy material is used, a separate sample of the foam must be poured, and used to make a density determination after it has set. The density must be 32 +/− 8 kg/m^3 (2 +/− 0.5 lb/ft^3).

(vi) *Steel sheet and plate.* Steel sheet and plate for the hull, floors, and other structural components must meet ASTM A 36 and ASTM A 653 as applicable (incorporated by reference, see § 160.135–5 of this subpart). Non-corrosive resistant steel must meet the coating mass and bend tests requirement specified under ASTM A 653. Compliance for this paragraph can be ascertained through supplier's certification papers or through conducting actual tests.

(vii) *Cloth.* The cloth material used for the construction of each partially enclosed lifeboat must meet the material specification of A–A–55308 (incorporated by reference, see § 160.135–5 of this subpart). This compliance can be ascertained through supplier's certification papers or through witnessing actual tests.

(viii) *Fuel tank.* Each fuel tank must be tested by a static head above the tank top of 3 m (10 ft) of water without showing any leaks or signs of permanent distortion.

(ix) *Welding.* It must be determined that structural components joined by welding was performed by welders who are appropriately qualified and that the welding procedure and materials are as per the plans approved under § 160.135–13(h) of this subpart.

(2) *Post assembly tests and inspections.* The finished lifeboat must be visually inspected inside and out. The manufacturer must develop and maintain a visual inspection checklist designed to ensure that all applicable requirements have been met and the lifeboat is equipped in accordance with approved plans. At a minimum, each lifeboat must be operated for 2 hours during which all lifeboat systems must be exercised.

§ 160.135–17 Marking and labeling.

(a) Each lifeboat must be marked with a plate or label permanently affixed to the hull in a conspicuous place readily accessible for inspection and sufficiently durable to withstand continuous exposure to environmental conditions at sea for the life of the lifeboat.

(b) The plate or label must be in English, but may also be in other languages.

(c) The plate or label must contain the—

(1) Name and address of the manufacturer;

(2) Manufacturer's model identification;

(3) Name of the independent laboratory that witnessed the prototype or production test and inspections;

(4) Serial number of the lifeboat;

(5) U.S. Coast Guard approval number;

(6) Month and year of manufacture;

(7) Material of hull construction;

(8) Number of persons for which the lifeboat is approved;

(9) Light load and full load (condition A and condition B weight); and

(10) Word ''SOLAS.''

§ 160.135–19 Operating instructions and information for the ship's training manual.

(a) Each lifeboat must have instructions and information for the ship's training manual that use the symbols from IMO Res. A.760(18) (incorporated by reference, see § 160.135–5 of this subpart) to describe

the location and operation of the lifeboat.

(b) The instructions and information required by paragraph (a) of this section may be combined with similar material for survival craft and rescue boats, and their launching systems.

(c) The lifeboat manufacturer must make the instructions and information required by paragraph (a) of this section available—

(1) In English to purchasers of a lifeboat approved by the Coast Guard; and

(2) In the form of an instruction placard providing simple procedures and illustrations for operation of the lifeboat. The placard must be not greater than 36 cm (14 in) by 51 cm (20 in), and must be made of durable material and suitable for display near installations of lifeboats on vessels.

§ 160.135–21 Operation and maintenance instructions.

(a) Each lifeboat must have operation and maintenance instructions that—

(1) Follow the general format and content specified in MSC.1 Circ. 1205 (incorporated by reference, see § 160.135–5 of this subpart); and

(2) Include a checklist for use in monthly, external visual inspections of the lifeboat.

(b) The lifeboat manufacturer must make the manual required by paragraph (a) of this section available in English to purchasers of a lifeboat approved by the Coast Guard.

(c) The operation and maintenance instructions required by paragraph (a) of this section may be combined with similar material for survival craft and rescue boats, and their launching systems.

§ 160.135–23 Procedure for approval of design, material, or construction change.

(a) Each change in design, material, or construction from the plans approved under 46 CFR 159.005–13 and § 160.135–13(h) of this subpart must be approved by the Commandant before being used in any production lifeboat. The manufacturer must submit any such change following the procedures in § 160.135–9 of this subpart, but documentation on items that are unchanged from the plans approved under 46 CFR 159.005–13 and § 160.135–13(h) of this subpart need not be resubmitted.

(b) Unless determined by the Commandant to be unnecessary, a prototype lifeboat with each change described in paragraph (a) of this section must be made and tested according to the procedures for new approvals in §§ 160.135–9 through 160.135–13 of this subpart.

(c) Determinations of equivalence of design, construction, and materials will be made by the Commandant only.

Subpart 160.151—Inflatable Liferafts (SOLAS)

■ 29. Revise § 160.151–1 to read as follows:

§ 160.151–1 Scope.

This subpart prescribes standards, tests, and procedures for approval by the Coast Guard of inflatable liferafts. This subpart does not apply to any inflatable liferaft approved by the Commandant before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION OF INTERIM RULE], so long as the liferaft satisfies the annual servicing requirements set forth in 46 CFR 160.151–57.

■ 30. Amend § 160.151–3 as follows:

■ a. In the definition for ''Commandant'', remove the text ''(CG–521)'' and add, in its place, the text ''(CG–5214)''; and

■ b. Add, in alphabetical order, the definition for ''Officer in Charge, Marine Inspection (OCMI)'', to read as follows:

§ 160.151–3 Definitions.

* * * * *

Officer in Charge, Marine Inspection (OCMI) means an officer of the Coast Guard designated as such by the Commandant and who fulfills the duties described in 46 CFR 1.01–15(b). The ''cognizant OCMI'' is the OCMI who has immediate jurisdiction over a vessel or geographic area for the purpose of performing the duties previously described.

■ 31. Revise § 160.151–5 to read as follows:

§ 160.151–5 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Coast Guard must publish notice of change in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at Commandant (CG–5214), U.S. Coast Guard, 2100 Second Street, SW., Stop 7126, Washington, DC 20593–7126. You may also inspect this material 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.* You may obtain copies of the material from the sources specified in the following paragraphs.

(b) American Society for Testing and Materials (ASTM), 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA, 19428–2959.

(1) ASTM F 1014–02 (Reapproved 2007), Standard Specification for Flashlights on Vessels, (approved May 1, 2007), IBR approved for § 160.151–21 (''ASTM F 1014'').

(2) [Reserved].

(c) General Services Administration, Federal Acquisition Service, Office of the FAS Commissioner, 2200 Crystal Drive, 11th Floor, Arlington, VA 22202, 703–605–5400.

(1) Federal Standard 595C, Colors Used in Government Procurement, (January 16, 2008), IBR approved for §§ 160.151–15 and 160.151–17 (''FED–STD–595C'').

(2) [Reserved].

(d) International Maritime Organization (IMO), Publications Section, 4 Albert Embankment, London SE1 7SR, United Kingdom, +44 (0)20 7735 7611, *http://www.imo.org/*.

(1) IMO Resolution A.657(16), Instructions for Action in Survival Craft, (adopted October 1989), IBR approved for § 160.151–21 (''IMO Res. A.657(16)'').

(2) IMO Resolution A.658(16), Use and Fitting of Retro-Reflective Materials on Life-Saving Appliances, (adopted October 19, 1989), IBR approved for § 160.151–15 (''IMO Res. A.658(16)'').

(3) Life-Saving Appliances, including LSA Code, 2010 Edition, (2010), pages 7–71 (''IMO LSA Code''), IBR approved for §§ 160.151–7, 160.151–15, 160.151–17, 160.151–21, 160.151–29, and 160.151–33.

(4) Life-Saving Appliances, including LSA Code, 2010 Edition, (2010), Revised recommendation on testing of life-saving appliances, pages 79–254 (''IMO Revised recommendation on testing''), IBR approved for §§ 160.151–21, 160.151–27, 160.151–29, 160.151–31, and 160.151–57.

(e) International Standards Organization (ISO): ISO Central Secretariat [ISO Copyright Office], Case Postale 56, CH 1211 Geneva 20, Switzerland.

(1) ISO 15738:2002(E), Ships and marine technology—Gas inflation systems for inflatable life-saving appliances, First Edition (February 1, 2002), IBR approved for § 160.151–15 (''ISO 15738'').

(2) ISO 17339:2002(E), Ships and marine technology—Sea anchors for survival craft and rescue boats, First Edition (November 15, 2002), IBR approved for § 160.151–21 (''ISO 17339'').

(3) ISO 18813:2006(E), Ships and marine technology—Survival equipment

for survival craft and rescue boats, First Edition (April 1, 2006), IBR approved for § 160.151–21 (''ISO 18813'').

(f) Military Specifications and Standards, Standardization Documents Order Desk, Building 4D, 700 Robins Avenue, Philadelphia PA 19111–5094, *https://assist.daps.dla.mil/quicksearch/*.

(1) MIL–C–17415F, Military Specification, Cloth, Coated, and Webbing, Inflatable Boat and Miscellaneous Use, (May 31, 1989), IBR approved for § 160.151–15 (''MIL–C–17415F'').

(2) [Reserved].

■ 32. Amend § 160.151–7 as follows:

■ a. In the introductory text, after the words ''Chapter III of SOLAS'', add the words ''and the IMO LSA Code (incorporated by reference, see § 160.151–5 of this subpart)''; and after the words ''provisions of'', remove the word ''SOLAS'' and add, in its place, the words ''the IMO LSA Code:'';

■ b. Revise paragraphs (a) and (b) to read as set forth below; and

■ c. Remove paragraphs (c), (d), and (e).

§ 160.151–7 Construction of inflatable liferafts.

* * * * *

(a) IMO LSA Code Chapter I/1.2, General requirements for life-saving appliances; and

(b) IMO LSA Code Chapter IV/4.2, Inflatable liferafts.

§ 160.151–11 [Amended]

■ 33. In § 160.151–11(b) introductory text, after the words ''must submit an application'', add the words ''to the Commandant''.

■ 34. Amend § 160.151–15 as follows:

■ a. In the introductory text, remove the words ''indicated in § 160.151–7'' and add, in their place, the words ''and the IMO LSA Code (incorporated by reference, see § 160.151–5 of this subpart)'';

■ b. In paragraph (a) introductory text, remove the words ''Regulation III/30.2.1'' and add, in their place, the words ''IMO LSA Code, Chapter I/1.2.1''; after the words ''meeting MIL–C–17415F'', add the words ''(incorporated by reference, see § 160.151–5 of this subpart)''; after the words ''equivalent or superior'' remove the symbol ''-''and add, in its place, the words ''and be capable of withstanding the prototype tests specified in 160.151–27 of this subchapter.'';

■ c. Remove paragraphs (a)(1), (a)(2), (a)(3), and (a)(4);

■ d. In paragraph (b), remove the words ''Regulation III/30.2.1'' and add, in their place, the words ''IMO LSA Code, Chapter I/1.2.2.1'';

■ e. In paragraph (c), remove the words ''Regulation III/30.2.1'' and add, in their place, the words ''IMO LSA Code Chapter I/1.2.2.1'';

■ f. In paragraph (d), remove the words ''Regulation III/30.2.4'' and add, in their place, the words ''IMO LSA Code, Chapter I/1.2.2.4'';

■ g. In paragraph (e), remove the words ''Regulation III/30.2.6'' and add, in their place, the words ''IMO LSA Code, Chapter I/1.2.2.6''; and remove the words ''(color number 34 of NBS Special Publication 440)'' and add, in their place, the words ''(color number 12197 of FED–STD–595C (incorporated by reference, see § 160.151–5 of this subpart))'';

■ h. In paragraph (f), remove the words ''Regulation III/30.2.7'' and add, in their place, the words ''IMO LSA Code, Chapter I/1.2.2.7''; and remove the words ''IMO Resolution A.658(16)'' and add, in their place, the words '' IMO Res. A.658(16) (incorporated by reference, see § 160.151–5 of this subpart)'';

■ i. In paragraph (g), remove the words ''Regulation III/38.1.4'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.1.1.4'';

■ j. In paragraph (h), remove the words ''Regulation III/38.2.2'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.1.2.2'';

■ k. In paragraph (i), remove the words ''Regulation III/38.3.1'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.1.3.1'';

■ l. Remove and reserve paragraph (j);

■ m. In paragraph (k), remove the words ''Regulation III/38.6.1'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.1.6.1'';

■ n. In paragraph (l) introductory text, remove the words ''Regulation III/39.2.3'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.2.2.3'';

■ o. Redesignate paragraphs (m), (n), and (o) as paragraphs (n), (o), and (p), respectively.

■ p. Add paragraph (m) to read as set forth below;

■ q. In newly redesignated paragraph (n), remove the words ''Regulation III/39.4.2'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.2.4.2'';

■ r. In newly redesignated paragraph (o), remove the words ''Regulation III/39.6.2'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.1.3.3''; after the word ''exterior'', add the words ''and interior''; and remove the word ''lamp'' and add, in its place, the word ''lamps''; and

■ s. In newly redesignated paragraph (p) introductory text, remove the words ''Regulation III/39.7.1'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.2.6.1''.

§ 160.151–15 Design and performance of inflatable liferafts.

* * * * *

(m) *Inflation systems (IMO LSA Code, Chapter IV/4.2.2.3).* Gas inflation systems, including gas-cylinder valves; gas-cylinder operating heads; high-pressure hose assemblies; and pressure relief, inflation/deflation, and non-return/transfer valves; must be certified as complying with the requirements of ISO 15738 (incorporated by reference, see § 160.151–5 of this subpart).

* * * * *

§ 160.151–17 [Amended]

■ 35. Amend 160.151–17 as follows:

■ a. In the introductory text, after the words ''regulations of SOLAS'', add the words ''and IMO LSA Code (incorporated by reference, see § 160.151–5 of this subpart)'';

■ b. In the heading of paragraph (a), remove the words ''Regulation III/39.5.1'' and add, in their place, the words ''the IMO LSA Code, Chapter IV/4.2.5'';

■ c. In paragraph (a)(2)(vii), remove the words ''(color number 34 of NBS Special Publication 440)'' and add, in their place, the words ''(color number 12197 of FED–STD–595C (incorporated by reference, see § 160.151–5 of this subpart))'';

■ d. In paragraph (b), remove the words ''Regulation III/39.4.1'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.2.4.1''; and

■ e. Remove paragraph (c).

■ 36. Amend § 160.151–21 as follows:

■ a. In the introductory text, after the words ''regulations of SOLAS'', add the words ''and the IMO LSA Code (incorporated by reference, see § 160.151–5 of this subpart)'';

■ b. In paragraph (a), remove the first instance of the words ''Regulation III/38.5.1.1'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.1.5.1.1''; and after the words ''buoyant heaving line'', remove the words ''described by Regulation III/38.5.1.1'';

■ c. In paragraph (b), remove the first instance of the words ''Regulation III/38.5.1.2'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.1.5.1.2''; and after the words ''folding knife'', remove the words ''carried as permitted by Regulation III/38.5.1.2'';

■ d. In paragraph (c), remove the first instance of the words ''Regulation III/38.5.1.3'' and add, in their place, the words ''(IMO LSA Code, Chapter IV/4.1.5.1.3 and ISO 18813 (incorporated by reference, see § 160.151–5 of this subpart))''; and after the words ''Each

bailer'', remove the words ''described by Regulation III/38.5.1.3'';

■ e. In paragraph (d), remove the first instance of the words ''Regulation III/38.5.1.4'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.1.5.1.4''; and after the words ''Each sponge'', remove the words ''described by Regulation III/38.5.1.4'';

■ f. In paragraph (e), remove the first instance of the words ''Regulation III/38.5.1.5'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.1.5.1.5 and ISO 17339 (incorporated by reference, see § 160.151–5 of this subpart)''; remove the two instances of the words ''described by Regulation III/38.5.1.5''; and add a sentence to the end of the paragraph to read as set forth below;

■ g. In paragraph (f), remove the words ''Regulation III/38.5.1.6'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.1.5.1.6 and ISO 18813''; and remove the words ''IMO Resolution A.689(17)'' and add, in their place, the words ''IMO Revised recommendation on testing (incorporated by reference, see § 160.151–5 of this subpart).'';

■ h. In paragraph (g), remove the first instance of the words ''Regulation III/38.5.1.7'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.1.5.1.7 and ISO 18813''; and after the words ''a tin-opener'', remove the words ''described by Regulation III/38.5.1.7'';

■ i. In paragraph (h), remove the first instance of the words ''Regulation III/38.5.1.8'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.1.5.1.8''; and after the words ''Each first-aid kit'', remove the words ''described by Regulation III/38.5.1.8'';

■ j. In paragraph (i), remove the first instance of the words ''Regulation III/38.5.1.9'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.1.5.1.9 and ISO 18813''; and after the words ''The whistle'', remove the words ''described by Regulation III/38.5.1.9'';

■ k. In paragraph (j), remove the first instance of the words ''Regulation III/38.5.1.10'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.1.5.1.10''; and after the words ''Each rocket parachute flare'', remove the words ''described by Regulation III/38.5.1.10'';

■ l. In paragraph (k), remove the first instance of the words ''Regulation III/38.5.1.11'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.1.5.1.11''; and after the words ''Each hand flare'', remove the words ''described by Regulation III/38.5.1.11'';

■ m. In paragraph (l), remove the first instance of the words ''Regulation III/38.5.1.12'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.1.5.1.12''; and after the words ''Each buoyant smoke signal'', remove the words ''described by Regulation III/38.5.1.12'';

■ n. In paragraph (m), remove the first instance of the words ''Regulation III/38.5.1.13'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.1.5.1.13''; after the words ''The waterproof electric torch'', remove the words ''described by Regulation III/38.5.1.13''; and after the words ''see § 160.151–5'', add the text ''of this subpart)'';

■ o. In paragraph (n), remove the words ''Regulation III/38.5.1.14'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.1.5.1.14'';

■ p. In paragraph (o), remove the first instance of the words ''Regulation III/38.5.1.15'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.1.5.1.15''; and after the words ''Each signalling mirror'' remove the words ''described by Regulation III/38.5.1.15'';

■ q. In paragraph (p), remove the first instance of the words ''Regulation III/38.5.1.16'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.1.5.1.16''; and after the words ''transparent waterproof container'', remove the words ''as described by Regulation III/38.5.1.16'';

■ r. In paragraph (q), remove the words ''Regulation III/38.5.1.17'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.1.5.1.17'';

■ s. In paragraph (r), remove the words ''Regulation III/38.5.1.18.'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.1.5.1.18'';

■ t. In paragraph (s), remove the first instance of the words ''Regulation III/38.5.1.19'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.1.5.1.19''; remove the words ''The fresh water required by Regulation III/38.5.1.19 must be ''emergency drinking water'''' and add, in their place, the words ''Emergency drinking water must be''; after the words ''The desalting apparatus'', remove the words ''described in Regulation III/38.5.1.19''; and remove the last sentence of the paragraph;

■ u. In paragraph (t), remove the first instance of the words ''Regulation III/38.5.1.20'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.1.5.1.20 and ISO 18813''; and after the words ''The drinking cup'', remove the words ''described in Regulation III/38.5.1.20'';

■ v. In paragraph (u), remove the first instance of the words ''Regulation III/38.5.1.21'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.1.5.1.21 and ISO 18813''; and after the words ''The anti-seasickness medicine'', remove the words ''required by Regulation III/38.5.1.21'';

■ w. In paragraph (v) introductory text, remove the first instance of the words ''Regulation III/38.5.1.22'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.1.5.1.22 and ISO 18813''; and after the words ''The instructions'', remove the words ''required by Regulation III/38.5.1.22'';

■ x. In paragraph (v)(3), remove the words ''IMO Resolution A.657(16)'' and add, in their place, the words ''IMO Res. A.657(16) (incorporated by reference, see § 160.151–5 of this subpart)'';

■ y. In paragraph (w) introductory text, remove the words ''Regulation III/38.5.1.23'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.1.5.1.23'';

■ z. In paragraph (w)(3), remove the words ''IMO Resolution A.657(16)'' and add, in their place, the words ''IMO Res. A.657(16)'';

■ aa. In paragraph (x), remove the first instance of the words ''Regulation III/38.5.1.24'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.1.5.1.24''; and after the words ''Each thermal protective aid'', remove the words ''described by Regulation III/38.5.1.24'';

■ bb. In paragraph (y) introductory text, remove the first instance of the words ''Regulation III/39.10.1.1'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.2.9.1.1 and ISO 18813''; and after the words ''The repair outfit'', remove the words ''required by Regulation III/39.10.1.1'';

■ cc. Revise paragraph (y)(2) to read as set out below;

■ dd. In paragraph (y)(3), remove the text ''; and'' and add, in its place, the text ''.'';

■ ee. Remove paragraph (y)(4); and

■ ff. In paragraph (z), remove the first instance of the words ''Regulation III/39.10.1.2'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.2.9.1.2''; and after the words ''The pump or bellows'', remove the words ''required by Regulation III/39.10.1.2''.

§ 160.151–21 Equipment required for SOLAS A and SOLAS B inflatable liferafts.

* * * * *

■ (e) * * * Sea anchors must be attached to the raft at a position so as to orient the primary entrance away from the seas as far as practicable while still allowing the sea anchor to be retrieved by a person inside the raft.

* * * * *

■ (y) * * *

■ (2) Five or more tube patches at least 50 mm (2 in) in diameter (the Commandant will consider self-

adhesive patches per ISO 18813 as an alternative); and

* * * * *

§ 160.151–27 [Amended]

■ 37. Amend § 160.151–27 as follows:

■ a. Remove each instance of the words ''IMO Resolution A.689(17)'' and add, in their place, the words ''IMO Revised recommendation on testing'';

■ b. In paragraph (a), remove the word ''inclusive''; and

■ c. In paragraph (c)(5), remove the word ''liters'' and add, in its place, the text ''L''.

§ 160.151–29 [Amended]

■ 38. In § 160.151–29, in the introductory text, remove the words ''Regulation III/39.5.1'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.3.5 (incorporated by reference, see § 160.151–5 of this subpart)''; and remove the words ''IMO Resolution A.689(17)'' and add, in their place, the words ''IMO Revised recommendation on testing (incorporated by reference, see § 160.151–5 of this subpart)''.

■ 39. Amend § 160.151–31 as follows:

■ a. Remove each instance of the words ''IMO Resolution A.689(17)'' and add, in their place, the words ''IMO Revised recommendation on testing'';

■ b. In paragraph (a) introductory text, remove the word ''part'' and add, in its place, the text ''46 CFR part''; and remove the words ''of this chapter'';

■ c. In paragraph (c), remove the symbol ''§ '' and add, in its place, the text ''46 CFR''; and remove the words ''of this chapter'';

■ d. In paragraph (d), after the words ''through 5.1.6 inclusive,'', add the words ''(incorporated by reference, see § 160.151–5 of this subpart)''; and

■ e. Add paragraph (h) to read as follows:

§ 160.151–31 Production inspections and tests of inflatable liferafts.

* * * * *

■ (h) The manufacturer must notify the cognizant Officer in Charge, Marine Inspection (OCMI) whenever final production inspections and tests are to be performed so that the OCMI may assign a marine inspector to the factory to witness the applicable tests and to ensure that the quality assurance program of the manufacturer is satisfactory.

§ 160.151–33 [Amended]

■ 40. Amend 160.151–33 as follows:

■ a. In paragraph (b) introductory text, remove the words ''Regulation III/39.7.3 of SOLAS'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.2.6.3 (incorporated by reference, see § 160.151–5 of this subpart)''; and

■ b. In paragraph (c) introductory text, remove the words ''Regulation III/39.8 of SOLAS'' and add, in their place, the words ''IMO LSA Code, Chapter IV/4.2.7.1''.

§ 160.151–57 [Amended]

■ 41. Amend 160.151–57 as follows:

■ a. In paragraph (b)(1), remove the words ''IMO Resolution A.689(17) paragraph 2/5.1.5'' and add, in their place, the words ''IMO Revised recommendation on testing, paragraph 2/5.1.5 (incorporated by reference, see § 160.151–5 of this subpart)'';

■ b. In paragraph (b)(5)(i), remove the words ''if its expiration date has passed'' and add, in their place, the words ''at the time of servicing if there is less than 6 months remaining before the expiration date'';

■ c. In paragraph (b)(11), remove the words ''IMO Resolution A.658(16)'' and add, in their place, the words ''IMO Revised recommendation on testing''; add the words ''46 CFR'' in front of the words ''part 164''; and remove the words ''of this subchapter'';

■ d. In paragraph (e), remove the words ''49 CFR 173.34'' and add, in their place, the text ''49 CFR 180.205'';

■ e. In paragraph (f), remove the words ''IMO Resolution A.689(17)'' and add, in their place, the words ''IMO Revised recommendation on testing''; and

■ f. In paragraph (g), after the text ''(b) through'', add the text ''(f)''.

§ 160.151–59 [Amended]

■ 42. In 160.151–59(a), remove the words ''regulations III/18.2, 19.3, 51, and 52 of SOLAS'' and add, in their place, the words ''SOLAS Chapter III, Regulation 35 (III/35)''.

§ 160.151–61 [Amended]

■ 43. In 160.151–61(a), remove the words ''regulations III/19.3 and III/52 of SOLAS'' and add, in their place, the words ''SOLAS Chapter III, Regulation 36 (III/36)''.

■ 44. Add subpart 160.156 to read as follows:

Subpart 160.156—Rescue Boats and Fast Rescue Boats (SOLAS)

Sec.

160.156–1 Scope.
160.156–3 Definitions.
160.156–5 Incorporation by reference.
160.156–7 Design, construction, and performance of rescue boats and fast rescue boats.
160.156–9 Preapproval review.
160.156–11 Fabrication of prototype rescue boats and fast rescue boats for approval.
160.156–13 Approval inspections and tests for prototype rescue boats and fast rescue boats.
160.156–15 Production inspections, tests, quality control, and conformance of rescue boats and fast rescue boats.
160.156–17 Marking and labeling.
160.156–19 Operating instructions and information for the ship's training manual.
160.156–21 Operation and maintenance instructions.
160.156–23 Procedure for approval of design, material, or construction change.

Subpart 160.156—Rescue Boats and Fast Rescue Boats (SOLAS)

§ 160.156–1 Scope.

This subpart prescribes standards, tests, and procedures for seeking Coast Guard approval of a rescue boat, including a fast rescue boat, complying with SOLAS and the IMO LSA Code, for use on waters other than protected waters as defined in 46 CFR 175.400.

§ 160.156–3 Definitions.

In addition to the definitions in the IMO LSA Code (incorporated by reference, see § 160.156–5 of this subpart), in this subpart, the term:

Commandant means the Commandant (CG–5214), U.S. Coast Guard, 2100 Second Street, SW., Stop 7126, Washington, DC 20593–7126.

Full load means the weight of the complete rescue boat, including all required equipment, provisions, fuel, and the number of persons for which it is approved. This is also known as the condition ''B'' weight.

Independent laboratory has the same meaning as 46 CFR 159.001–3. A list of accepted independent laboratories is available from the Commandant and online at *http://cgmix.uscg.mil.*

Light load means the weight of the complete rescue boat empty and does not include fuel, required equipment, or the equivalent weight of persons. This is also known as the condition ''A'' weight.

Officer in Charge, Marine Inspection (OCMI) means an officer of the Coast Guard designated as such by the Commandant and who fulfills the duties described in 46 CFR 1.01–15(b). The ''cognizant OCMI'' is the OCMI who has immediate jurisdiction over a vessel or geographic area for the purpose of performing the duties previously described.

SOLAS means the International Convention for the Safety of Life at Sea, 1974, as amended.

§ 160.156–5 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal

Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Coast Guard must publish notice of change in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at Commandant (CG–5214), U.S. Coast Guard, 2100 Second Street, SW., Stop 7126, Washington, DC 20593–7126. You may also inspect this material 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.* You may obtain copies of the material from the sources specified in the following paragraphs.

(b) American Society for Testing and Materials (ASTM), 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959.

(1) ASTM A 36/A 36M–08, Standard Specification for Carbon Structural Steel, (approved May 15, 2008), IBR approved for §§ 160.156–7 and 160.156–15 (''ASTM A 36'').

(2) ASTM A 276–08a, Standard Specification for Stainless Steel Bars and Shapes, (approved October 1, 2008), IBR approved for § 160.156–7 (''ASTM A 276'').

(3) ASTM A 313/A 313M–08, (approved October 1, 2008), Standard Specification for Stainless Steel Spring Wire, IBR approved for § 160.156–7 (''ASTM A 313'').

(4) ASTM A 314–08, Standard Specification for Stainless Steel Billets and Bars for Forging, (approved October 1, 2008), IBR approved for § 160.156–7 (''ASTM A 314'').

(5) ASTM A 653/A 653M–08, Standard Specification for Steel Sheet, Zinc-Coated (Galvanized) or Zinc-Iron Alloy-Coated (Galvannealed) by the Hot-Dip Process, (approved July 15, 2008), IBR approved for §§ 160.156–7, 160.156–11 and 160.156–15 (''ASTM A 653'').

(6) ASTM B 209–07, Standard Specification for Aluminum and Aluminum-Alloy Sheet and Plate, (approved August 1, 2007), IBR approved for § 160.156–7 (''ASTM B 209'').

(7) ASTM D 638–08, Standard Test Method for Tensile Properties of Plastics, (approved April 1, 2008), IBR approved for § 160.156–11 (''ASTM D 638'').

(8) ASTM D 790–07e1, Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials, (approved September 1, 2007), IBR approved for § 160.156–11 (''ASTM D 790'').

(9) ASTM D 2584–08, Standard Test Method of Ignition Loss for Cured Reinforced Resins, (approved May 1, 2008), IBR approved for §§ 160.156–11 and 160.156–15 (''ASTM D 2584'').

(10) ASTM D 4029–09, Standard Specification for Finished Woven Glass Fabrics, (approved January 15, 2009), IBR approved for § 160.156–7 (''ASTM D 4029'').

(11) ASTM F 1166–07, Standard Practice for Human Engineering Design for Marine Systems, Equipment, and Facilities, (approved January 1, 2007), IBR approved for §§ 160.156–7 and 160–156–13 (''ASTM F 1166'').

(c) General Services Administration, Federal Acquisition Service, Office of the FAS Commissioner, 2200 Crystal Drive, 11th Floor, Arlington, VA 22202, 703–605–5400.

(1) Federal Standard 595C, Colors Used in Government Procurement, (January 16, 2008), IBR approved for § 160.156–7 ''(FED–STD–595C'').

(2) [Reserved].

(d) International Maritime Organization (IMO), Publications Section, 4 Albert Embankment, London SE1 7SR, United Kingdom, +44 (0)20 7735 7611, *http://www.imo.org/.*

(1) IMO Resolution A.658(16), Use and Fitting of Retro-Reflective Materials on Life-Saving Appliances, (adopted October 19, 1989), IBR approved for § 160.156–7 (''IMO Res. A.658(16)'').

(2) IMO Resolution A.760(18), Symbols Related to Life-Saving Appliances and Arrangements, (adopted November 4, 1993), IBR approved for §§ 160.156–7 and 160.156–19 (''IMO Res. A.760(18)'').

(3) Life-Saving Appliances, including LSA Code, 2010 Edition, (2010), pages 7–71 (''IMO LSA Code''), IBR approved for §§ 160.156–3, 160.156–7 and 160.156–13.

(4) Life-Saving Appliances, including LSA Code, 2010 Edition, (2010), Revised recommendation on testing of live-saving appliances, pages 79–254 (''IMO Revised recommendation on testing''), IBR approved for §§ 160.156–7 and 160.156–13.

(5) MSC/Circular 980, Standardized Life-saving Appliance Evaluation and Test Report Forms, (February 13, 2001), IBR approved for §§ 160.156–7 and 160.156–13 (''IMO MSC Circ. 980'').

(6) MSC.1/Circular 1205, Guidelines for Developing Operation and Maintenance Manuals for Lifeboat Systems, (May 26, 2006), IBR approved for § 160.156–21 (''IMO MSC.1 Circ. 1205'').

(e) International Organization for Standardization (ISO): ISO Central Secretariat [ISO Copyright Office], Case Postale 56, CH–1211 Geneve 20, Switzerland.

(1) ISO 527–1:1993(E), Plastics—Determination of tensile properties, Part 1: General Principles, First Edition (June 15, 1993), IBR approved for § 160.156–11 (''ISO 527'').

(2) ISO 1172:1996(E), Textile-glass-reinforced plastics—Prepregs, moulding compounds and laminates—Determination of the textile-glass and mineral-filler content—Calcination methods, Second Edition (December 15, 1996), IBR approved for §§ 160.156–11 and 160.156–15 (''ISO 1172'').

(3) ISO 14125:1998(E), Fibre-reinforced plastic composites—Determination of flexural properties, First Edition (March 1, 1998), IBR approved for § 160.156–11 (''ISO 14125'').

(4) ISO 15372:2000(E), Ships and marine technology—Inflatable rescue boats—Coated fabrics for inflatable chambers, First Edition (December 1, 2002), IBR approved for §§ 160.156–7 and 160.156–15 (''ISO 15372'').

(f) Military Specifications and Standards, Standardization Documents Order Desk, Building 4D, 700 Robins Avenue, Philadelphia PA 19111–5094, *https://assist.daps.dla.mil/quicksearch/.*

(1) MIL–C–19663D, Military Specification, Cloth, Woven Roving, For Plastic Laminate, (August 4, 1988), IBR approved for § 160.156–7 (''MIL–C–19663D'').

(2) MIL–P–17549D(SH), Military Specification, Plastic Laminates, Fibrous Glass Reinforced, Marine Structural, (August 31, 1981), IBR approved for §§ 160.156–7 and 160.156–11 (''MIL–P–17549D(SH)'').

(3) MIL–R–21607E(SH), Military Specification, Resins, Polyester, Low Pressure Laminating, Fire-Retardant, (May 25, 1990), IBR approved for § 160.156–11 (''MIL–R–21607E(SH)'').

(g) Society of Automotive Engineers (SAE), 400 Commonwealth Drive, Warrendale, PA 15096.

(1) SAE J1527 (Revised JAN93), Marine Fuel Hoses, (February 5, 1993), IBR approved for § 160.156–7 (''SAE J1527'').

(2) [Reserved].

(h) Underwriters Laboratories (UL), 2600 NW., Lake Rd, Camas, WA 98607–8542.

(1) UL 1102, UL Standard for Safety for Nonintegral Marine Fuel Tanks, Fifth Edition (February 4, 1999), IBR approved for § 160.156–7 (''UL 1102'').

(2) UL 1185, Standard for Safety for Portable Marine Fuel Tanks, Fourth Edition (September 26, 1996), IBR approved for § 160.156–7 (''UL 1185'').

§ 160.156–7 Design, construction and performance of rescue boats and fast rescue boats.

(a) To seek Coast Guard approval of a rescue boat, including a fast rescue boat, a manufacturer must comply with, and each rescue boat must meet, the requirements of the following:

(1) IMO LSA Code chapter V (incorporated by reference, see § 160.156–5 of this subpart);

(2) IMO Revised recommendation on testing, part 1/7 (incorporated by reference, see § 160.156–5 of this subpart) applicable to the type of rescue boat;

(3) 46 CFR part 159; and

(4) This subpart.

(b) Each rescue boat must meet the following requirements:

(1) *Design.* (i) Each rescue boat must be designed to be operable by persons wearing immersion suits.

(ii) Each rescue boat should be designed following standard human engineering practices described in ASTM F 1166 (incorporated by reference, see § 160.156–5 of this subpart). Design limits should be based on a range from the fifth percentile female to the ninety-fifth percentile male values for critical body dimensions and functional capabilities as described in ASTM F 1166. The dimensions for a person wearing an immersion suit correspond to the arctic-clothed dimensions of ASTM F 1166.

(2) *Visibility from operator's station.* (i) The operator's station must be designed such that the operator, when seated at the control station, has visibility 360 degrees around the rescue boat, with any areas obstructed by the rescue boat structure or its fittings visible by moving the operator's head and torso.

(ii) The operator, while still being able to steer and control the speed of the rescue boat, must be able to see the water—

(A) Over a 90 degree arc within 3 m (10 ft) of each side of the rescue boat;

(B) Over a 30 degree arc within 1 m (3 ft, 3 in) of each side of the rescue boat; and

(C) Within 0.5 m (1 ft, 8 in) of the entrances designated for recovering persons from the water.

(iii) In order to see a person in the water during recovery or docking operations, a hatch must be provided in fully enclosed rescue boats so that the operator can stand with his or her head outside the rescue boat for increased visibility, provided the operator can still steer and control the speed of the rescue boat.

(3) *Construction.* Each major rigid structural component of each rescue boat must be constructed of steel, aluminum, or Fiber Reinforced Plastic (FRP), or materials accepted by the Commandant as equivalent or superior.

(i) *General.* Metals in contact with each other must be either galvanically compatible or insulated with suitable non-porous materials. Provisions must also be made to prevent loosening or tightening resulting from differences of thermal expansion, freezing, buckling of parts, galvanic corrosion, or other incompatibilities.

(ii) *Steel.* Sheet steel and plate must be low carbon, commercial quality, either corrosion resistant or galvanized as per ASTM A 653, coating designation G90 (incorporated by reference, see § 160.156–5 of this subpart). Structural steel plates and shapes must be carbon steel as per ASTM A 36 (incorporated by reference, see § 160.156–5 of this subpart), or an equivalent or superior steel accepted by the Commandant. All steel products, except corrosion resistant steel, must be galvanized to provide high quality zinc coatings suitable for the intended service life in a marine environment. Corrosion resistant steel must be a type 302 stainless steel per ASTM A 276, ASTM A 313, or ASTM A 314 (incorporated by reference, see § 160.156–5 of this subpart) or another corrosion resistant stainless steel of equal or superior corrosion resistant characteristics.

(iii) *Aluminum.* Aluminum and aluminum alloys must conform to ASTM B 209 (incorporated by reference, see § 160.156–5 of this subpart) and be high purity for good marine corrosion resistance, free of iron, and containing not more than 0.6 percent copper.

(iv) *Fiber Reinforced Plastic (FRP).*

(A) *Resin.* Any resin used for the hull, canopy, hatches, rigid covers, and enclosures for the engine, transmission, and engine accessories, must be fire retardant and accepted by the Commandant in accordance with 46 CFR part 164, subpart 164.120.

(B) *Glass reinforcement.* Any glass reinforcement used must have good laminated wet strength retention and must meet the appropriate specification in this paragraph. Glass cloth must be a finished fabric woven from ''E'' electrical glass fiber yarns meeting ASTM D 4029–09 commercial style designation 1564 (incorporated by reference, see § 160.156–5 of this subpart). Woven roving must conform to MIL–C–19663D (incorporated by reference, see § 160.156–5 of this subpart). Other glass materials equivalent or superior in strength, design, wet out, and efficiency will be given consideration on specific request to the Commandant.

(C) *Laminate.* All exposed surfaces of any finished laminate must present a smooth finish, and there must be no protruding surface fibers, open voids, pits, cracks, bubbles, or blisters. The laminate must be essentially free from resin-starved or overimpregnated areas, and no foreign matter must remain in the finished laminate. The entire laminate must be fully cured and free of tackiness, and must show no tendency to delaminate, peel, or craze in any overlay. The laminate must not be released from the mold until a Barcol hardness reading of not less than 40–55 is obtained from at least 10 places on the non-gel coated surface, including all interior inner and outer hull surfaces and built-in lockers. The mechanical properties of the laminate must meet the requirements for a Grade 3 laminate as specified in Table I of MIL–P–17549D(SH) (incorporated by reference, see § 160.156–5 of this subpart). Other grades will be given consideration on specific request to the Commandant.

(4) *Welding.* Welding must be performed by welders certified by the Commandant, a classification society recognized by the Commandant in accordance with 46 CFR 8.220, the U.S. Navy, or the national body where the rescue boat is constructed or the national body's designated recognized organization. Only electrodes intended for use with the material being welded may be used. All welds must be checked using appropriate non-destructive tests.

(5) *Rescue boat buoyancy.* (i) The buoyancy material must be accepted by the Commandant as meeting the performance requirements of IMO Revised recommendation on testing, Part 1, 6.2.2 to 6.2.7, with a density of 32 ± 8 kg/m^3 (2 ± 0.5 lb/ft^3). The buoyancy foam or rescue boat manufacturer must certify the results of the testing to IMO Revised recommendation on testing, part 1, 6.2.2 to 6.2.7 and submit those results to the Commandant. A list of accepted buoyancy foams may be obtained from the Commandant upon request.

(ii) All voids in the hull and canopy required to provide buoyancy for positive stability and self righting must be completely filled with Coast Guard-accepted buoyancy material.

(iii) Air in the inflated collar of a rigid-hull inflatable rescue boat will not be considered inherently buoyant material for the purposes of meeting the additional 280 N/person requirement of the LSA Code, chapter IV/4.4.4.

(6) *Coated fabric.* Any coated fabric used in the construction of inflatable chambers on a rescue boat must be shown to have been subjected to the criteria listed in IMO MSC Circ. 980 for

Inflation Chamber Characteristics Test (incorporated by reference, see § 160.156–5 of this subpart) by meeting the requirements of ISO 15372 (incorporated by reference, see § 160.156–5 of this subpart). The color of the finished fabric must be vivid reddish orange color number 12197 of FED–STD–595C (incorporated by reference, see § 160.156–5 of this subpart), or a durable fluorescent color of a similar hue. Each seam must be at least as strong as the weakest of the materials joined by the seam. Each seam must be covered with tape where necessary to prevent lifting of and damage to fabric edges.

(7) *Engines.* (i) In order to be accepted by the Commandant, any spark ignition engine fitted to an approved rescue boat must meet the U.S. Environmental Protection Agency emission requirements in 40 CFR part 91 or part 1045, as applicable, or for a compression ignition engine the requirements in 40 CFR part 89, part 94, or part 1042, as applicable, and have reports containing the same information as recommended by MSC Circ. 980 (incorporated by reference, see § 160.156–5 of this subpart) certified and witnessed by a U.S. Coast Guard inspector or an independent laboratory.

(ii) A hydraulic system, if used to start the engine, must be in accordance with 46 CFR part 58, subpart 58.30, with hose and fittings in accordance with 46 CFR part 56, subpart 56.60 except that—

(A) Push-on type fittings such as Aeroquip 1525–X, 25156–X, and FC332–X are not permitted; and

(B) The length of nonmetallic flexible hose is limited to 760 mm (30 in). Longer nonmetallic flexible hoses may be allowed in emergency steering systems at the discretion of the Commandant.

(iii) If a hand pump is provided, or if the engine has a manual starting system, adequate space must be provided for the hand pump or hand start operation.

(8) *Fuel system.* (i) The fuel system must meet 46 CFR 56.50–75(b) and, except as specified in this paragraph, the fuel tank must meet 46 CFR 58.50–10.

(ii) The fuel tank and fuel system must be in accordance with paragraph (b)(8)(ii)(A), (B), or (C) of this section, as follows:

(A) Permanently installed fuel systems must meet the requirements in 46 CFR 160.135–7.

(B) Portable fuel systems for outboard engines must meet UL 1185 (incorporated by reference, see § 160.156–5 of this subpart) or equivalent, except that hoses must be Coast Guard Type A per SAE J1527 (incorporated by reference, see § 160.156–5 of this subpart), and hose clamps, primers, filters, and strainers must be successfully tested in accordance with 33 CFR 183.590. Anti-siphon devices must be provided in the fuel system to prevent fuel spillage when the hose is disconnected. Arrangements must be provided to secure the fuel tank in its normal operating position on the rescue boat.

(C) Fuel systems for outboard engines using non-integral, permanently installed fuel tanks must meet the requirements of 33 CFR part 183, subpart J—Fuel Systems. UL 1102 (incorporated by reference, see § 160.156–5 of this subpart) meets these requirements for fuel tanks.

(9) *Starting system batteries.* Each battery fitted in a totally enclosed rescue boat must be stored in a sealed compartment with exterior venting. If the rescue boat has more than one engine, then only one starting battery is required per engine.

(10) *Exhaust.* Engine exhaust must be routed away from bilge and potential oil drips. Any paint used on engines, manifolds, or exhaust must not give off fumes when heated. All exhaust lagging must be non-absorbent.

(11) *Propeller guard.* Each propeller on a rescue boat must be fitted with a propeller guard with a maximum opening of 76 mm (3 in) on all sides on which a person is likely to be exposed.

(12) *Control and steering station.* Rescue boat starting, maneuvering, and steering controls must be provided at the control and steering station.

(i) The throttle must be a continuous manual control and must be able to be set and locked at any position.

(ii) The control and steering station must be designed and laid out in accordance with ASTM F 1166 sections 9 and 10, so that controls and displays are unambiguous, accessible, and easy to reach and use from the operator's normal seated position, while wearing an immersion suit or a lifejacket.

(iii) Each control, gauge, or display must be identified by a marking posted on, above, or adjacent to the respective item. Each control must operate in a logical manner and be marked with an arrow to show direction of movement of control which will cause an increased response. Each gauge must be marked with the normal operating range and indicate danger or abnormal conditions. Each marking must be permanent and weatherproof.

(iv) Gauges, and audio and visual alarms, must be provided to monitor at least the following parameters on inboard engines—

(A) Coolant temperature, for a liquid cooled engine;

(B) Oil pressure, for an engine with an oil pump;

(C) Tachometer, for an engine not provided with over-speed protection; and

(D) State of charge, or rate of charge, for each rechargeable engine starting power source.

(13) *Drain plug.* The position of each drain plug must be clearly indicated by a permanent marking inside the lifeboat. The marking must be an arrow pointing in the direction of the plug, and the words ''Drain Plug'' must be 76 mm (3 in) high and have letters of a color that contrast with their background. The marking must be clearly visible to a person within the vicinity of the drain plug.

(14) *Remote steering.* The procedure to change over from remote to local steering must be simple, not require the use of tools, and be clearly posted. There must be sufficient clear space to install, operate, remove, and stow the removable tiller arm. The tiller arm and its connection to the rudder stock must be of sufficient strength so that there is no slippage or bending of the tiller arm. Rudder stops or other means must be provided to prevent the rudder from turning too far on either side.

(15) *Lifelines.* Buoyant lifelines must be of ultraviolet resistant material.

(16) *Rails provided as handholds.* Rails provided as handholds on rigid and rigid-inflated rescue boats must extend for half the length of the rescue boat on both sides of the hull, and the clearance between the rail and hull must be at least 38 mm (1.5 in). The rails must be attached to the hull below the chine or turn of the bilge, must be faired to prevent any fouling, and not project beyond the widest part of the rescue boat.

(17) *Equipment list.* A weatherproof equipment list must be permanently mounted in a conspicuous and prominent location on a stowage locker or compartment, or on inside of canopy. The list must include a stowage plan oriented such that the stowage location of each item of loose equipment is readily apparent.

(18) *Release mechanism.* Each release mechanism fitted to a rescue boat, including a fast rescue boat, must be identified at the application for approval of the prototype rescue boat and must be approved under subparts 160.133 or 160.170 of this part. The release lever or control must be red in color, and the area immediately surrounding the control must be a sharply contrasting light color. An illustrated operating instruction plate or

placard, showing the correct off-load and emergency on-load release procedure and recovery procedure, must be posted so that it is visible and legible from the helmsman's normal operating position. The plate or placard must be corrosion resistant and weatherproof and must be marked with the word ''Danger''.

(19) *Painter/painter release.* Each rescue boat must be fitted with a device to secure the painter near the bow of the rescue boat. The device must be arranged such that the rescue boat does not exhibit unsafe or unstable characteristics when being towed by the ship with the ship underway at 5 knots. A quick-release device must be provided, which allows the painter to be released from inside the rescue boat while under tension. The quick-release handle must be clearly identified by a label.

(20) *Canopy lamp.* Any exterior rescue boat position-indicating light must be approved by the Commandant under approval series 161.101.

(21) *Manually controlled interior light.* Any interior light must be approved by the Commandant under approval series 161.101.

(22) *Manual bilge pump.* Each rescue boat that is not automatically self-bailing must be fitted with a manual bilge pump approved under 46 CFR part 160, subpart 160.044, or an engine-powered bilge pump.

(23) *Labels and notices.* Any labels, caution and danger notices, and any operating, maintenance, or general instructions, must be in accordance with ASTM F 1166, Section 15, in terms of format, content, lettering size and spacing, color, and posted location. They must be illustrated with symbols in accordance with IMO Res. A.760(18) (incorporated by reference, see § 160.156–5 of this subpart), as applicable. Information and instruction plates, not specifically mentioned in this section, must not be posted in the vicinity of the control and steering station without prior approval from the Commandant. Identification label plates, if required, must be posted on or above the component or equipment to be identified.

(24) *Stowage.* Each stowage compartment must be supported and secured against movement. It must have adequate hand access for removing and storing the required equipment, and for cleaning the inside of the compartment. There must be sufficient stowage volume to store the equipment required by 46 CFR 199.175.

(25) *Rescue boat equipment.* The rescue boat must be designed to accommodate and carry the equipment required by 46 CFR 199.175.

(26) *Exterior color.* The primary color of the exterior of the hull, exterior of any canopy or bow cover, and the interior of a rescue boat not covered by a canopy or bow cover must be a highly visible color equivalent to vivid reddish orange color number 12197 of FED–STD–595C, or a durable fluorescent color of a similar hue.

(27) *Navigation light.* Each rescue boat must have navigation lights that are in compliance with the applicable sections of the International and Inland Navigation Rules and meet 46 CFR 111.75–17.

(28) *Retroreflective material.* The exterior of each rescue boat and canopy must be marked with Type II retroreflective material approved under 46 CFR part 164, subpart 164.018. The arrangement of the retroreflective material must comply with IMO Res. A.658(16) (incorporated by reference, see § 160.156–5 of this subpart).

(c) Determinations of equivalence of design, construction, and materials will be made by the Commandant only.

§ 160.156–9 Preapproval review.

(a) Except as provided in paragraph (c) of this section, the Commandant must conduct the preapproval review, required by this section, in accordance with 46 CFR 159.005–5.

(b) *Manufacturer requirements.* To seek Coast Guard approval of a rescue boat, the manufacturer must submit an application to the Commandant meeting the requirements of 46 CFR 159.005–5 for preapproval review. To meet the requirements of 46 CFR 159.005–5(a)(2), the manufacturer must submit in triplicate—

(1) A list of drawings, specifications, manuals, and any other documentation submitted, with each document identified by number, title, revision issue, and date;

(2) General arrangement and assembly drawings, including principal dimensions;

(3) Seating-arrangement plan, including a dimensioned seat form to scale;

(4) A complete material list, with each material referenced to a U.S. national standard or, if a copy is provided in English, an equivalent international standard;

(5) Plans for carriage and, in detail, stowage of equipment;

(6) Hull, canopy, and critical parts lay-up schedule for Fiber Reinforced Plastic (FRP) rescue boats, including fast rescue boats;

(7) Hull and canopy construction drawings, including particulars of joints, welds, seams, and other fabricating details;

(8) Weights and thickness of each major FRP structural component, including the hull, canopy, and inner liners, before outfitting;

(9) Specification and identification of materials such as steel, aluminum, resin, foam, fiberglass, coated fabric, and plastic used in the rescue boat's manufacture;

(10) Fabrication details for each major structural component, including details of each welded joint;

(11) Lines plans;

(12) Propulsion system specifications and arrangement and installation drawings;

(13) Steering system drawings and specifications;

(14) Release mechanism installation drawings and the mechanism's Coast Guard approval number;

(15) Plans for critical subassemblies;

(16) Hydraulic systems drawings and specifications, if installed;

(17) Electrical system schematics and specifications;

(18) Stability data, including righting arm curves in the light load and load condition for both intact and flooded;

(19) Drawings of all signs and placards, showing actual inscription, format, color, size, and location on the rescue boat;

(20) Complete data pertinent to the installation and use of the proposed rescue boat, including—

(i) The light load (condition A) and full load (condition B) weights; and

(ii) Complete details of the lifting arrangement to include enough detail for operators of the rescue boat to select a suitable release mechanism approved under subpart 160.133 or 160.170 of this part;

(21) An operation, maintenance, and training manual as described in §§ 160.156–19 and 160.156–21 of this subpart;

(22) A description of the quality control procedures and record keeping that will apply to the production of the rescue boat, which must include but is not limited to—

(i) The system for checking material certifications received from suppliers;

(ii) The method for controlling the inventory of materials;

(iii) The method for checking quality of fabrication, seams, and joints, including welding inspection procedures; and

(iv) The inspection checklists used during various stages of fabrication to assure that the approved lifeboat complies with the approved plans and the requirements of this subpart;

(23) Full details of any other unique capability;

(24) Any other drawing(s) necessary to show that the rescue boat complies with the requirements of this subpart;

(25) The location or address of all manufacturing sites, including the name and address of any subcontractors, where the rescue boat will be constructed; and

(26) The name of the independent laboratory that will perform the duties prescribed in §§ 160.156–11 and 160.156–15 of this subpart.

(c) At the request of the manufacturer and discretion of the Commandant, an independent laboratory may conduct preapproval review required by this section so long as the preapproval review is conducted in accordance with the procedures agreed upon between the independent laboratory and Commandant under 46 CFR part 159, subpart 159.010.

(d) *Plan quality.* The plans and specifications submitted to the Commandant under this section must—

(1) Be provided in English, including all notes, inscriptions, and designations for configuration control;

(2) Address each of the applicable items in paragraph (b) of this section in sufficient detail to show that the lifeboat meets the construction requirements of this subpart;

(3) Accurately depict the proposed rescue boat;

(4) Be internally consistent;

(5) Be legible; and

(6) If reviewed by an independent laboratory under paragraph (c) of this section, include the independent laboratory's attestation that the plans meet the quality requirements of this section.

(e) *Alternatives.* Alternatives in materials, parts, or construction, and each item replaced by an alternative, must be clearly indicated as such in the plans and specifications submitted to the Commandant under this section.

(f) *Coast Guard review.* If the plans or specifications do not comply with the requirements of this section, Coast Guard review may be suspended, and the applicant notified accordingly.

§ 160.156–11 Fabrication of prototype rescue boats and fast rescue boats for approval.

(a) If the manufacturer is notified that the information submitted in accordance with § 160.156–9 of this subpart is satisfactory to the Commandant, the manufacturer may proceed with fabrication of the prototype rescue boat as set forth in this section.

(b) Unless the Commandant directs otherwise, an independent laboratory must perform or witness, as appropriate, inspections, tests, and oversight required by this section. Prototype inspections and tests of a rescue boat must be carried out in accordance with the procedures for independent laboratory inspection in 46 CFR part 159, subpart 159.007 and in this section, unless the Commandant authorizes alternative tests and inspections. The Commandant may prescribe additional prototype tests and inspections necessary to maintain quality control and to monitor compliance with the requirements of this subpart.

(c) Fabrication of a rescue boat must proceed in the following sequence:

(1) The manufacturer must arrange for an independent laboratory (or Coast Guard inspector if required under paragraph (b) of this section) to inspect, test, and oversee the rescue boat during its fabrication and prepare an inspection and test report meeting the requirements of 46 CFR 159.005–11.

(2) The independent laboratory must make such inspections as are necessary to determine that the prototype is constructed by the methods and with the materials specified in the plans reviewed under § 160.156–9 of this subpart. By conducting at least one inspection during its construction, the independent laboratory must determine the prototype rescue boat conforms with those plans by inspecting—

(i) *Fiber Reinforced Plastic (FRP) Construction.*

(A) FRP components of each prototype rescue boat outer hull and any FRP inner hull or liner components that are bonded or bolted to the outer hull must have a layup made of unpigmented clear resins so that details of construction are visible for inspection. Test panels representative of each prototype layup must be tested in accordance with MIL–P–17549D(SH) (incorporated by reference, see § 160.156–5 of this subpart). If an accepted MIL–R–21607E(SH) Grade B resin is used for the prototype rescue boat, additives for fire retardancy must not be used so that the laminate is translucent for inspection purposes. A prototype test rescue boat with Grade B resins will not be marked in accordance with § 160.156–17 of this subpart for use as a production rescue boat regardless of the outcome of the performance tests. Whichever accepted resin the manufacturer decides to use for the prototype rescue boat, the same resin must be used in the production rescue boats.

(B) The hull, canopy, and major structural laminates of each prototype FRP rescue boat must be tested for resin content, ultimate flexural strength, and tensile strength. The test samples must be cut out from the prototype rescue boat, or be laid up at the same time, using the same procedures and by the same operators as the laminate used in the rescue boat. The number of samples used for each test, and the conditions and test methods used, must be as per the applicable test specified in this paragraph. The resin content must be determined as per ASTM D 2584 or ISO 1172 (incorporated by reference, see § 160.156–5 of this subpart). The flexural ultimate strength must be determined by ASTM D 790 method I (test condition ''A'', flatwise, dry) or the corresponding ISO 14125 test method (incorporated by reference, see § 160.156–5 of this subpart). The tensile strength, lengthwise, must be determined as per ASTM D 638 or ISO 527 (incorporated by reference, see § 160.156–5 of this subpart).

(C) Each major FRP component, such as the hull, canopy, and inner liner(s) of each prototype FRP rescue boat, must be examined and weighed after it is completed but before it is assembled. If the rescue boat is constructed by the spray lay-up technique, the hull and canopy thicknesses must be measured using ultrasonic or equivalent techniques;

(ii) *Steel construction.* Steel sheet and plate used for the hull, floors, and other structural components of a prototype steel rescue boat must meet the bend tests requirement specified under ASTM A 653 (incorporated by reference, see § 160.156–5 of this subpart) after galvanizing or other anti-corrosion treatment has been applied. This may be demonstrated through supplier's certification papers or through witnessing actual tests;

(iii) *Welding.* Structural components of each prototype rescue boat joined by welding must be joined by the welding procedures and materials per the plans reviewed under § 160.156–9 of this subpart and by welders appropriately qualified;

(iv) *Buoyancy material.* If block foam buoyancy material is used, each piece must be weighed after it is cut and shaped to make sure that the correct amount of foam is installed. If foamed-in-place buoyancy material is used, a separate sample of the foam must be poured, and used to make a density determination after it has set. The density must be 32 ± 8 kg/m^3 (2 ± 0.5 lb/ft^3). Each major subassembly such as the hull-with-liner and canopy-with-liner must be weighed after the buoyancy foam is installed and before it is further assembled;

(v) *Coated fabric.* Coated fabric for inflatable collars used in the construction of each rescue boat must

meet the requirements specified under § 160.156–7(b)(3) of this subpart. This may be demonstrated through a supplier's certification papers or through witnessing actual tests;

(vi) Installation of the propulsion system; and

(vii) Installation of the steering system.

(3) The independent laboratory must submit the inspection report to the Commandant.

§ 160.156–13 Approval inspections and tests for prototype rescue boats and fast rescue boats.

(a) After the Commandant notifies the manufacturer that the prototype rescue boat is in compliance with the requirements of § 160.156–11 of this subpart, the manufacturer may proceed with the prototype approval inspections and tests required under this section. The prototype rescue boat, the construction of which was witnessed under § 160.135–11 of this part, must be used for the tests in this section.

(b) Except as provided in paragraph (f) of this section, the Coast Guard must conduct the approval inspections and witness the approval tests required under this section.

(c) *Manufacturer requirements.* To proceed with approval inspections and tests required by this section, the manufacturer must—

(1) Notify the Commandant and cognizant Officer in Charge, Marine Inspection (OCMI) of where the approval inspections and tests required under this section will take place, and such notification must be in sufficient time to allow making travel arrangements;

(2) Arrange a testing schedule that allows for a Coast Guard inspector to travel to the site where the testing is to be performed;

(3) Admit the Coast Guard inspector to any place where work or testing is performed on rescue boats or their component parts and materials for the purpose of—

(i) Conducting inspections as necessary to determine that the prototype is constructed by the methods and with the materials specified in the plans reviewed under § 160.156–9, and the inspection report under § 160.156–11, of this subpart;

(ii) Assuring that the quality assurance program of the manufacturer is satisfactory;

(iii) Witnessing tests; and

(iv) Taking samples of parts or materials for additional inspections or tests; and

(4) Make available to the Coast Guard inspector the affidavits or invoices from the suppliers of all essential materials used in the production of rescue boats, together with records identifying the lot or serial numbers of the rescue boats in which such materials were used.

(d) *Tests.* (1) *Prototype rescue boat readiness.* All tests must be conducted on a completely outfitted rescue boat, including fixed equipment such as a compass, searchlight, and navigating lights. Loose equipment may be substituted by weights.

(2) *FRP prototype rescue boat lay-up.* For the prototype of each design of an FRP rescue boat, the lay-up must be made of unpigmented resins and clear gel coat.

(3) *Fuel tank.* Each non-portable fuel tank must be tested by a static head above the tank top of 3 m (10 ft) of water without showing any leaks or signs of permanent distortion.

(4) *IMO Revised recommendation on testing.* Each prototype rescue boat of each design must pass each of the tests for the applicable hull type described in the IMO Revised recommendation on testing, part 1, section 7 (incorporated by reference, see § 160.156–5 of this subpart). Tests must be conducted in accordance with these paragraphs of IMO Revised recommendation on testing, Part 1, with the following modifications:

(i) *Fire retardancy/release mechanism and engine tests* (Paragraphs 1/6.2, 6.9, 6.10, 6.14). The tests in the following IMO Revised recommendation on testing paragraphs may be accomplished independent of the rescue boat, and may be considered completed and need not be repeated if the tests have been previously shown to meet the following necessary requirements—

(A) Paragraphs 6.9.3 through 6.9.6;

(B) Paragraphs 6.10.2 through 6.10.6; and

(C) Paragraphs 6.14.6 through 6.14.8.

(ii) *Impact test* (Paragraph 1/6.4). The rigid vertical surface must not be displaced or deformed as a result of the test.

(iii) *Flooded stability test for rigid rescue boats only* (Paragraph 1/6.8). Any materials used to raise the test weights representing the rescue boat occupants above the seat pan must be at least as dense as fresh water.

(iv) *Rescue boat operational test, operation of engine* (Paragraph 1/7.1.5). For the 4-hour rescue boat maneuvering period, the rescue boat must not (except for a short period to measure towing force and to demonstrate towing fixture durability) be secured, and must be run through its full range of speeds and full range of all controls throughout the period.

(v) *Survival recovery test* (Paragraph 1/6.10.8). The recovery demonstration must show that no more than two crewmembers are required to recover a helpless person of ninety-fifth percentile by weight described in ASTM F 1166 (incorporated by reference, see § 160.156–5 of this subpart) while the crewmembers and helpless person are each wearing a lifejacket.

(vi) *Rescue boat seating space test* (Paragraph 1/7.1.3). The average mass of persons used to test the rescue boat seating space must be determined by weighing as a group or individually. Each person must wear an inherently buoyant SOLAS lifejacket with at least 150 N of buoyancy or a Coast Guard-approved lifejacket approved under approval series 160.155. The operator(s) must demonstrate that the rescue boat can be operated while wearing a Coast Guard approved, insulated-buoyant immersion suit approved under approval series 160.171. The Commandant will give consideration to requests to test at, and designate rescue boats for, a heavier occupant weight than that stated in the IMO LSA Code, chapter V (incorporated by reference, § 160.156–5 of this subpart).

(5) *Visual inspection.* Each rescue boat must be visually inspected to confirm—

(i) Compliance with this subpart;

(ii) Conformance with the plans reviewed under § 160.156–9 of this subpart; and

(iii) Ease of operation and maintenance.

(e) *Test waiver.* The Commandant may waive certain tests for a rescue boat identical in construction to smaller and larger rescue boats that have successfully completed the tests. Tests associated with rescue boat components that have already been approved by the Commandant are not required to be repeated.

(f) At the request of the manufacturer and discretion of the Commandant, an independent laboratory may perform approval inspections and witness approval tests required by this section so long as the inspections and tests are performed and witnessed in accordance with the procedures agreed upon between the independent laboratory and Commandant under 46 CFR part 159, subpart 159.010.

(g) After completion of approval inspections and tests required by this section, the manufacturer must comply with the requirements of 46 CFR 159.005–9(a)(5) by preparing and submitting to the Commandant for review—

(1) The prototype approval test report containing the same information

recommended by IMO MSC Circ. 980 (incorporated by reference, see § 160.156–5 of this subpart). The report must include a signed statement by the Coast Guard inspector (or independent laboratory as permitted by paragraph (f) of this section) who witnessed the testing, indicating that the report accurately describes the testing and its results; and

(2) The final plans of the rescue boat as built. The plans must include, in triplicate—

(i) The instructions for training and maintenance described in §§ 160.156–19 and 160.156–21 of this subpart; and

(ii) The final version of the plans required under § 160.156–9 of this subpart.

(h) The Commandant will review the report and plans submitted under paragraph (g) of this section, and, if satisfactory to the Commandant, will approve the plans under 46 CFR 159.005–13.

§ 160.156–15 Production inspections, tests, quality control, and conformance of rescue boats and fast rescue boats.

(a) Unless the Commandant directs otherwise, an independent laboratory must perform or witness, as appropriate, inspections, tests, and oversight required by this section. Production inspections and tests of rescue boats must be carried out in accordance with the procedures for independent laboratory inspection in 46 CFR part 159, subpart 159.007 and in this section, unless the Commandant authorizes alternative tests and inspections. The Commandant may prescribe additional production tests and inspections necessary to maintain quality control and to monitor compliance with the requirements of this subpart.

(b) *Manufacturer's responsibility.* The manufacturer must—

(1) Institute a quality control procedure to ensure that all production rescue boats are produced to the same standard, and in the same manner, as the prototype rescue boat approved by the Commandant. The manufacturer's quality control personnel must not work directly under the department or person responsible for either production or sales;

(2) Schedule and coordinate with the independent laboratory (or Coast Guard inspector if required under paragraph (a) of this section) to ensure that all tests are performed as described in this section;

(3) Submit to the Commandant, a yearly report that contains the following—

(i) Serial number and date of final assembly of each rescue boat constructed;

(ii) Name of the representative of the independent laboratory (or Coast Guard inspector if required under paragraph (a) of this section); and

(iii) Name of the vessel and company receiving the rescue boat, if known;

(4) Ensure that the arrangement and materials entering into the construction of the rescue boat are in accordance with plans approved under § 160.156–13(h) of this subpart;

(5) Allow an independent laboratory (or Coast Guard inspector if required under paragraph (a) of this section) access to any place where materials are stored for the rescue boat, work or testing is performed on rescue boats or their component parts and materials, or records are retained to meet the requirements of paragraph (c) of this section, for the purpose of—

(i) Assuring that the quality control program of the manufacturer is satisfactory;

(ii) Witnessing tests; or

(iii) Taking samples of parts or materials for additional inspections or tests; and

(6) Ensure that the independent laboratory conducts the inspections and witnesses the tests required by paragraph (e) of this section, and further conducts a visual inspection to verify that the rescue boats are being made in accordance with the plans approved under § 160.156–13(h) of this subpart and the requirements of this subpart.

(c) *Recordkeeping.* The manufacturer must maintain records in accordance with 46 CFR 159.007–13. The manufacturer must keep records of all items listed in this section for at least 5 years from the date of termination of approval of each rescue boat. The records must include—

(1) A copy of this subpart, other CFR sections referenced in this subpart, and each applicable document listed in § 160.156–5 of this subpart;

(2) A copy of approved plans, documentation, and certifications;

(3) A current certificate of approval for each approved rescue boat;

(4) Affidavits, certificates, or invoices from the suppliers identifying all essential materials used in the production of approved rescue boats, together with records identifying the serial numbers of the rescue boats in which such materials were used;

(5) Start and finish date and time of the lay-up of each major Fiber Reinforced Plastic (FRP) component such as the hull, canopy, and inner liner and the names of the operator(s);

(6) Start and finish date and time of pouring of foam-in-place rigid buoyancy foam, and name of operator(s);

(7) Records of all structural welding and name of operator(s);

(8) Records of welder certificates, training and qualifications;

(9) Date and results of calibration of test equipment and the name and address of the company or agency that performed the calibration;

(10) The serial number of each production rescue boat, along with records of its inspections and test carried out under this section; and

(11) The original purchaser of each rescue boat and the vessel on which it was installed, if known.

(d) *Independent laboratory responsibility.* The independent laboratory must perform or witness, as appropriate, the inspections and tests under paragraph (e) in this section for each Coast Guard-approved rescue boat to be installed on a U.S.-flagged vessel. If the manufacturer also produces rescue boats for approval by other maritime safety administrations, the inspections may be coordinated with inspection visits for those administrations.

(e) *Production inspections and tests.* Each approved rescue boat must be inspected and tested in accordance with each of the following procedures:

(1) *In-process inspections and tests.* In accordance with the interval prescribed in paragraph (d)(1) of this section, each production rescue boat must be examined during lay-up of the hull to verify that the lay-up conforms to the approved drawings. Each FRP major component, such as the hull, canopy, and inner liner, must be examined and weighed after it is completed but before assembled. If the rescue boat is constructed by the spray lay-up technique, the hull and canopy thicknesses must be measured using ultrasonic or equivalent techniques. Laboratory tests of laminates must be conducted at this time. Test samples must be cut out from the rescue boat itself or be laid up at the same time, using the same procedures, and by the same operators as the laminate used in the rescue boat. The number of samples used for each test, and the conditions and test methods used, must be as described in the applicable test specified in this paragraph.

(i) *Weight.* The weight of each FRP section, such as hull, canopy, and inner liner, must be within 10 percent of similar sections of the prototype rescue boat. These weights must be the bare laminate weights. Backing plates that are molded into the laminate may be included.

(ii) *Thickness.* The average thickness of each section of sprayed-up laminate must be within 20 percent of the corresponding sections of the prototype.

(iii) *Resin content.* Laminate samples from the hull, canopy, and inner liners must be tested in accordance with ASTM D 2584 or ISO 1172 (incorporated by reference, see § 160.156–5 of this subpart). The resin content must be within 8 percentage points of the prototype results. If the resin content does not comply, flexural ultimate strength and tensile tests in paragraph (e)(1)(iv) of this section must be conducted.

(iv) *Flexural ultimate strength and tensile tests.* Each laminate sample from each major component, such as hull and liner, that does not comply with the resin content requirement in paragraph (e)(1)(iii) of this section, and from each component of every fifth production rescue boat, must be subjected to the flexural ultimate strength and tensile strength tests as described in § 160.156–11(c)(2)(i)(B) of this subpart. The values must be at least 90 percent of the prototype results.

(v) *Buoyancy material.* If block foam buoyancy material is used, each piece must be weighed after it is cut and shaped to make sure that the correct amount of foam is installed. If foamed-in-place buoyancy material is used, a separate sample of the foam must be poured, and used to make a density determination after it has set. The density must be 32 +/− 8 kg/m^3 (2 +/− 0.5 lb/ft^3).

(vi) *Steel sheet and plate.* Steel sheet and plate for the hull, floors, and other structural components must meet ASTM A 36 and ASTM A 653 as applicable (incorporated by reference, see § 160.156–5 of this subpart). Non-corrosive resistant steel must meet the coating mass and bend tests requirement specified under ASTM A 653. Compliance for this paragraph can be ascertained through supplier's certification papers or through conducting actual tests.

(vii) *Fabric.* The coated fabric for inflatable collars, when used, for the construction of each rescue boat must meet ISO 15372 (incorporated by reference, see § 160.156–5 of this subpart). This compliance can be ascertained through a supplier's certification papers or through witnessing actual tests.

(viii) *Fuel tank.* Each fuel tank must be tested by a static head above the tank top of 3 m (10 ft) of water without showing any leaks or signs of permanent distortion.

(ix) *Welding.* It must be determined that structural components joined by welding was performed by welders who are appropriately qualified and that the welding procedure and materials are as per the plans approved under § 160.156–13(h) of this subpart.

(2) *Post assembly tests and inspections.* The finished rescue boat must be visually inspected inside and out. The manufacturer must develop and maintain a visual inspection checklist designed to ensure that all applicable requirements have been met and the rescue boat is equipped in accordance with approved plans. At a minimum, each rescue boat must be operated for 2 hours, during which all rescue boat systems must be exercised.

§ 160.156–17 Marking and labeling.

(a) Each rescue boat must be marked with a plate or label permanently affixed to the hull in a conspicuous place readily accessible for inspection and sufficiently durable to withstand continuous exposure to environmental conditions at sea for the life of the rescue boat.

(b) The plate or label must be in English, but may also be in other languages.

(c) The plate or label must contain the—

(1) Name and address of the manufacturer;

(2) Manufacturer's model identification;

(3) Name of the independent laboratory that witnessed the prototype or production tests;

(4) Serial number of the rescue boat;

(5) U.S. Coast Guard approval number;

(6) Month and year of manufacture;

(7) Material of hull construction;

(8) Number of persons for which the rescue boat is approved;

(9) Light load and full load (condition A and condition B weight); and

(10) Word ''SOLAS.''

§ 160.156–19 Operating instructions and information for the ship's training manual.

(a) Each rescue boat must have instructions and information for the ship's training manual, that use the symbols from IMO Res. A.760(18) (incorporated by reference, see § 160.156–5 of this subpart) to describe the location and operation of the rescue boat.

(b) The instructions and information required by paragraph (a) of this section may be combined with similar material for survival craft and rescue boats, and their launching systems.

(c) The rescue boat manufacturer must make the instructions and information required by paragraph (a) of this section available—

(1) In English to purchasers of a rescue boat approved by the Coast Guard; and

(2) In the form of an instruction placard providing simple procedures and illustrations for operation of the rescue boat. The placard must be not greater than 36 cm (14 in) by 51 cm (20 in), and must be made of durable material and suitable for display near installations of rescue boats on vessels.

§ 160.156–21 Operation and maintenance instructions.

(a) In order to comply with SOLAS, each rescue boat must have operation and maintenance instructions that—

(1) Follows the general format and content specified in MSC.1 Circ. 1205 (incorporated by reference, see § 160.156–5 of this subpart); and

(2) Includes a checklist for use in monthly, external inspections of the rescue boat.

(b) The rescue boat manufacturer must make the manual required by paragraph (a) of this section available in English to purchasers of a rescue boat approved by the Coast Guard.

(c) The operation and maintenance instructions required by paragraph (a) of this section may be combined with similar material for survival craft and rescue boats, and their launching systems.

§ 160.156–23 Procedure for approval of design, material, or construction change.

(a) Each change in design, material, or construction from the plans approved under 46 CFR 159.005–13 and § 160.156–13(h) of this subpart must be approved by the Commandant before being used in any production rescue boat. The manufacturer must submit any such change following the procedures set forth in § 160.156–9 of this subpart, but documentation on items that are unchanged from the plans approved under 46 CFR 159.005–13 and § 160.156–13(h) of this subpart need not be resubmitted.

(b) Unless determined by the Commandant to be unnecessary, a prototype rescue boat with each change described in paragraph (a) of this section must be made and tested according to the procedures for new approvals in §§ 160.156–9 through 160.156–13 of this subpart.

(c) Determinations of equivalence of design, construction, and materials will be made by the Commandant only.

■ 45. Add subpart 160.170 to read as follows:

Subpart 160.170—Davit-Launched Liferaft Automatic Release Hooks (SOLAS)

Sec.
160.170–1 Scope.
160.170–3 Definitions.
160.170–5 Incorporation by reference.
160.170–7 Design, construction, and performance of automatic release mechanisms.
160.170–9 Preapproval review.
160.170–11 [Reserved]
160.170–13 Approval inspections and tests for prototype automatic release mechanisms.
160.170–15 Production inspections, tests, quality control, and conformance of release mechanisms.
160.170–17 Marking and labeling.
160.170–19 Operating instructions and information for the ship's training manual.
160.170–21 Operation and maintenance instructions.
160.170–23 Procedure for approval of design, material, or change.
Subpart 160.170—Davit-Launched Liferaft Automatic Release Hooks (SOLAS)

§ 160.170–1 Scope.

This subpart prescribes standards, tests, and procedures for seeking Coast Guard approval of an automatic release mechanism complying with SOLAS and the IMO LSA Code, for use with davit-launched liferafts approved under subparts 160.051 or 160.151 of this part, and single-fall rescue boats approved under subpart 160.156 of this part.

§ 160.170–3 Definitions.

In addition to the definitions in the IMO LSA Code (incorporated by reference, see § 160.170–5 of this subpart), in this subpart, the term:

Commandant means the Commandant (CG–5214), U.S. Coast Guard, 2100 Second Street, SW., Stop 7126, Washington, DC 20593–7126.

Full load means the weight of the complete rescue boat including all required equipment, provisions, fuel (if applicable), and the number of persons for which it is approved. This is also known as the ''condition B'' weight.

Independent laboratory has the same meaning as 46 CFR 159.001–3. A list of accepted independent laboratories is available from the Commandant and online at *http://cgmix.uscg.mil.*

Light load means the weight of the complete rescue boat empty and does not include fuel, required equipment, or the equivalent weight of persons. This is also known as the ''condition A'' weight.

Officer in Charge, Marine Inspection (OCMI) means an officer of the Coast Guard designated as such by the Commandant and who fulfills the duties described in 46 CFR 1.01–15(b). The ''cognizant OCMI'' is the OCMI who has immediate jurisdiction over a vessel or geographic area for the purpose of performing the duties previously described.

SOLAS means the International Convention for the Safety of Life at Sea, 1974, as amended.

§ 160.170–5 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Coast Guard must publish notice of change in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at Commandant (CG–5214), U.S. Coast Guard, 2100 Second Street, SW., Stop 7126, Washington, DC 20593–7126. You may also inspect this material 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.* You may obtain copies of the material from the sources specified in the following paragraphs.

(b) American Society for Testing and Materials (ASTM), 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959.

(1) ASTM A 36/A 36M–08, Standard Specification for Carbon Structural Steel, (approved May 15, 2008), IBR approved for § 160.170–7 (''ASTM A 36'').

(2) ASTM A 276–08a, Standard Specification for Stainless Steel Bars and Shapes, (approved October 1, 2008), IBR approved for § 160.170–7 (''ASTM A 276'').

(3) ASTM A 313/A 313M–08, Standard Specification for Stainless Steel Spring Wire, (approved October 1, 2008), IBR approved for § 160.170–7 (''ASTM A 313'').

(4) ASTM A 314–08, Standard Specification for Stainless Steel Billets and Bars for Forging, (approved October 1, 2008), IBR approved for § 160.170–7 (''ASTM A 314'').

(5) ASTM A 653/A 653M–08, Standard Specification for Steel Sheet, Zinc-Coated (Galvanized) or Zinc-Iron Alloy-Coated (Galvannealed) by the Hot-Dip Process, (approved July 15, 2008), IBR approved for §§ 160.170–7, 160.170–13, and 160.170–15 (''ASTM A 653'').

(6) ASTM F 1166–07, Standard Practice for Human Engineering Design for Marine Systems, Equipment, and Facilities, (approved January 1, 2007), IBR approved for § 160.170–7 (''ASTM F 1166'').

(c) International Maritime Organization (IMO), Publications Section, 4 Albert Embankment, London SE1 7SR, United Kingdom, +44 (0)20 7735 7611, *http://www.imo.org/.*

(1) IMO Resolution A.760(18), Symbols Related to Life-Saving Appliances and Arrangements, (adopted November 4, 1993), IBR approved for § 160.170–19 (''IMO Res. A.760(18)'').

(2) Life-Saving Appliances, including LSA Code, 2010 Edition, (2010), pages 7–71 (''IMO LSA Code''), IBR approved for §§ 160.170–3 and 160.170–7.

(3) Life-Saving Appliances, including LSA Code, 2010 Edition, (2010), Revised recommendation on testing of live-saving appliances, pages 79–254 (''IMO Revised recommendation on testing''), IBR approved for §§ 160.170–7, 160.170–13, 160.170–15, and 160.170–17.

(4) MSC/Circular 980, Standardized Life-saving Appliance Evaluation and Test Report Forms, (February 13, 2001), IBR approved for § 160.170–13 (''IMO MSC Circ. 980'').

(5) MSC.1/Circular 1205, Guidelines for Developing Operation and Maintenance Manuals for Lifeboat Systems, (May 26, 2006), IBR approved for § 160.170–21 (''IMO MSC.1 Circ. 1205'').

§ 160.170–7 Design, construction, and performance of automatic release mechanisms.

(a) To seek Coast Guard approval of a release mechanism, a manufacturer must comply with, and each release mechanism must meet, the requirements of the following—

(1) IMO LSA Code, Chapter VI/6.1.5 (incorporated by reference, see § 160.170–5 of this subpart);

(2) IMO Revised recommendation on testing Part 1/8.2 (incorporated by reference, see § 160.170–5 of this subpart).

(3) 46 CFR part 159; and

(4) This subpart.

(b) Each release mechanism must meet the following requirements—

(1) *Design.* All functions of the release mechanism, including removal of interlocks, operation of the release handle, resetting the hooks, and reattaching the falls to the hooks, must be designed to be operable by persons wearing immersion suits;

(2) Each release mechanism should be designed following standard human engineering practices described in ASTM F 1166 (incorporated by reference, see § 160.170–5 of this subpart). Design limits should be based on a range from the fifth percentile

female to the ninety-fifth percentile male values for critical body dimensions and functional capabilities as described in ASTM F 1166. The dimensions for a person wearing an immersion suit correspond to the arctic-clothed dimensions of ASTM F 1166;

(3) *Steel.* Each major structural component of each release mechanism must be constructed of steel. Other materials may be used if accepted by the Commandant as equivalent or superior. Sheet steel and plate must be low-carbon, commercial quality, either corrosion resistant or galvanized as per ASTM A 653 (incorporated by reference, see § 160.170–5 of this subpart), coating designation G115. Structural steel plates and shapes must be carbon steel as per ASTM A 36 (incorporated by reference, see § 160.170–5 of this subpart). All steel products, except corrosion resistant steel, must be galvanized to provide high-quality zinc coatings suitable for the intended service life in a marine environment. Each fabricated part must be galvanized after fabrication. Corrosion resistant steel must be a type 302 stainless steel per ASTM A 276, ASTM A 313 or ASTM A 314 (incorporated by reference, see § 160.170–5 of this subpart) or another corrosion resistant stainless steel of equal or superior corrosion resistant characteristics;

(4) *Welding.* Welding must be performed by welders certified by the Commandant, a classification society recognized by the Commandant in accordance with 46 CFR 8.220, the U.S. Navy, or the national body where the release mechanism is constructed or the national body's designated recognized organization. Only electrodes intended for use with the material being welded may be used. All welds must be checked using appropriate non-destructive tests;

(5) Metals in contact with each other must be either galvanically compatible or insulated with suitable non-porous materials. Provisions must also be made to prevent loosening or tightening resulting from differences of thermal expansion, freezing, buckling of parts, galvanic corrosion, or other incompatibilities;

(6) Screws, nuts, bolts, pins, keys, and other similar hardware, securing moving parts must be fitted with suitable lock washers, cotter pins, or locks to prevent them from coming adrift;

(7) The on-load operation of the release mechanism must require two separate, deliberate actions by the operator;

(8) To prevent an accidental release during recovery of the boat, the release hooks must not be able to carry any weight until the release mechanism is properly reset;

(9) The release and recovery procedures must be included as an illustrated operation instruction plate or placard. The plate or placard must be corrosion resistant and weatherproof and must be marked with the word ''Danger''. The illustrations must correspond exactly to those used in the instruction and maintenance manual provided by the manufacturer;

(10) The release lever or control must be red in color, and the area immediately surrounding the control must be a sharply contrasting light color;

(11) Each load carrying part of the release mechanism, including its connection to the boat, must be designed with a safety factor of six based on the ultimate strength of the materials used;

(12) The release lever and its connection to the release mechanism must be of sufficient strength so that there is no deformation of the release lever or the release control assembly during on-load release;

(13) Positive means of lubrication must be provided for each bearing which is not permanently lubricated. Points of lubrication must be so located that they are clearly visible and accessible in the installed position in the boat; and

(14) A hydraulic system, if used to activate the release mechanism, must be in accordance with 46 CFR part 58, subpart 58.30, with hose and fittings in accordance with 46 CFR part 56, subpart 56.60, except that—

(i) Push-on type fittings such as Aeroquip 1525–X, 25156–X, and FC332–X are not permitted;

(ii) The length of nonmetallic flexible hose is limited to 760 mm (30 in); and

(iii) If a hand pump is provided, adequate space must be provided for the hand pump or hand operation.

(c) Determinations of equivalence of design, construction, and materials will be made by the Commandant only.

§ 160.170–9 Preapproval review.

(a) Except as provided in paragraph (c) of this section, the Commandant must conduct the preapproval review, required by this section, in accordance with 46 CFR 159.005–5.

(b) *Manufacturer requirements.* To seek Coast Guard approval of a release mechanism, the manufacturer must submit an application to the Commandant meeting the requirements of 46 CFR 159.005–5 for preapproval review. To meet the requirements of 46 CFR 159.005–5(a)(2), the manufacturer must submit in triplicate—

(1) A list of drawings, specifications, manuals, and any other documentation submitted, with each document identified by number, title, revision issue, and date;

(2) General arrangement and assembly drawings, including principal dimensions;

(3) Stress calculations for all load carrying parts, including the release hooks, release mechanisms, and connections;

(4) Hydraulic systems drawings and specifications, if installed;

(5) Drawings of all signs and placards showing actual inscription, format, color, and size;

(6) An operation, maintenance, and training manual as described in §§ 160.170–19 and 160.170–21 of this subpart;

(7) A description of the quality control procedures and recordkeeping that will apply to the production of the release mechanism, which must include but is not limited to—

(i) The system for checking material certifications received from suppliers;

(ii) The method for controlling the inventory of materials;

(iii) The method for checking quality of fabrication and joints, including welding inspection procedures; and

(iv) The inspection checklists used during various stages of fabrication to assure that the approved release mechanism complies with the approved plans and the requirements of this subpart;

(8) Full details of any other unique capability;

(9) Any other drawing(s) necessary to show that the release mechanism complies with the requirements of this subpart;

(10) The location or address of all manufacturing sites, including the name and address of any subcontractors, where the release mechanism will be constructed; and

(11) The name of the independent laboratory that will perform the duties prescribed in § 160.170–15 of this subpart.

(c) At the request of the manufacturer and discretion of the Commandant, an independent laboratory may conduct preapproval review required by this section, so long as the preapproval review is conducted in accordance with the procedures agreed upon between the independent laboratory and Commandant under 46 CFR part 159, subpart 159.010.

(d) *Plan quality.* The plans and specifications submitted to the Commandant under this section must—

(1) Be provided in English, including all notes, inscriptions, and designations for configuration control;

(2) Address each of the applicable items in paragraph (b) of this section in sufficient detail to show that the release mechanism meets the construction requirements of this subpart;

(3) Accurately depict the proposed automatic release hook;

(4) Be internally consistent;

(5) Be legible; and

(6) If reviewed by an independent laboratory under paragraph (c) of this section, include the independent laboratory's attestation that the plans meet the quality requirements of this section.

(e) *Alternatives.* Alternatives in materials, parts, or construction, and each item replaced by an alternative, must be clearly indicated as such in the plans and specifications submitted to the Commandant under this section.

(f) *Coast Guard review.* If the plans or specifications do not comply with the requirements of this section, Coast Guard review may be suspended, and the applicant notified accordingly.

§ 160.170–11 [Reserved]

§ 160.170–13 Approval inspections and tests for prototype automatic release mechanisms.

(a) If the manufacturer is notified that the information submitted in accordance with § 160.170–9 of this subpart is satisfactory to the Commandant, the manufacturer may proceed with fabrication of the prototype release mechanism, and the approval inspections and tests required under this section.

(b) Except as provided in paragraph (f) of this section, the Coast Guard must conduct the approval inspections and witness the approval tests required under this section.

(c) *Manufacturer's requirements.* To proceed with approval inspections and tests required by this section, the manufacturer must—

(1) Notify the Commandant and cognizant Officer in Charge, Marine Inspection (OCMI) of where the approval inspections and tests required under this section will take place, and such notification must be in sufficient time to allow making travel arrangements;

(2) Arrange a testing schedule that allows for a Coast Guard inspector to travel to the site where the testing is to be performed;

(3) Admit the Coast Guard inspector to any place where work or testing is performed on release mechanisms or their component parts and materials for the purpose of—

(i) Conducting inspections as necessary to determine that the prototype—

(A) Conforms with the plans reviewed under § 160.170–9 of this subpart;

(B) Is constructed by the methods and with the materials specified in the plans reviewed under § 160.170–9 of this subpart; and

(C) When welding is part of the construction process, is constructed by the welding procedure and materials as per the plans reviewed under § 160.170–9 of this subpart, and the welders are appropriately qualified;

(ii) Assuring that the quality-assurance program of the manufacturer is satisfactory;

(iii) Witnessing tests; and

(iv) Taking samples of parts or materials for additional inspections or tests; and

(4) Make available to the Coast Guard inspector the affidavits or invoices from the suppliers of all essential materials used in the production of release mechanisms, together with records identifying the lot or serial numbers of the release mechanisms in which such materials were used.

(d) *Tests.* (1) *Prototype release mechanism readiness.* All tests must be conducted on a complete release mechanism.

(2) *IMO Revised recommendation on testing.* Each prototype release mechanism of each design must pass each of the tests described in IMO Revised recommendation on testing, Part 1, paragraph 8.2 (incorporated by reference, see § 160.170–5 of this subpart). Tests must be conducted in accordance with these paragraphs of IMO Revised recommendation on testing, Part 1, with the following modifications:

(i) *Visual inspection.* Each release mechanism must be visually inspected to confirm—

(A) Compliance with this subpart;

(B) Conformance with the examined plans; and

(C) Ease of operation and maintenance.

(ii) *Materials.* Steel meeting ASTM A 653 (incorporated by reference, see § 160.170–5 of this subpart) must meet the coating mass and bend tests requirement specified under ASTM A 653 after galvanizing or other anti-corrosion treatment has been applied. This compliance can be ascertained through a supplier's certification or by conducting actual tests.

(iii) *Tensile tests.* The release mechanism hook assembly and supporting structure must be tensile tested in a jig built to load the hook assembly in the same way or ways it would be loaded when used with a liferaft or rescue boat. The hook assembly will be approved for a maximum of one-sixth of the highest load applied.

(iv) *Universal joints.* This test is required if the release mechanism employs universal joints to transmit the release power from the control to the hook release. One of each type and size of universal joint must be set up in a jig with the angles of leads set at 0 (zero), 30, and 60 degrees, respectively. A torque of 540 Nm (400 ft lb) must be applied. This torque must be applied with the connecting rod secured beyond the universal and with the lever arm in the horizontal position. There must be no permanent set, or undue stress, as a result of this test.

(v) *Hydraulic controls.* If the release mechanism includes a fluid power and control system, a test of the hydraulic controls must be conducted in accordance with 46 CFR 58.30–35.

(e) *Test waiver.* The Commandant may waive certain tests for a release mechanism identical in construction to smaller and larger release mechanisms that have successfully completed the tests. However, stress calculations in accordance with § 160.170–9(b) of this subpart must still be submitted. Tests associated with release mechanism components that have already been accepted by the Commandant are not required to be repeated.

(f) At the request of the manufacturer and discretion of the Commandant, an independent laboratory may perform approval inspections and witness approval tests required by this section so long as the inspections and tests are performed and witnessed in accordance with the procedures agreed upon between the independent laboratory and Commandant under 46 CFR part 159, subpart 159.010.

(g) After completion of approval inspections and tests required by this section, the manufacturer must comply with the requirements of 46 CFR 159.005–9(a)(5) by preparing and submitting to the Commandant for review—

(1) The prototype approval test report containing the same information recommended by IMO MSC Circ. 980 (incorporated by reference, see § 160.170–5 of this subpart). The report must include a signed statement by the Coast Guard inspector (or independent laboratory as permitted by paragraph (f) of this section) who witnessed the testing, indicating that the report accurately describes the testing and its results; and

(2) The final plans of the release mechanism as built. The plans must include, in triplicate, the instructions for training and maintenance described

in §§ 160.170–19 and 160.170–21 of this subpart, respectively.

(h) The Commandant will review the report and plans submitted under paragraph (g) of this section, and if satisfactory to the Commandant, will approve the plans under 46 CFR 159.005–13.

§ 160.170–15 Production inspections, tests, quality control, and conformance of release mechanisms.

(a) Unless the Commandant directs otherwise, an independent laboratory must perform or witness, as appropriate, inspections, tests, and oversight required by this section. Production inspections and tests of release mechanisms must be carried out in accordance with the procedures for independent laboratory inspection in 46 CFR part 159, subpart 159.007 and in this section unless the Commandant authorizes alternative tests and inspections. The Commandant may prescribe additional production tests and inspections necessary to maintain quality control and to monitor compliance with the requirements of this subpart.

(b) *Manufacturer's responsibility.* The manufacturer must—

(1) Institute a quality control procedure to ensure that all production release mechanisms are produced to the same standard, and in the same manner, as the prototype release mechanism approved by the Commandant. The manufacturer's quality control personnel must not work directly under the department or person responsible for either production or sales;

(2) Schedule and coordinate with the independent laboratory (or Coast Guard inspector if required under paragraph (a) of this section) to ensure that all tests are performed as described in this section;

(3) Submit to the Commandant, a yearly report that contains the following—

(i) Serial number and date of final assembly of each release mechanism constructed;

(ii) The name of the representative of the independent laboratory (or Coast Guard inspector if required under paragraph (a) of this section); and

(iii) Serial number and model name of the liferaft or rescue boat with which the release hook is to be used, if known;

(4) Ensure that the arrangement and materials entering into the construction of the release mechanism are in accordance with plans approved under § 160.170–13(h) of this subpart;

(5) Allow an independent laboratory (or Coast Guard inspector if required under paragraph (a) of this section) access to any place where materials are stored for the release mechanism, work or testing is performed on release mechanisms or their component parts and materials, or records are retained to meet the requirements of paragraph (c) of this section, for the purpose of—

(i) Assuring that the quality control program of the manufacturer is satisfactory;

(ii) Witnessing tests; or

(iii) Taking samples of parts or materials for additional inspections or tests; and

(6) Ensure that the independent laboratory (or Coast Guard inspector if required under paragraph (a) of this section) conducts the inspections and witnesses the tests required by paragraph (e) of this section, and further conducts a visual inspection to verify that the release mechanisms are being made in accordance with the plans approved under § 160.170–13(h) of this subpart and the requirements of this subpart.

(c) *Recordkeeping.* The manufacturer must maintain records in accordance with 46 CFR 159.007–13. The manufacturer must keep records of all items listed in this section for at least 5 years from the date of termination of approval of each release mechanism. The records must include—

(1) A copy of this subpart, other CFR sections referenced in this subpart, and each document listed in § 160.170–5 of this subpart;

(2) A copy of the approved plans and documentation;

(3) A current certificate of approval for each approved release mechanism;

(4) Affidavits, certificates, or invoices from the suppliers identifying all essential materials used in the production of approved release mechanisms, together with records identifying the serial numbers of the release mechanisms in which such materials were used;

(5) Records of all structural welding and name of operator(s);

(6) Records of welder certificates, training, and qualifications;

(7) Date and results of calibration of test equipment and the name and address of the company or agency that performed the calibration;

(8) The serial number of each production release gear, along with records of its inspections and tests carried out under this section; and

(9) The original purchaser of each release gear and the vessel on which it was installed, if known.

(d) *Independent laboratory responsibility.* The independent laboratory must perform or witness, as appropriate, the inspections and tests under paragraph (e) of this section for each Coast Guard-approved release mechanism to be installed on a U.S.-flagged vessel. If the manufacturer also produces release mechanisms for approval by other maritime safety administrations, the inspections may be coordinated with inspection visits for those administrations.

(e) *Production inspections and tests.* Each finished release mechanism must be visually inspected. The manufacturer must develop and maintain a visual inspection checklist designed to ensure that all applicable requirements have been met. Each approved release mechanism constructed with non-corrosion resistant steel must be confirmed to have met the coating mass and bend tests requirement specified under ASTM A 653 (incorporated by reference, see § 160.170–5 of this subpart) after galvanizing or other anti-corrosion treatment has been applied. This compliance can be ascertained through a supplier's certification papers or through conducting actual tests.

(f) Each approved release mechanism must pass each of the tests described in IMO Revised recommendation on testing, part 2, paragraph 6.2 (incorporated by reference, see § 160.170–5 of this subpart). However, each approved release mechanism for installation of a single-fall rescue boat must pass each of the tests described in IMO Revised recommendation on testing, part 2, paragraph 5.3.1 and 5.3.4.

§ 160.170–17 Marking and labeling.

(a) Each hook body of a release mechanism must be marked with a plate or label permanently affixed in a conspicuous place readily accessible for inspection and sufficiently durable to withstand continuous exposure to environmental conditions at sea for the life of the release mechanism.

(b) The plate or label must be in English, but may also be in other languages.

(c) The plate or label must contain the—

(1) Manufacturer's name and model identification;

(2) Name of the independent laboratory that witnessed the prototype or production tests;

(3) Serial number of the release mechanism;

(4) U.S. Coast Guard approval number;

(5) Month and year of manufacture;

(6) Safe working load of the release mechanism;

(7) Number of the test certificate in accordance with IMO Revised recommendation on testing, part 2/6.2.2

(incorporated by reference, see § 160.170–5 of this subpart); and

(8) Word ''SOLAS.''

§ 160.170–19 Operating instructions and information for the ship's training manual.

(a) In order to comply with SOLAS, each release mechanism must have instructions and information for the ship's training manual that use the symbols from IMO Res. A.760(18) (incorporated by reference, see § 160.170–5 of this subpart) to describe the location and operation of the winch.

(b) The instructions and information required by paragraph (a) of this section may be combined with similar material for survival craft and rescue boats, and their launching systems.

(c) The release mechanism manufacturer must make the instructions and information required by paragraph (a) of this section available—

(1) In English to purchasers of release mechanisms approved by the Coast Guard; and

(2) In the form of an instruction placard providing simple procedures and illustrations for operation of the release mechanism. The placard must be not greater than 36 cm (14 in) by 51 cm (20 in), and must be made of durable material and suitable for display inside a lifeboat and rescue boat, and near launching apparatuses on vessels.

§ 160.170–21 Operation and maintenance instructions.

(a) Each release mechanism must have operation and maintenance instructions that—

(1) Follows the general format and content specified in IMO MSC.1 Circ. 1205 (incorporated by reference, see § 160.170–5 of this subpart); and

(2) Includes a checklist for use in monthly, external inspections of the release mechanism.

(b) The release mechanism manufacturer must make the manual required by paragraph (a) of this section available in English to purchasers of a release mechanism approved by the Coast Guard.

(c) The operation and maintenance instructions required by paragraph (a) of this section may be combined with similar material for survival craft and rescue boats, and their launching systems.

§ 160.170–23 Procedure for approval of design, material, or construction change.

(a) Each change in design, material, or construction from the plans approved under 46 CFR 159.005–13 and § 160.170–13(h) of this subpart must be approved by the Commandant before being used in any production release mechanism. The manufacturer must submit any such change following the procedures in § 160.170–9 of this subpart, but documentation on items that are unchanged from the plans approved under 46 CFR 159.005–13 and § 160.170–13(h) of this subpart need not be resubmitted.

(b) Unless determined by the Commandant to be unnecessary, a prototype release mechanism with each change described in paragraph (a) of this section must be made and tested according to the procedures for new approvals in §§ 160.170–9 through 160.170–13 of this subpart.

(c) Determinations of equivalence of design, construction, and materials will be made by the Commandant only.

■ 46. Add subpart 160.900 to read as follows:

Subpart 160.900—Preemption

Sec.

160.900–1 Preemption of State or local law.

160.900–3 [Reserved]

Subpart 160.900—Preemption

§ 160.900–1 Preemption of State or local law.

The regulations in this part have preemptive effect over State or local regulation within the same field.

§ 160.900–3 [Reserved]

PART 164—MATERIALS

■ 47. The authority citation for part 164 continues to read as follows:

Authority: 46 U.S.C. 3306, 3703, 4302; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; 49 CFR 1.46.

■ 48. Add subpart 164.120 to read as follows:

Subpart 164.120—Fire Retardant Resins for Lifeboats and Rescue Boats

Sec.

164.120–1 Scope.

164.120–3 Definitions.

164.120–5 Incorporation by reference.

164.120–7 Acceptance criteria.

164.120–9 Procedure for acceptance.

164.120–11 Production quality control requirements.

164.120–13 Marking, labeling, and instructions for use.

164.120–15 Procedure for acceptance of material change.

Subpart 164.120—Fire Retardant Resins for Lifeboats and Rescue Boats

§ 164.120–1 Scope.

This subpart contains performance requirements, acceptance tests, and production testing and inspection requirements for fire retardant resins used in the construction of lifeboats approved under 46 CFR part 160, subpart 160.135 and rescue boats approved under 46 CFR part 160, subpart 160.156.

§ 164.120–3 Definitions.

In this subpart, the term:

Acceptance means certification by the Coast Guard that a component is suitable for use in the manufacture of Coast Guard-approved lifeboats and rescue boats.

Commandant means the Commandant (CG–5214), U.S. Coast Guard, 2100 Second Street, SW., Stop 7126, Washington, DC 20593–7126.

§ 164.120–5 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Coast Guard must publish notice of change in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at Commandant (CG–5214), U.S. Coast Guard, 2100 Second Street, SW., Stop 7126, Washington, DC 20593–7126. You may also inspect this material 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.* You may obtain copies of the material from the sources specified in the following paragraphs.

(b) American Society for Testing and Materials (ASTM), 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA, 19428–2959.

(1) ASTM D 543–06, Standard Practices for Evaluating the Resistance of Plastics to Chemical Reagents, (approved April 1, 2006), IBR approved for § 164.120–7 (''ASTM D 543'').

(2) ASTM D 570–98 (Reapproved 2005), Standard Test Method for Water Absorption of Plastics, (approved November 1, 2005), IBR approved for § 164.120–7 (''ASTM D 570'').

(3) ASTM D 638–08, Standard Test Method for Tensile Properties of Plastics, (approved April 1, 2008), IBR approved for § 164.120–7 (''ASTM D 638'').

(4) ASTM D 695–08, Standard Test Method for Compressive Properties of Rigid Plastics, (approved August 1, 2008), IBR approved for § 164.120–7 (''ASTM D 695'').

(5) ASTM D 790–07e1, Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials,

(approved September 1, 2007), IBR approved for § 164.120–7 (''ASTM D 790'').

(6) ASTM D 792–08, Standard Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement, (approved June 15, 2008), IBR approved for § 164.120–7 (''ASTM D 792'').

(7) ASTM D 1045–08, Standard Test Methods of Sampling and Testing Plasticizers used in Plastics, (approved August 1, 2008), IBR approved for § 164.120–7 (''ASTM D 1045'').

(8) ASTM D 1824–95 (Reapproved 2002), Standard Test Method for Apparent Viscosity of Plastisols and Organosols at Low Shear Rates, (approved March 15, 1995), IBR approved for § 164.120–7 (''ASTM D 1824'').

(9) ASTM D 2471–99, Standard Test Method for Gel Time and Peak Exothermic Temperature of Reacting Thermosetting Resins, (approved November 10, 1999), IBR approved for § 164.120–7 (''ASTM D 2471'').

(10) ASTM D 2583–07, Standard Test Method for Indentation Hardness of Rigid Plastics by Means of a Barcol Impressor, (approved March 1, 2007), IBR approved for § 164.120–7 (''ASTM D 2583'').

(11) ASTM D 2584–08, Standard Test Method of Ignition Loss for Cured Reinforced Resins, (approved May 1, 2008), IBR approved for § 164.120–7 (''ASTM D 2584'').

(12) ASTM G 154–06, Standard Practice for Operating Fluorescent Light Apparatus for UV Exposure of Nonmetallic Materials, (approved June 5, 2006), IBR approved for § 164.120–7 (''ASTM G 154–06'').

(c) International Maritime Organization (IMO), Publications Section, 4 Albert Embankment, London SE1 7SR, United Kingdom, +44 (0)20 7735 7611, *http://www.imo.org/.*

(1) MSC Circular 1006, Guidelines On Fire Test Procedures For Acceptance Of Fire-Retardant Materials For The Construction Of Lifeboats, (approved June 18, 2001), IBR approved for § 164.120–7 (''IMO MSC Circ. 1006'').

(2) [Reserved].

(d) International Organization for Standardization (ISO): ISO Central Secretariat [ISO Copyright Office], Case Postale 56, CH–1211 Geneve 20, Switzerland.

(1) ISO 62:2008(E), Plastics—Determination of water absorption, Third Edition (February 15, 2008), IBR approved for § 164.120–7 (''ISO 62'').

(2) ISO 175:1999(E), Plastics—Methods of test for the determination of the effects of immersion in liquid chemicals, Second Edition (May 1, 1999), IBR approved for § 164.120–7 (''ISO 175'').

(3) ISO 14125:1998(E), Fibre-reinforced plastic composites—Determination of flexural properties, First Edition (March 1, 1998), IBR approved for § 164.120–7 (''ISO 14125'').

(4) ISO 527–1:1993(E), Plastics—Determination of tensile properties, Part 1: General Principles, First Edition (June 15, 1993), IBR approved for § 164.120–7 (''ISO 527'').

(5) ISO 604:2002(E), Plastics—Determination of compressive properties, Third Edition (March 1, 2002), IBR approved for § 164.120–7 (''ISO 604'').

(6) ISO 1172:1996(E), Textile-glass-reinforced plastics—Prepregs, moulding compounds and laminates—Determination of the textile-glass and mineral-filler content—Calcination methods, Second Edition (December 15, 1996), IBR approved for § 164.120–7 (''ISO 1172'').

(7) ISO 1183–1:2004(E), Plastics—Methods for determining the density of non-cellular plastics—Part 1: Immersion method, liquid pyknometer method and titration method, First Edition (February 1, 2004), IBR approved for § 164.120–7 (''ISO 1183'').

(8) ISO 1675–1985(E), Plastics—Liquid resins—Determination of density by the pyknometer method, Second Edition (August 15, 1985), IBR approved for § 164.120–7 (''ISO 1675'').

(9) ISO 2039–2:1987(E), Plastics—Determination of hardness—Part 2: Rockwell hardness, Second Edition (July 15, 1987), IBR approved for § 164.120–7 (''ISO 2039–2'').

(10) ISO 2114:2000(E), Plastics (polyester resins) and paints and varnishes (binders)—Determination of partial acid value and total acid value, Third Edition (August 1, 2000), IBR approved for § 164.120–7 (''ISO 2114'').

(11) ISO 2535:2001(E), Plastics—Unsaturated-polyester resins—Measurement of gel time at ambient temperature, Third Edition (July 15, 2001), IBR approved for § 164.120–7 (''ISO 2535'').

(12) ISO 2555:1989(E), Plastics—Resins in the liquid state or as emulsions or dispersions—Determination of apparent viscosity by the Brookfield test method, Second Edition (February 1, 1989, Corrected and reprinted February 1, 1990), IBR approved for § 164.120–7 (''ISO 2555'').

(e) Military Specifications and Standards, Standardization Documents Order Desk, Building 4D, 700 Robbins Avenue, Philadelphia, PA 19111–5094, *https://assist.daps.dla.mil/quicksearch/.*

(1) MIL–R–7575C, Military Specification, Resin, Polyester, Low-Pressure Laminating, (June 29, 1966), IBR approved for § 164.120–7 (''MIL–R–7575C'').

(2) MIL–R–21607E(SH), Military Specification, Resins, Polyester, Low Pressure Laminating, Fire-Retardant, (May 25, 1990), IBR approved for § 164.120–7 (''MIL–R–21607E(SH)'').

(3) MIL–R–24719(SH), Military Specification, Resins, Vinyl Ester, Low Pressure Laminating, (May 4, 1989), IBR approved for § 164.120–7 (''MIL–R–24719(SH)'').

§ 164.120–7 Acceptance criteria.

(a) The laminating resin must pass the inspections and tests specified in this section. The inspections and tests required by this section, including weathering of samples, are the responsibility of the manufacturer and must be performed by an independent laboratory.

(1) *Polyester resins.* (i) The resin must meet the specifications of Grade A, Class O resin of MIL–R–7575C (incorporated by reference, see § 164.120–5 of this subpart) and meet the specifications conforming to Grade A (standard flame resistance) of MIL–R–21607E(SH) (incorporated by reference, see § 164.120–5 of this subpart).

(ii) MIL–R–21607E(SH) Grade B resins will be given consideration upon request.

(2) *Vinyl ester resins.* The resin must meet the specifications of Grade B (fire retardant) resin of MIL–R–24719(SH) (incorporated by reference, see § 164.120–5 of this subpart) and must be tested and meet the requirements of weathering and post-weathering mechanical testing as shown in Table 164.120–7 of this section. Samples for the weathering must be prepared in accordance with MIL–R–7575C paragraph 4.3.1.1.

(3) *All other resins.* Each resin formulation submitted for Coast Guard approval, other than those addressed in paragraphs (a)(1) and (2) of this section, must be tested and meet the requirements of Table 164.120–7 of this section.

(b) [Reserved].

TABLE 164.120–7—ALTERNATIVE TEST METHOD STANDARDS FOR LAMINATING RESINS FOR USE IN LIFEBOATS, RESCUE BOATS, AND OTHER LIFESAVING EQUIPMENT [1]

Property	Test methods
(c) Material Identification Tests [2]	
(1) Uncatalyzed Liquid Resin:	
(i) Specific gravity	ISO 1675 or ASTM D 1045.
(ii) Viscosity	ISO 2555 or ASTM D 1824.
(iii) Acid number	ISO 2114 or ASTM D 1045.
(2) Catalyzed Resin:	
(i) Max gel time	ISO 2535 or ASTM D 2471.
(ii) Peak exotherm	ASTM D 2471.
(3) Cured Unfilled Resin:	
(i) Barcol hardness	ISO 2039–2 or ASTM D 2583.
(ii) Specific gravity/density	ISO 1183 or ASTM D 792.

Property	Test method	Requirements [3]
(d) Lengthwise Mechanical & Physical Properties of Glass Cloth Base Plastic Laminate		
(Lengthwise direction of test specimens is parallel to the warp direction of glass fabric.)		
(1) Tested Under Standard Conditions:		
(i) Ultimate strength, flatwise	ISO 14125 or ASTM D 790	345 MPa (50,000 lb/in^2).
(ii) Initial modulus of elasticity, flatwise	ISO 14125 or ASTM D 790	18,616 MPa (2.7 × 10E6 lb/in^2).
(iii) Ultimate tensile strength	ISO 527 or ASTM D 638	278 MPa (40,000 lb/in^2).
(iv) Ultimate compressive strength, edgewise	ISO 604 or ASTM D 695	241 MPa (35,000 ln/in^2).
(v) Fire retardant	MSC Circ. 1006	Pass.
(vi) Water absorption, 24-hour immersion	ISO 62 or ASTM D 570	0.5% max change in weight.
(vii) Barcol hardness	ISO 2039–2 or ASTM D 2583	55.
(viii) Specific gravity/density	ISO 1183 or ASTM D 792	([2]).
(ix) Resin content, percentage	ISO 1172 or ASTM D 2584	([2]).
(2) Tested Under Wet Conditions (Specimens must be immersed for 2 hours in boiling distilled water as per ASTM D 570 paragraph 7.5. The specimens must then be cooled in water at 23° C and tested wet at standard conditions immediately after removal from the water.):		
(i) Ultimate strength, flatwise	ISO 14125 or ASTM D 790	310 MPa (45,000 lb/in^2).
(ii) Initial modulus of elasticity, flatwise	ISO 14125 or ASTM D 790	17,237 MPa (2.5 × 10E6 lb/in^2).
(iii) Ultimate tensile strength	ISO 527 or ASTM D 638	278 MPa (40,000 lb/in^2).
(iv) Ultimate compressive strength, edgewise	ISO 604 or ASTM D 695	241 MPa (35,000 ln/in^2).
(3) Tested Under Elevated Temperature Conditions (Specimens must be exposed to 70° C for 1 hour and tested at that temperature.):		
(i) Ultimate strength, flatwise	ISO 14125 or ASTM D 790	276 MPa (40,000 lb/in^2).
(ii) Initial modulus of elasticity, flatwise	ISO 14125 or ASTM D 790	15,858 MPa (2.3 × 10E6 lb/in^2).
(4) Tested After Exposure to Liquid Chemicals (Standard test chemical reagents.)		
(i) Change in mass & dimensions	ISO 175 or ASTM D 543	0.1% max.
(ii) Ultimate strength	ISO 14125 or ASTM D 790	([2]).
(5) Tested After Weathering (Specimens must be weathered by either: 1 year per MIL–R–7575C or 500-hour exposure per ASTM G154 Table X2.1 Cycle 1 or 3.):		
(i) Ultimate strength, flatwise	ISO 14125 or ASTM D 790	310 MPa (45,000 lb/in^2).
(ii) Initial modulus of elasticity, flatwise	ISO 14125 or ASTM D 790	17,237 MPa (2.5 × 10E6 lb/in^2).
(iii) Fire retardant	MSC Circ. 1006	Pass.

[1] Each standard in this table is incorporated by reference, see § 164.120–5 of this subpart.
[2] There are no requirements for these properties, but the values must be determined and reported. Calculations for ultimate flexural strength after immersion in chemical fluids must be based on the dimensions of the specimens before immersion.
[3] The specimens must show no cracking, crazing, softening, delamination, or any other visible deterioration after conditioning exposure or immersions.

§ 164.120–9 Procedure for acceptance.

(a) Fire retardant resin is not subject to formal approval, but will be accepted by the Coast Guard on the basis of this subpart for use in the manufacture of lifesaving equipment. Coast Guard acceptance of fire retardant resin for use in the manufacture of lifesaving equipment does not guarantee Coast Guard acceptance of the manufactured lifesaving equipment.

(b) *Resin manufacturer requirements.* The resin manufacturer must submit the test report, material data sheet, including instructions for use, and quality control procedures in accordance with 46 CFR 159.005–9.

(c) *Independent laboratory requirements.* The independent laboratory must perform each inspection and test required by § 164.120–7 of this subpart, and prepare a report in accordance with 46 CFR 159.005–11

and submit the report to the Commandant for acceptance.

§ 164.120–11 Production quality control requirements.

The resin manufacturer must institute a quality control procedure to ensure that all Coast Guard-accepted resin is produced to the same standard, and in the same manner as the tested resin accepted by the Commandant. The manufacturer's quality control personnel must not work directly under the department or person responsible for either production or sales.

§ 164.120–13 Marking, labeling, and instructions for use.

(a) *Marking and labeling.* Each container for the resin must be permanently marked with at least the following information—

(1) Manufacturer's name or trademark, batch number, date of manufacture, and date of expiration;

(2) Chemical type of the resin;

(3) Maximum usable storage life of the resin (uncatalyzed and catalyzed) and recommended storage conditions;

(4) Maximum allowable shelf life at various temperatures of impregnated fabric before curing; and

(5) Precautionary markings.

(b) Instructions for use must be included with each shipment of approved material and must include—

(1) Recommended mixing and impregnating procedures, including recommended types, percentages, and manner of utilization of catalysts, retardants, and fillers, as applicable;

(2) Range of time, temperature, and pressure cycles recommended to effect the cure for laminates; and

(3) Precautionary information on usage, storage, and handling.

§ 164.120–15 Procedure for acceptance of material change.

(a) Each change in material from the resin accepted under § 164.120–9 of this subpart must be accepted by the Commandant before being used in any production lifeboat or rescue boat. The manufacturer must submit any such change following the procedures set forth in § 164.120–9 of this subpart, but documentation on items that are unchanged from the resin accepted under § 164.120–9 of this subpart need not be resubmitted.

(b) Determinations of equivalence of materials will be made by the Commandant only.

■ 49. Add subpart 164.900 to read as follows:

Subpart 164.900—Preemption

Sec.
164.900–1 Preemption of State or local law.
164.900–3 [Reserved]

Subpart 164.900—Preemption

§ 164.900–1 Preemption of State or local law.

The regulations in this part have preemptive effect over State or local regulation within the same field.

§ 164.900–3 [Reserved]

PART 180—LIFESAVING EQUIPMENTS AND ARRANGEMENTS

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

Authority: 46 U.S.C. 2104, 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

■ 51. In § 180.150, revise paragraph (a) introductory text and add paragraph (c) to read as follows:

§ 180.150 Survival craft embarkation arrangements.

(a) A launching appliance described in paragraph (c) of this section, or a marine evacuation system approved under approval series 160.175, must be provided for each inflatable liferaft and inflatable buoyant apparatus when either—

* * * * *

(c) Each launching appliance for a davit-launched liferaft must include an automatic disengaging apparatus approved under 46 CFR part 160, subpart 160.170 and be either—

(1) A davit approved under 46 CFR part 160, subpart 160.132 for use with a liferaft, with a winch approved under 46 CFR part 160, subpart 160.115 for use with a liferaft; or

(2) A launching appliance approved on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION OF INTERIM RULE] under approval series 160.163.

PART 199—LIFESAVING SYSTEMS FOR CERTAIN INSPECTED VESSELS

■ 52. The authority citation for part 199 continues to read as follows:

Authority: 46 U.S.C. 3306, 3703; Pub. L 103–206, 107 Stat. 2439; Department of Homeland Security Delegation No. 0170.1.

■ 53. Revise § 199.150(a) to read as follows:

§ 199.150 Survival craft launching and recovery arrangements; general.

(a)(1) Each launching appliance must be approved under 46 CFR part 160, subpart 160.132 for use with the intended craft, with a winch approved under 46 CFR part 160, subpart 160.115 for use with the intended craft.

(2) Each launching appliance for a davit-launched liferaft must include an automatic disengaging apparatus approved under 46 CFR part 160, subpart 160.170 and be either—

(i) A launching appliance described in paragraph (a)(1) of this section; or

(ii) A launching appliance approved on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION OF INTERIM RULE] under approval series 160.163.

* * * * *

Dated: September 22, 2011.

J.G. Lantz,

Director of Commercial Regulations and Standards, U.S. Coast Guard.

[FR Doc. 2011–25035 Filed 10–7–11; 8:45 am]

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Part V

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, 423 et al.

Medicare Program; Proposed Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Proposed Changes; Considering Changes to the Conditions of Participation for Long Term Care Facilities; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, 423, and 483

[CMS–4157–P]

RIN 0938–AQ86

Medicare Program; Proposed Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Proposed Changes; Considering Changes to the Conditions of Participation for Long Term Care Facilities

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: The proposed rule would revise the Medicare Advantage (MA) program (Part C) regulations and prescription drug benefit program (Part D) regulations to implement new statutory requirements; strengthen beneficiary protections; exclude plan participants that perform poorly; improve program efficiencies; and clarify program requirements. We are also considering changes to the long term care facility conditions of participation pertaining to pharmacy services.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 12, 2011.

ADDRESSES: In commenting, please refer to file code CMS–4157–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Click on the link ''Submit electronic comments on CMS regulations with an open comment period.'' (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–4157–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–4157–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments (one original and two copies) to one of the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–1066 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:
Christian Bauer, (410) 786–6043, and Kathryn Jansak, (410) 786–9364, General information.
Christopher McClintick, (410) 786–4682, Part C issues.
Deborah Larwood, (410) 786–9500, Part D issues.
Kristy Nishimoto, (206) 615–2367, Part C and D enrollment and appeals issues.
Deondra Moseley, (410) 786–4577, Part C and D payment issues.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–4157–P.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received at: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone at 1–800–743–3951.

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Regulations Text

Acronyms

AO Accrediting Organization
ADS Automatic Dispensing System
AEP Annual Enrollment Period
AHFS American Hospital Formulary Service
AHFS–DI American Hospital Formulary Service-Drug Information
AHRQ Agency for Health Care Research and Quality
ALJ Administrative Law Judge
ANOC Annual Notice of Change
AOR Appointment of Representative
BBA Balanced Budget Act of 1997 (Pub. L. 105–33)
BBRA [Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113)
BIPA [Medicare, Medicaid, and SCHIP] Benefits Improvement Protection Act of 2000 (Pub. L. 106–554)
BLA Biologics License Application
CAHPS Consumer Assessment Health Providers Survey
CAP Corrective Action Plan
CCIP Chronic Care Improvement Program
CC/MCC Complication/Comorbidity and Major Complication/Comorbidity
CCS Certified Coding Specialist
CDC Centers for Disease Control
CHIP Children's Health Insurance Programs
CMR Comprehensive Medical Review
CMS Centers for Medicare & Medicaid Services
CMS–HCC CMS Hierarchal Condition Category
CTM Complaints Tracking Module
COB Coordination of Benefits
CORF Comprehensive Outpatient Rehabilitation Facility
CPC Certified Professional Coder
CY Calendar year
DEA Drug Enforcement Administration
DIR Direct and Indirect Remuneration
DME Durable Medical Equipment
DMEPOS Durable Medical Equipment, Prosthetic, Orthotics, and Supplies
D–SNPs Dual Eligible SNPs
DOL U.S. Department of Labor
DRA Deficit Reduction Act of 2005 (Pub. L. 109–171)
DUM Drug Utilization Management
EGWP Employer Group/Union-Sponsored Waiver Plan
EOB Explanation of Benefits
EOC Evidence of Coverage
ESRD End-Stage Renal Disease
FACA Federal Advisory Committee Act
FDA Food and Drug Administration
FEHBP Federal Employees Health Benefits Plan
FFS Fee-For-Service
FIDE Fully-integrated Dual Eligible
FIDE SNPs Fully-integrated Dual Eligible Special Needs Plans
FMV Fair Market Value
FY Fiscal year
GAO Government Accountability Office
HAC Hospital-Acquired Conditions
HCPP Health Care Prepayment Plans
HEDIS HealthCare Effectiveness Data and Information Set
HHS [U.S. Department of] Health and Human Services
HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191)
HMO Health Maintenance Organization
HOS Health Outcome Survey
HPMS Health Plan Management System
ICD–9–CM Internal Classification of Disease, 9th, Clinical Modification Guidelines
ICEP Initial Coverage Enrollment Period
ICL Initial Coverage Limit
ICR Information Collection Requirement
ID Identification
IPPS [Acute Care Hospital] Inpatient Prospective Payment System
IRE Independent Review Entity
IVC Initial Validation Contractor
LEP Late Enrollment Penalty
LIS Low Income Subsidy
LPPO Local Preferred Provider Organization
LTC Long Term Care
MA Medicare Advantage
MAAA Member of the American Academy of Actuaries
MA–PD Medicare Advantage-Prescription Drug Plan
MIPPA Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275)
MOC Medicare Options Compare
MOOP Maximum Out-of-Pocket
MPDPF Medicare Prescription Drug Plan Finder
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173)
MS–DRG Medicare Severity Diagnosis Related Group
MSA Metropolitan Statistical Area
MSAs Medical Savings Accounts
MSP Medicare Secondary Payer
MTM Medication Therapy Management
MTMP Medication Therapy Management Program

NAIC National Association Insurance Commissioners
NCPDP National Council for Prescription Drug Programs
NCQA National Committee for Quality Assurance
NDA New Drug Application
NDC National Drug Code
NGC National Guideline Clearinghouse
NIH National Institutes of Health
NOMNC Notice of Medicare Non-coverage
NPI National Provider Identifier
OIG Office of Inspector General
OMB Office of Management and Budget
OPM Office of Personnel Management
OTC Over the Counter
PART C Medicare Advantage
PART D Medicare Prescription Drug Benefit Program
PBM Pharmacy Benefit Manager
PDE Prescription Drug Event
PDP Prescription Drug Plan
PFFS Private Fee for Service Plan
POA Present on Admission (Indicator)
POS Point-of-Sale
PPO Preferred Provider Organization
PPS Prospective Payment System
P&T Pharmacy & Therapeutics
QIO Quality Improvement Organization
QRS Quality Review Study
PACE Programs of All Inclusive Care for the Elderly
RADV Risk Adjustment Data Validation
RAPS Risk Adjustment Payment System
RHIA Registered Health Information Administrator
RHIT Registered Health Information Technician
RPPO Regional Preferred Provider Organization
SEP Special Enrollment Periods
SHIP State Health Insurance Assistance Programs
SNF Skilled Nursing Facility
SNP Special Needs Plan
SPAP State Pharmaceutical Assistance Programs
SSA Social Security Administration
SSI Supplemental Security Income
TPA Third Party Administrator
TrOOP True Out-of-Pocket
U&C Usual and Customary
UPIN Uniform Provider Identification Number
USP U.S. Pharmacopoeia

SUPPLEMENTARY INFORMATION:

I. Background

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) created a new ''Part C'' in the Medicare statute (sections 1851 through 1859 of the Social Security Act (the Act)) which established what is now known as the Medicare Advantage (MA) program. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), enacted on December 8, 2003, added a new ''Part D'' to the Medicare statute (sections 1860D–1 through 1860D–42 of the Act) entitled the Medicare Prescription Drug Benefit Program, and made significant changes to the existing Part C program, which it named the Medicare Advantage (MA) Program. The MMA directed that important aspects of the Part D program be similar to, and coordinated with, regulations for the MA program. Generally, the provisions enacted in the MMA took effect January 1, 2006. The final rules implementing the MMA for the MA and Part D prescription drug programs appeared in the January 28, 2005 **Federal Register** (70 FR 4588 through 4741 and 70 FR 4194 through 4585, respectively).

Since the inception of both Parts C and D, we have periodically revised our regulations either to implement statutory directives or to incorporate knowledge obtained through experience with both programs. For instance, in September 2008 and January 2009, we issued Part C and D regulations (73 FR 54226 and 74 FR 1494, respectively) to implement provisions in the Medicare Improvement for Patients and Providers Act (MIPPA) (Pub. L. 110–275). We promulgated a separate interim final rule in January 2009 to address MIPPA provisions related to Part D plan formularies (74 FR 2881). In April 2010, we issued Part C and D regulations (75 FR 19678) which strengthened various program participation and exit requirements; strengthened beneficiary protections; ensured that plan offerings to beneficiaries included meaningful differences; improved plan payment rules and processes; improved data collection for oversight and quality assessment; implemented new policies; and clarified existing program policy.

In a final rule that appeared in the April 15, 2011 **Federal Register** (76 FR 21432), we continued our process of implementing improvements in policy consistent with those included in the April 2010 final rule, and also implemented changes to the Part C and Part D programs made by recent legislative changes. The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010, as passed by the Senate on December 24, 2009, and the House on March 21, 2010. The Health Care and Education Reconciliation Act (Pub. L. 111–152), which was enacted on March 30, 2010, modified a number of Medicare provisions in Pub. L. 111–148 and added several new provisions. The Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health Care and Education Reconciliation Act (Pub. L. 111–152) are collectively referred to as the Affordable Care Act. The Affordable Care Act included significant reforms to both the private health insurance industry and the Medicare and Medicaid programs. Provisions in the Affordable Care Act concerning the Part C and D programs largely focused on beneficiary protections, MA payments, and simplification of MA and Part D program processes. These provisions affected implementation of our policies regarding beneficiary cost-sharing, assessing bids for meaningful differences, and ensuring that cost-sharing structures in a plan are transparent to beneficiaries and not excessive. In the April 2011 final rule, we revised regulations on a variety of issues based on the Affordable Care Act and our experience in administering the MA and Part D programs. The rule covered areas such as marketing, including agent/broker training; payments to MA organizations based on quality ratings; standards for determining if organizations are fiscally sound; low income subsidy policy under the Part D program; payment rules for non-contract health care providers; extending current network adequacy standards to Medicare medical savings account (MSA) plans that employ a network of providers; establishing limits on out-of-pocket expenses for MA enrollees; and several revisions to the special needs plan requirements, including changes concerning SNP approvals.

II. Provisions of the Proposed Regulations

In the sections that follow, we discuss the proposed changes to the regulations in 42 CFR parts 417, 422, and 423 governing the MA and prescription drug benefit programs. We also are considering changes to the regulations setting forth Medicare conditions of participation for long-term care facilities, which are currently codified at 42 CFR part 483. To better frame the discussion, we have structured the overall preamble narrative by topic area rather than by subpart order. Accordingly, our proposals address the following five specific topic areas:

- Implementing provisions of MIPPA and the Affordable Care Act.
- Strengthening beneficiary protections.
- Excluding poor performers.
- Improving program efficiencies.
- Clarifying program requirements.

Several of the proposed revisions and clarifications affect both the MA and prescription drug programs, while a few affect cost contracts under section 1876 of the Act. Within each topic area, we provide a chart that lists the associated regulatory citations and we discuss the provisions in order of appearance in the proposed regulations. We are also considering changing the long term care facility conditions of participation

pertaining to pharmacy services and, accordingly, cover that issue under the appropriate topic in the preamble section, in order of regulation location under consideration.

We note that these regulations would be effective 60 days after the publication of the final rule that would finalize the proposed changes discussed in this proposed rule, except where otherwise noted in the preamble. Only one proposed item would have a different effective date: section 175(b) of MIPPA provides that the proposed amendments requiring that benzodiazepines and, for specified health conditions, barbiturates be considered as Part D drugs apply to prescriptions dispensed on or after January 1, 2013.

A. Implementing Statutory Provisions

This section contains three provisions, two of which would implement sections of the Affordable Care Act and one which would implement a MIPPA mandate. We propose to consolidate and codify previous guidance regarding the Coverage Gap Discount Program mandated by the Affordable Care Act. Through this consolidation we aim to provide stakeholders a central, clear source of direction. Regulations under a MIPPA provision would provide first line treatment for beneficiaries with certain health conditions who require benzodiazepines and, as specified, barbiturates. We believe that implementing section 6005 of the Affordable Care Act, which requires us to collect Pharmacy Benefit Manager (PBM) spread amounts, would establish necessary transparency related to entities that provide pharmacy benefits management services to Part D sponsors. The changes based on provisions in the Affordable Care Act and MIPPA are detailed in Table 1.

TABLE 1—PROVISIONS TO IMPLEMENT STATUTORY PROVISIONS

Preamble section	Provision	Part 423	
		Subpart	Section(s)
II.A.1.	Coverage Gap Discount Program	Subpart C	§ 423.100
		Subpart K	§ 423.505
		Subpart T	§ 423.1000
		Subpart T	§ 423.1002
		Subpart W (new)	§ 423.2300–§ 423.2345
II.A.2.	Inclusion of Benzodiazepines and Barbiturates as Part D Covered Drugs	Subpart C	§ 423.100
II.A.3.	Pharmacy Benefit Manager's Transparency Requirements	Subpart K	§ 423.501
			§ 423.514

1. Coverage Gap Discount Program (§ 423.100, § 423.505(b), § 423.1000, § 423.1002, and § 423.2300 through § 423.2345 (Subpart W))

The Medicare Prescription Drug Benefit was enacted into law on December 8, 2003, in section 101 of the MMA and codified in sections 1860D–1 through 1860D–42 of the Act. Section 101 of the MMA amended Title XVIII of the Act by redesignating Part D as Part E and inserting new Part D, which establishes the voluntary Prescription Drug Benefit Program (Part D). The Part D program is available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B. We contract with private companies referred to as Part D sponsors to administer the Part D program via stand alone prescription drug plans (PDPs) and prescription drug plans offered by Medicare Advantage Organizations (MA–PDs). The Part D program became effective January 1, 2006.

The MMA established standard Part D prescription drug coverage that consists of coverage subject to an annual deductible, 25 percent coinsurance (or an actuarially equivalent cost-sharing design) up to the initial coverage limit (ICL), and catastrophic coverage for individuals who exceed the annual maximum true out-of-pocket (TrOOP) threshold with cost-sharing equal to the greater of a $2/$5 copayment or coinsurance of 5 percent. Prior to the enactment of the Affordable Care Act, under standard coverage, individuals that did not receive additional cost-sharing subsidies from CMS or additional coverage by other secondary payers (for example, State Pharmaceutical Assistance Programs) were responsible for paying one hundred percent of the Part D negotiated price for covered Part D claims above the ICL until their TrOOP costs exceed the annual threshold amount.

The Affordable Care Act made several amendments to Part D of Title XVIII of the Act, including adding sections 1860D–43 and 1860D–14A of the Act, and amending section 1860D–2(b) of the Act. Beginning on January 1, 2011, these amendments started phasing out the Part D coverage gap, or ''donut hole'' for Medicare beneficiaries who do not already receive low-income subsidies from CMS by establishing the Medicare Coverage Gap Discount Program (Discount Program) and gradually increasing coverage in the coverage gap for both generic drugs (beginning in 2011) and brand name drugs and biological products (beginning in 2013). By 2020, beneficiary cost-sharing for all covered brand-name and generic drugs and biological products will equal 25 percent until they reach catastrophic coverage.

The Discount Program makes manufacturer discounts available at the point-of-sale to applicable Medicare beneficiaries receiving applicable drugs while in the coverage gap. In general, the discount on each applicable drug is 50 percent of an amount equal to the negotiated price of the drug (less any dispensing fee). Manufacturers must agree to provide these discounts by signing an agreement with CMS in order for their applicable drugs to continue to be covered under Medicare Part D, unless we use our authority under section 1860D–43(c) of the Act to make an exception that allows coverage without an agreement.

While manufacturer discounts under the Discount Program must be made available at point-of-sale, the Affordable Care Act does not specify how this should be done. At the same time, it prohibits us from receiving or distributing any funds of the manufacturer under the program. In order to provide point-of-sale discounts, we determined that an entity must have the information necessary to determine at that point in time that the drug is discountable, the beneficiary is eligible for the discount, the claim is wholly or partly in the coverage gap, and the amount of the discount, taking into consideration negotiated plan prices and that plan supplemental benefits must pay before the discount amount can be determined. We determined that

the only entities that have the information necessary to provide point-of-sale discounts under the Discount Program are Part D sponsors. Only the Part D sponsor knows which Part D drugs are on its formulary and which enrollees have obtained an exception to receive a non-formulary Part D drug. The Part D sponsor has the low-income subsidy (LIS) information for beneficiaries that is necessary to exclude such claims from the Discount Program. The Part D sponsor tracks gross drug spend and TrOOP costs, which are necessary for determining when the beneficiary enters and exits the coverage gap. In addition, only the Part D sponsor knows which portion of the claim is in the coverage gap. For these reasons, we believe only the Part D sponsor can accurately provide the discount at point-of-sale.

We explored the viability of a model whereby a third party administrator (TPA) could directly adjudicate the discount payment to pharmacies. In this hypothetical model, the pharmacy would submit the Part D claim to the Part D sponsor and receive information on the response that would direct the pharmacy to bill the third party for applicable claims. While this model initially showed promise, our discussions with industry through National Council of Prescription Drug Program (NCPDP) workgroups revealed that neither the current Health Insurance Portability and Accountability Act (HIPAA) electronic pharmacy claims billing standard nor the next HIPAA approved version of the billing standard could support the transfer of information from the Part D sponsor that would be necessary to specify the appropriate claims and appropriate discount amounts to be billed to the third party administrator, or allow for accurate coordination of benefits among payers. Consequently, we determined that this model cannot be used to implement the Discount Program in the foreseeable future.

Section 1860D–14A(d)(5) of the Act authorizes us to implement the Discount Program through program instruction. We used this authority to issue program guidance to Part D sponsors, with an abbreviated notice and comment period, instructing them to provide applicable discounts on applicable drugs to applicable beneficiaries at point-of-sale beginning on January 1, 2011. The guidance also specified that Part D sponsors would report discount amounts to us, that we would invoice manufacturers on a quarterly basis for these discounts, and that the manufacturers would repay each Part D sponsor directly for the invoiced discount provided on the manufacturers' behalf. We determined that this model was necessary because Part D sponsors needed to provide the discounts at point-of-sale (as explained previously) and we needed to coordinate the discount payments between manufacturers and Part D sponsors to ensure discounts were appropriately provided by the Part D sponsors and reimbursed by the manufacturers without directly receiving or distributing manufacturer funds (which we are prohibited from doing by section 1860D–14A(d)(2)(A) of the Act).

We needed to implement the Discount Program through program instruction because of the January 1, 2011 implementation deadline. Although not required, we are now proposing to codify most existing Discount Program requirements (that is, those that we have previously implemented through the relevant Agreements and guidance) through full notice and comment rulemaking to provide additional transparency and a formal framework for operating the Discount Program and enforcing its requirements.

a. Scope (§ 423.2300)

Subpart W of part 423 implements provisions included in sections 1860D–14A and 1860D–43 of the Act. This subpart sets forth requirements as follows:

- Condition of coverage of drugs under Part D.
- The Medicare Coverage Gap Discount Program Agreement.
- Coverage gap discount payment processes for Part D sponsors.
- Provision of applicable discounts on applicable drugs for applicable beneficiaries.
- Manufacturer audit and dispute resolution processes.
- Resolution of beneficiary disputes involving coverage gap discounts.
- Compliance monitoring and civil money penalties.
- The termination of the Discount Program Agreement.

b. Definitions (§ 423.2305)

Proposed § 423.2305 includes definitions for terms that are frequently used in this subpart. Those terms we believe need additional clarification are described separately in this section of the proposed rule.

(1) Applicable Beneficiary

Applicable beneficiary is defined in § 423.100. We clarify that enrollees in employer-sponsored group prescription drug plans (as defined in § 423.454) may qualify as applicable beneficiaries.

(2) Applicable Drug

Applicable drug is defined in § 423.100. We clarify that applicable drugs include all covered Part D drugs marketed under a new drug application (NDA) or biologics license application (BLA) (other than a product licensed under section 351(k) of the Public Health Service Act). This means that such drugs and biological products would be subject to an applicable discount in the coverage gap even if a Part D sponsor otherwise considers the product to be generic under its benefit. Conversely, covered Part D drugs that are marketed under trade names and generally thought of as brand-name drugs or biological products, but are not approved under an NDA or licensed under a BLA (other than a product licensed under section 351(k) of the Public Health Service Act), are not applicable drugs that would be subject to an applicable discount in the coverage gap. Finally, drugs excluded from Part D under section 1860D–2(e)(2)(A) of the Act are not covered Part D drugs and therefore, such drugs would not be applicable drugs subject to an applicable discount even if covered by the Part D sponsor under an enhanced benefit. Part D sponsors would need to make these determinations on a National Drug Code (NDC) by NDC basis.

The second part of the definition provides that an applicable drug is either available on-formulary if a Part D sponsor uses a formulary, or available under the benefits provided by a Part D sponsor that does not use a formulary, or available to a particular beneficiary through an exception or appeal for that particular beneficiary. Applicable drugs covered under transition and emergency fill policies are considered covered through an exception and, therefore, would be subject to applicable discounts.

In addition, we interpret the definition of an applicable drug for purposes of the Discount Program to exclude Part D compounds. While Part D sponsors may cover compounds with at least one Part D drug ingredient, and that ingredient would be an applicable drug if dispensed on its own, in light of the operational difficulty in accurately determining which portion(s) of a Part D compound represents the Part D drug, we believe that the applicable drug determination must be made with respect to the compound as a whole. Given that a compound as a whole is not approved under an NDA or BLA, a compound does not meet the definition of an applicable drug.

(3) Incurred Costs

Section 3301 of the Affordable Care Act amends section 1860D–2(b)(4) of the Act by adding subparagraph (E) when applying subparagraph (A) to include the negotiated price (as defined in paragraph (6) of section 1860D–14A(g) of the Act) of an applicable drug of a manufacturer that is furnished to an applicable beneficiary under Medicare Coverage Gap Discount Program regardless of whether part of such costs were paid by a manufacturer under such program, except that incurred costs shall not include the portion of the negotiated price that represents the reduction in coinsurance resulting from the application of paragraph (2)(D) (that is, gap coverage). Therefore, we propose to revise the definition of incurred costs in § 423.100 by adding the following language to paragraph (2)(ii) of such definition—''or by a manufacturer as payment for an applicable discount (as defined § 423.2305) under the Medicare Coverage Gap Discount Program (as defined in § 423.2305)''. This would mean that all applicable discounts paid by manufacturers would be treated as incurred costs for purposes of calculating the beneficiary's TrOOP.

(4) Manufacturer

Section 1860D–14A(g)(5) of the Act defines manufacturer under the Discount Program as any entity which is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drug products, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law. We propose to adopt this statutory language in § 423.2305 and also add the following clarifying language ''but includes entities otherwise engaged in repackaging or changing the container, wrapper, or labeling of any applicable drug product in furtherance of the distribution of the applicable drug from the original place of manufacture to the person who makes the final delivery or sale to the ultimate consumer for use.'' We propose adding this language to the definition to be consistent with the definition of the term ''manufacturer'' in section 510 for the Federal Food Drug and Cosmetic Act as well as to track the defined term in the Discount Program Agreement.

Moreover, we believe this is the only practical way to define manufacturer so that we can accurately assign responsibility for the discounts. While applicable drugs may actually be made by a limited number of companies, many more companies commonly repackage or relabel drug products and market them with their own labeler codes. Registered drug establishments are required by law to provide the FDA with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution. (See section 510 of the Federal Food, Drug, and Cosmetic Act 921 U.S.C. 360.) Each listed product is identified by a unique NDC, which identifies the labeler, product, and trade package size. The first segment, the labeler code, identifies the firm that manufactures (including repackers and relabelers) or distributes (under its own name) the drug. Therefore, we can accurately identify the company responsible for labeling the product and require this company to pay the discount. Alternatively, it would be very difficult, if not impossible, to track such relabeled or repackaged products back to the original maker of the drug if we limited the definition of manufacturer to the original maker. We would interpret ''entities otherwise engaged in repackaging or changing the container, wrapper, or labeling * * *'' to mean the companies associated with the unique labeler codes that are included in the NDCs of the applicable drugs dispensed by pharmacies, therefore these companies would be considered manufacturers under the Discount Program.

Applicable drugs are marketed with labels that include a labeler code identifying the company that labels the product. While the same applicable drug may be marketed by multiple companies, only one company is linked to a unique labeler code. All manufacturers of applicable drugs, meaning all companies that label applicable drugs with unique labeler codes, would be required to sign an agreement for any applicable drugs with such labeler codes to be covered under Medicare Part D as of January 1, 2011. Only one manufacturer would be identified with each labeler code and, therefore, only one manufacturer would be responsible for paying applicable discounts associated with that labeler code at any given time.

(5) Medicare Part D Discount Information

In accordance with section 1860D–14A(d)(3)(C) of the Act, we require the TPA to provide adequate and timely information to manufacturers, consistent with the Discount Program Agreement with the manufacturers, as necessary for the manufacturer to fulfill its obligations under the Discount Program. Accordingly, we require the TPA to invoice each manufacturer each quarter on behalf of Part D sponsors for the applicable discounts advanced by the Part D sponsors to applicable beneficiaries and reported to CMS on the prescription drug event (PDE) records. The TPA also provides information to the manufacturer along with each quarterly invoice that is derived from applicable data elements available on PDE records as determined by CMS. We propose to define this information in § 423.2305 as Medicare Part D Discount Information.

Generally, the Medicare Part D Discount Information would include certain claim-level detail derived from the PDE record. Information such as applicable drug NDC, dispensing pharmacy, quantity dispensed, date of service, days supply, prescription and fill number, and reported gap discount would be provided. We would provide this information so that a manufacturer could evaluate the accuracy of claimed discounts and resolve disputes concerning the manufacturer's payment obligations under the Discount Program.

Under the current Medicare Coverage Gap Discount Program Agreement with manufacturers, ''Medicare Part D Discount Information'' refers to the information derived from applicable data elements available on PDEs and set forth in Exhibit A of the Agreement that will be sent from the TPA to the manufacturer along with each quarterly invoice. However, section III(f) of the Agreement generally prohibits us from disclosing any identifying beneficiary information under the Discount Program. Although the ''Medicare Part D Discount Information'' does not include specific beneficiary identifiers, an issue arises when the volume of claims for an applicable drug is so low that the data provided as ''Medicare Part D Discount Information'' could be used to identify a Medicare beneficiary.

In order to protect the identity of Medicare beneficiaries, we have a cell-size suppression policy that prohibits disclosure of data if the data cell contains 10 or fewer individuals. In applying this policy to the Discount Program, CMS would be unable to disclose all the data elements currently specified as ''Medicare Part D Discount Information'' when 10 or fewer beneficiaries with the same applicable drug (identified as having the same first two segments of NDC) have claims at the same pharmacy. This threshold is based on all Part D claims for an applicable drug (identified as having the

same first two segment of the NDC) at the same pharmacy, not 10 or fewer applicable beneficiaries with coverage gap claims.

When we agreed to provide the data elements specified in Exhibit A of the current Medicare Coverage Gap Discount Program Agreement, we did not take into consideration this issue that arises if claims volume is so low that this information could reasonably be used to identify a beneficiary. Consequently, we believe we would need to further limit the information that could be provided to manufacturers based upon the prohibition on releasing beneficiary identifying information. We propose withholding the Service Provider Identifier information when a claim qualifies as low volume (that is, 10 or fewer beneficiaries receiving the same drug product at the same pharmacy). This would mean that the remaining claims-level detail would be provided, but it would not specify the service provider for each claim. By doing this, we would comply with the CMS cell size suppression policy while still providing claims-level detail that would be helpful to manufacturers for evaluating the accuracy of the invoiced discount payments. We seek comments on this proposal.

(6) Negotiated Price

We propose to define negotiated price for purposes of the Discount Program consistent with section 1860D–14A(g)(6), which defines ''negotiated price'' in terms of its meaning in § 423.100 as of the date of enactment of the section (that is, as of March 23, 2010), except that such definition does not include dispensing fees. Part D vaccine administration fees would be excluded from the definition of negotiated price for purposes of the Discount Program because we believe that, for purposes of the Discount Program, they are analogous to dispensing fees, which are explicitly excluded from the definition of negotiated price for purposes of determining the applicable discount. Unlike sales tax, dispensing fees and vaccine administration fees pay for services apart from the applicable drug itself. This is made clear by the fact that a vaccine administration fee may be billed separately from the dispensing of the vaccine. Sales tax remains included in the definition of negotiated price under the Discount Program. Thus, we are proposing to define ''negotiated price'' for purposes of the Discount Program and this subpart as: the price for a covered Part D drug that— (1) the Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug; (2) is reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point-of-sale; and (3) excludes any dispensing fee or vaccine administration fee for the applicable drug.

Further, although the statutory definition speaks only to the negotiated price with respect to a network pharmacy, given that there is no limitation on an applicable beneficiary's entitlement to applicable discounts on applicable drugs obtained out-of-network, we do not believe Congress intended to exclude these discounts from the Discount Program. Therefore, we propose to specify in § 423.2305 that the negotiated price also means, for purposes of out-of-network claims, the plan allowance as determined under § 423.124, less any dispensing fee and vaccine administration fee.

(7) Other Health or Prescription Drug Coverage

Section 1860D–14A(c)(1)(A)(v) of the Act requires that the applicable discount get applied before any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of applicable beneficiaries. Section 423.2305 of the proposed rule would define the term ''other health or prescription drug coverage'' as any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of applicable beneficiaries. This would include any programs that provide coverage or financial assistance outside of Part D. Thus, the applicable discount would apply before any ''other health or prescription drug coverage'' such as state pharmaceutical assistance programs (SPAPs), Aids Drug Assistance Programs (ADAPs), Indian Health Service, or supplemental coverage required by the Commonwealth of Puerto Rico.

In addition, we propose to include in the definition of ''other health or prescription drug coverage'' any coverage offered through employer group health or waiver plans (EGWPs) other than basic prescription drug coverage as defined in § 423.100. We would also propose to make a conforming change to the definition of supplemental benefits in § 423.100 to exclude benefits offered by EGWPs. Our proposal with respect to EGWPs would mean that a manufacturer discount always would be applied before any additional coverage beyond Part D, whether offered by the EGWP itself or by another party. We believe a clear standard in this regard is necessary to ensure we can properly administer the Discount Program for EGWP enrollees in light of our existing policies and procedures with respect to EGWP plans.

Under current waivers authorized by section 1860D–22(b) of the Act, EGWP sponsors submit only one formulary and standard-defined benefit package for review by CMS. EGWP sponsors may then customize actual formularies and benefit packages for specific employer or union clients, for example, by adding drugs to their formularies that are not covered under the basic benefit and/or reducing enrollee cost-sharing. Until now, we have allowed EGWP sponsors to determine whether any benefits offered under the EGWPs were Medicare (Part D) or non-Medicare (non-Part D) benefits because we did not collect information about or otherwise oversee specific EGWP benefit packages. However, with the implementation of the Discount Program, determining whether such benefits are supplemental Part D benefits (which would be applied before the applicable discount) or non-Medicare benefits (which would apply after the discount) is significant. We believe that many EGWP sponsors have already restructured their benefits so that the EGWP provides only basic Part D coverage (with full coverage gap) and considers any additional benefits as non-Medicare benefits. Given that we do not receive or review the final benefit packages and formularies offered to EGWP enrollees, we propose to exercise our waiver authority under section 1860D–22(b) of the Act to exclude all benefits offered by EGWPs from the definition of supplemental benefits and, therefore, these benefits, other than basic prescription drug coverage (as defined in § 423.100), would be considered ''other health or prescription drug coverage'' for purposes of the Discount Program. We seek comments on this proposal.

As an alternative to this proposal, we considered requiring EGWP sponsors to submit their final benefit packages for review and approval. Under this option, we would have limited EGWPs to offering only supplemental benefits that meet the requirements of § 423.104(f)(1)(ii). However, in addition to the significant challenges associated with expanding our review process to

accommodate another 25,000 to 50,000 benefit packages, this ultimately would not prevent employers or unions from offering separate benefits that would not be overseen or regulated by us; and therefore, would not provide the clear standard for distinguishing supplemental benefits from other health or prescription drug coverage for purposes of determining the applicable discount. Moreover, this alternative approach could adversely affect EGWP enrollees to the extent it would require EGWPs to make significant changes in order to bring their supplemental benefits in line with Part D rules—because it might prompt EGWPs to drop those supplemental benefits altogether or otherwise reduce coverage. Consequently, we believe it is better to clearly remove all employer sponsored benefits, other than basic prescription drug coverage as defined in § 423.100, from our purview, which we believe would leave EGWP enrollees in the same place they are today, while, as noted above, providing all participants in the Discount Program a bright line test for determining when the applicable discount applies.

c. Condition for Coverage of Drugs Under Part D (§ 423.2310)

Section 1860D–43(a) of the Act specifies that in order for coverage under Part D to be available for the covered Part D drugs (as defined in section 1860D–2(e) of the Act)) of a manufacturer, that manufacturer must agree to participate in the Discount Program, enter into a Discount Program Agreement, and enter into an agreement with the TPA. Although the statute appears to plainly contemplate that all manufacturers of covered Part D drugs must sign Discount Program Agreements in order for coverage under Part D to be available for such drugs, when read in context with the other provisions governing the Discount Program, we believe the plainest reading of section 1860D–43(a) is both inappropriate and infeasible. Thus, in implementing the Discount Program last year, we specified in program guidance that the exclusion from Part D coverage applies only to the applicable drugs of a manufacturer that fails to sign the Agreement and participate in the Program. We currently apply the exclusion from Part D coverage only to a manufacturer's applicable drugs. Other Part D drugs, such as generic drugs (as defined in § 423.4) of a manufacturer continue to be covered under Medicare Part D irrespective of the manufacturer's participation in the Discount Program. We propose to codify this policy in regulations.

The rationale for our narrower interpretation of section 1860D–43(a) of the Act is based on concern about beneficiary access to generic drugs and consideration of other contemporaneous provisions governing the Discount Program. First, given that the purpose of the Discount Program is to reduce financial burdens on beneficiaries in the coverage gap, we do not think that the requirements of section 1860D–43(a) of the Act were intended to potentially limit the availability of less expensive generic Part D drugs (which would occur if the generic products of a non-participating manufacturer were excluded). Rather, they were intended to ensure that manufacturers of brand name drugs had a strong incentive to participate in the Discount Program. When we were implementing the Discount Program last year, we were particularly concerned, in light of the short timeframe provided by the Affordable Care Act for collecting signed agreements from participating manufacturers for 2011, that a strict reading of the exclusion would have had the unintended consequence of negatively affecting the availability of generic drugs under Part D beginning January 1, 2011.

As noted above, we further believe that section 1860D–43(a) of the Act must be read in its proper context—in other words, it must coexist with all of the other requirements of the Discount Program, which are set forth in section 1860D–14A of the Act. Section 1860–D–14A of the Act requires manufacturers to provide discounts on applicable drugs at the point-of-sale, to provide appropriate data to CMS, and to comply with other requirements imposed by us or the TPA. Further, as described in more detail below, manufacturers with an agreement are subject to periodic audits by CMS and civil money penalties. Finally, section 1860D–14A of the Act specifies that, beginning with 2012, a manufacturer must enter into a Discount Program Agreement for a year no later than January 30 of the previous year—in other words, for a manufacturer to participate in the Discount Program for 2012, it would have had to have signed a Discount Program Agreement by January 30, 2011. In addition to these statutory requirements, there are administrative aspects of the Discount Program that include, but are not limited to, establishing connectivity with the TPA and with CMS, establishing electronic fund transfer accounts with more than 700 Part D sponsors, maintaining labeler code information with CMS, and reviewing file layouts and records for quarterly invoicing and payment reconciliation.

None of these statutory or administrative requirements is relevant to manufacturers of non-applicable drugs. Indeed, it would be impossible for a manufacturer with no applicable drugs to ''participate'' in the Discount Program (as a strict reading of section 1860D–43(a)(1) would require). Further, it would be wasteful and burdensome to require manufacturers of non-applicable drugs to undertake all of the administrative requirements set forth in the Discount Program Agreement with respect to drugs that are not subject to the requirements of section 1860D–14A of the Act.

With that in mind, we next turn to the issue of manufacturers with applicable drugs that also have non-applicable drugs. In our view, the same rationale applies to these manufacturers—although they can participate in the Discount Program with respect to their applicable drugs, they cannot do so with respect to their non-applicable drugs. We believe it would be both unfair and potentially very disruptive to beneficiaries to treat manufacturers of non-applicable drugs differently based on whether they also happen to make applicable drugs. For example, suppose that a manufacturer with no applicable drugs declines to participate in the Discount Program because it is literally unable to comply with the statutory requirements of section 1860D–14A of the Act. This manufacturer then acquires or begins to manufacture an applicable drug on February 1. If this manufacturer then was subject to the broader exclusion in section 1860D–43(a) of the Act arguably all of its drugs—both generic and applicable—would be non-covered for a period of almost two years. We do not believe that Congress intended such a disruptive result. Rather, we believe it is more appropriate to consider section 1860D–43(a) of the Act as excluding the applicable drugs of a manufacturer that fails to participate in the Discount Program.

In light of all of these considerations, we believe the a reasonable interpretation of 1860D–43(a) of the Act—one that preserves Congressional intent both to ensure manufacturer participation in the Discount Program and to alleviate financial burden for beneficiaries—is that the exclusion from Part D coverage applies only to the applicable drugs of manufacturers that fail to enter into a Discount Program Agreement and participate in the Discount Program. We seek comments on this proposal.

Section 1860D–43(c)(1) of the Act authorizes CMS to allow coverage for drugs that are not covered by Discount Program Agreements if CMS has made a determination that the availability of the drug is essential to the health of beneficiaries under this part, and we propose to codify this requirement in § 423.2310(b) of our proposed rule. However, we believe it is highly unlikely that we will need to exercise this authority given the strong participation by manufacturers in the Discount Program since 2011 and the likely availability of therapeutic alternatives for any Part D drugs.

d. Medicare Coverage Gap Discount Program Agreement (§ 423.2315)

Section 1860D–14A of the Act requires us to enter into agreements with manufacturers that participate in the Discount Program and to establish a model agreement in accordance with terms specified under section 1860D–14A(b) of the Act that provides for the performance of duties required under section 1860D–14A(c)(1) of the Act. We established the model agreement on August 1, 2010 and propose to codify in § 423.2315 those provisions that we believe must be included in the model agreement in order to meet the statutory requirements in these sections.

(1) Obligations of the Manufacturer

Section 1860D–14(A)(b)(1) of the Act specifies that the Discount Program Agreement between CMS and the manufacturers shall require manufacturers to provide applicable beneficiaries access to applicable discounts for applicable drugs of the manufacturer at the point-of-sale. In light of how the Discount Program has been structured (see the discussion section II.A.1. of this proposed rule), we would propose to implement this requirement as set forth in the current Discount Program Agreement; that is, we would propose in § 423.2315(b)(2) to require manufacturers to reimburse all applicable discounts provided by Part D sponsors on behalf of the manufacturer for all applicable drugs having NDCs with the manufacturer's FDA-assigned labeler code(s) that were invoiced to the manufacturer within a maximum of 3 years of the date of dispensing based upon information reported to CMS by Part D sponsors and used by CMS or the TPA to calculate the invoice.

In order for CMS and Part D sponsors to determine which applicable drugs are covered by Discount Program Agreements, the manufacturers must provide CMS with the FDA-assigned labeler code(s) for all applicable drug NDCs covered by their Discount Program Agreement. Under the current Discount Program Agreement, manufacturers must provide all of their labeler codes to CMS and must promptly update CMS with any additional labeler codes for applicable drugs no later than three business days after having received written notification of the codes from the FDA. We included this requirement in the Discount Program Agreement because, for the reasons previously described, it is the most efficient and accurate way to track which manufacturer is responsible for paying the applicable discount for an applicable drug and to assist plan sponsors in determining which drugs are applicable drugs. We maintain an up-to-date listing of the labeler codes covered under the Discount Program Agreements on the CMS website so that Part D sponsors can determine which labeler codes are covered by a Discount Program Agreement. To ensure that we have up-to-date information for this purpose, § 423.2315(b)(4) would require manufacturers to provide CMS with all labeler codes for all the manufacturer's applicable drugs and promptly update CMS with additional labeler codes for applicable drugs no later than three business days after having received written notification of the codes from the FDA.

To permit CMS and Part D sponsors to accurately identify applicable drugs, we propose to codify the requirement set forth in the Discount Program Agreement that manufacturers electronically list and maintain up-to-date electronic listing of all NDCs of the manufacturer, including the timely removal of discontinued NDCs, in the FDA NDC Directory. We believe this requirement will help ensure that all currently marketed applicable drugs are subject to the applicable discount and that only currently marketed applicable drugs are subject to the discount. Because manufacturers know the regulatory and marketing status of their products, they are in the best position to make this information available to Part D sponsors and CMS. We believe maintaining an up-to-date FDA electronic listing provides the most efficient, timely, and authoritative mechanism to accomplish this purpose while placing little additional burden on manufacturers that already must use the FDA electronic registration and listing system to comply with other FDA requirements.

We also propose to require manufacturers to maintain up-to-date NDC listings with the electronic database vendors for which they provide their NDCs for pharmacy claims processing. Part D sponsors rely upon these databases for adjudication of pharmacy claims at the point-of-sale, including discounting applicable drugs, and, therefore it is imperative that the information in these databases is accurate and up-to-date. Our proposal would require manufacturers to ensure that electronic database vendors are prospectively notified of NDCs for products that no longer are available on the market. We believe this requirement will benefit manufacturers because it will ensure that applicable discounts cease being applied as of the last lot expiration date of an applicable drug that is no longer on the market.

In implementing the Discount Program Agreement, we required manufacturers to pay each Part D sponsor in the manner specified by us within 38 calendar days of receipt of an invoice and Medicare Part D Discount Information for the quarterly applicable discounts included on the invoice. As previously described, we implemented the Discount Program such that Part D sponsors pay applicable discounts on behalf of manufacturers in order to comply with the statutory mandate that discounts be provided at the point-of-sale; and therefore, we require manufacturers to reimburse plan sponsors promptly because it is the manufacturers that are financially responsible for payment of applicable discounts. Given this structure, we propose to codify this requirement at § 423.2315(b)(3). We further propose in § 423.2315(b)(10) to require that manufacturers pay the quarterly invoices to accounts established by Part D sponsors via electronic funds transfer, unless otherwise specified by CMS, and within 5 business days of the transfer provide the TPA with electronic documentation in a manner specified by CMS. We believe these requirements are appropriate because they provide sufficient time for manufacturers to process the information in order to make the payments and are generally consistent with manufacturer obligations under the Medicaid Drug Rebate Program. Moreover, § 423.2315(b)(2) would prohibit manufacturers from withholding discount payments for their applicable drugs pending dispute resolution and, therefore, the 38-day requirement applies even if the manufacturer decides to dispute discount payments. As noted in our May 21, 2010 guidance, we believe this requirement is necessary to ensure that the manufacturer discounts are paid to Part D sponsors in a timely manner and are not delayed due to disputed amounts. We address our proposals with respect to

manufacturers' disputes later in this section of the proposed rule.

Section 1860D–14A(b)(2) of the Act requires each manufacturer with a Discount Program Agreement in effect to collect and have available appropriate data, as determined by CMS, to ensure that it can demonstrate to CMS compliance with the requirements under the Discount Program. In § 423.2315 (b)(5), we would codify this requirement by specifying that such information would include data related to manufacturer labeler codes, FDA drug approvals, FDA NDC Directory listings, NDC expiration dates, utilization and pricing information relied on by the manufacturer to dispute quarterly invoices and any other data we determine are necessary to carry out the Discount Program, and that manufacturers must collect, have available and maintain such information for a period of not less than 10 years from the date of payment of the invoice. The minimum 10-year retention requirement aligns with the standard Part D record retention requirement for Part D sponsors, thereby ensuring that applicable information would be maintained by manufacturers for the same time period.

Section 423.2315(b)(6) would require manufacturers to comply with the audit and the dispute resolution requirements proposed in § 423.2330, which are discussed in section II.A.1.g. of this proposed rule.

Section 1860D–43(a)(3) of the Act requires manufacturers to enter into and have in effect, under terms and conditions specified by CMS, a contract with a third party that CMS contracted with under subsection (d)(3) of section 1860D–14A of the Act. We propose to codify this requirement in § 423.2315(b)(9) by requiring the manufacturer to enter into and have in effect, under terms and conditions specified by CMS, an agreement with the TPA that has a contract under section 1860D–14A(d)(3) of the Act.

Finally, proposed § 423.2315(b)(11) would restrict the use of information disclosed to the manufacturer on the invoice, as part of the Medicare Part D Discount Information, or upon audit or dispute such that the manufacturer could use such information only for purposes of paying the discount under the Discount Program. This means that manufacturers would be allowed to use the information only as necessary to evaluate the accuracy of claimed discounts and resolve disputes concerning the manufacturer's payment obligations under the Discount Program. We believe this is an important limitation because we are making claim-level detail available to manufacturers that is not otherwise available to the public and therefore, should not be used for reasons beyond which it is being made available. As specified in the Data Use Provisions in Exhibit C of the Discount Program Agreement, the manufacturer would be prohibited from using the information to perform any functions not governed by the Discount Program Agreement, including, but not limited to, determination of non-Coverage Gap Discount payments to Part D sponsors and their subcontractors, payments to other providers of health and drug benefits under any Federal health care program or for marketing activities. Nevertheless, we recognize that manufacturers need to account for the discounts for financial statement forecasting and accounting purposes and therefore, these restrictions would not apply to the use of aggregated, summary-level data (that is, not prescription or claim-level data) for such purposes.

(2) Length of Agreement

Section 1860D–14A(b)(4)(A) of the Act states that an agreement shall be effective for an initial period of not less than 18 months and shall automatically be renewed for a period of not less than 1 year unless terminated under section 1860D–14A(b)(4)(B) of the Act. To ensure that the end of the initial term of each Discount Program Agreement corresponds to the end of a calendar year, § 423.2315(c)(3) would specify that all Discount Program Agreements have an initial period of 24 months, with automatic renewal for a period of one year each January 1 thereafter, unless the agreement is terminated in accordance with § 423.2345.

e. Payment Processes for Part D Sponsors (§ 423.2320)

(1) Interim Payments

Section 1860D–14A(c)(1)(A)(ii) of the Act requires that manufacturer discounts be provided to applicable beneficiaries at the point-of-sale. To ensure that Part D sponsors have the funds available to advance the gap discounts at the point-of-sale, we are proposing to provide monthly interim coverage gap payments to Part D sponsors under § 423.2320(a).

We propose to base these interim payments on a percentage of the coverage gap drug cost assumptions submitted with plan bids under § 423.265 and negotiated and approved under § 423.272, adjusted as necessary to account for applicable drug costs for applicable beneficiaries. Recognizing that Part D sponsors receive payments from manufacturers for invoiced discount amounts during the quarterly invoice process, we seek to ensure that Part D sponsors do not receive duplicate Discount Program payments for the manufacturer discounts advanced to beneficiaries at the point-of-sale. Thus, we propose to offset the Part D payments made to the Part D sponsor for each Part D plan by the discount amounts invoiced to manufacturers for that Part D plan.

EGWPs are not required to submit Part D bids. Thus, we do not have the information necessary to estimate the cost of manufacturer discounts for these Part D plans. Similar to our current policy for prospective low-income cost sharing subsidy and reinsurance subsidy payments, we propose not to provide interim payments to EGWPs. However, EGWPs will receive final reconciled coverage gap payments under the reconciliation process described in § 423.2320(b).

Program of All-inclusive Care for the Elderly (PACE) plans would not receive interim coverage gap payments because their enrollees already have zero cost-sharing without any coverage gap.

(2) Coverage Gap Discount Reconciliation

Because the interim coverage gap payments are estimates, Part D sponsors may incur actual Discount Program costs that are greater or less than the interim coverage gap payments. We would perform a cost-based reconciliation to ensure that Part D sponsors are paid dollar for dollar for all manufacturer discount amounts as reported on invoiced PDE data submitted for Part D payment reconciliation. This process is termed ''Coverage Gap Discount Reconciliation'' under § 423.2320(b) and will occur after Part D payment reconciliation.

The purpose of the coverage gap discount reconciliation is to make Part D sponsors whole for the gap discount amounts provided to applicable beneficiaries at the point-of-sale. In general, we would calculate the Coverage Gap Discount Reconciliation amount by subtracting the interim coverage gap payments from all manufacturer discount amounts as they are reported on PDE records by Part D sponsors. If the difference is positive, we would pay the difference to Part D sponsors. If the interim coverage gap payments exceed the manufacturer discount amounts, we would recover the difference from Part D sponsors.

Manufacturer discount amounts reported on PDE records submitted by the PDE submission deadline for Part D

payment reconciliation are included in Coverage Gap Discount Reconciliation. We would continue to accept PDEs with manufacturer discount amounts for 37 months following the end of the benefit year. Any manufacturer discount amounts reported on PDE records submitted after the PDE submission deadline for Part D payment reconciliation would continue to be invoiced to manufacturers and manufacturers would remit payments for invoiced coverage gap discount amounts to Part D sponsors.

f. Provision of Applicable Discounts on Applicable Drugs for Applicable Beneficiaries (§ 423.2325)

(1) Obligations of Part D Sponsors; Provision of Point-of-Sale Discounts

Section 1860D–14A(c)(1)(A)(ii) of the Act requires the manufacturer discounts to be provided at the point-of-sale. As extensively discussed previously in this subpart, manufacturer discounts can be provided at point-of-sale only if the entity adjudicating the electronic pharmacy claim has the information necessary to determine at that point in time: (1) The drug is an applicable drug; (2) the beneficiary is an applicable beneficiary; (3) the claim is wholly or partly in the coverage gap; and (4) the amount of the discount, taking into consideration Part D supplemental benefits that pay first. We have determined that the only entity capable of providing the discount at point-of-sale is the Part D sponsor because no other entity would have all four pieces of information. Therefore, § 423.2325(a) would require Part D sponsors to provide applicable beneficiaries with applicable discounts on applicable drugs at point-of-sale. Part D sponsors would be required by § 423.2325(b)(1) to determine that: (1) An enrollee is an applicable beneficiary (as defined in § 423.100); (2) a Part D drug is an applicable drug (as defined in § 423.100); and (3) the amount of the applicable discount (as defined in § 423.2305) in order to provide a discount at point-of-sale.

Part D sponsors would use the date of dispensing for purposes of providing an applicable discount at point-of-sale and determining the amount of such discount. However, if later information changes the beneficiary's eligibility for the applicable discount back to the date of dispensing (for example, retroactive low-income subsidy status changes, or retroactive changes resulting from automated TrOOP balance transfers between Part D sponsors via Financial Information Reporting (FIR) transactions), or changes the amount of the applicable discount or the applicable beneficiary's cost sharing, we propose to require, in § 423.2325(b)(2), that Part D sponsors make retroactive adjustments to the applicable discount as necessary to reflect such changes. For example, if a claim for an applicable drug was originally adjudicated in the initial coverage phase but later moved into the coverage gap as a result of receipt of an automated TrOOP balance transfer from a previous Part D sponsor, the applicable discount and the corrected beneficiary cost-sharing would be reported on the adjusted PDE. Conversely, if an original claim was adjudicated in the coverage gap with an applicable discount but later reprocessed in the catastrophic phase as a result of an automated TrOOP balance transfer, the applicable discount reported on the adjusted PDE is the mechanism for refunding the manufacturer.

If an applicable beneficiary has a claim for an applicable drug that straddles the coverage gap and another phase of the Part D benefit, section 1860D–14A(g)(4)(C) of the Act requires Part D sponsors only provide the discount on the portion of the negotiated price of the applicable drug that falls at or above the initial coverage limit and below the annual out-of-pocket threshold. Because our proposed definition of negotiated price for purposes of the Discount Program would exclude both the dispensing fee and vaccine administration fee, § 423.2325(b)(3) would require the dispensing fee and vaccine administration fee be included in the portion of the negotiated price that falls below the ICL or above the annual out-of-pocket threshold, to the extent possible (that is, as much of the dispensing fee that can be included in the portion below the ICL or above the annual out-of-pocket threshold). If the portion of the negotiated price that falls below the ICL or above the annual out-of-pocket threshold is less than the sum of the dispensing fee and vaccine administration fee, the dispensing fee must be included first in the portion that falls below the ICL or above the annual out-of-pocket threshold. The Affordable Care Act authorizes CMS to establish procedures to determine the discount at point-of-sale and is silent on the order in which negotiated price and non-negotiated price apply (as opposed to with supplemental and other health or prescription drug coverage) and thus, we propose this requirement in order to further support the statutory goal of alleviating the burden of the coverage gap on applicable beneficiaries.

Section 423.2325(b)(4) would require Part D sponsors to determine whether any affected beneficiaries need to be notified by the Part D sponsor that an applicable drug is eligible for Part D coverage whenever CMS specifies a retroactive effective date for a labeler code and would require the Part D sponsors to notify such beneficiaries. This situation could occur if participating manufacturers fail to notify CMS when a new labeler code becomes available or otherwise fail to provide us with all of their labeler codes as required. As required in proposed § 423.2315(b)(4), manufacturers participating in the Discount Program must submit to CMS all of their labeler codes. We make the participating labeler code information available to Part D sponsors so they can determine which drug products are covered by Discount Program Agreements. Part D sponsors cannot cover any applicable drugs marketed with labeler codes that are not specified by CMS as participating in the Discount Program. Consequently, a manufacturer's failure to provide a labeler code to CMS could result in beneficiaries being denied access to both covered Part D drugs and applicable discounts.

While we anticipate such occurrences will be very rare, we believe it is necessary that Part D sponsors determine whether affected beneficiaries need to be notified once CMS makes the labeler code and effective date information available to the Part D sponsor. For example, Part D sponsors generally would need to notify affected beneficiaries that had denied claims if their claims history reasonably indicates that the beneficiary either might still need the previously denied drug or paid for the drug out-of-pocket. If the claims history indicates that the beneficiary has not received an alternative replacement medication since the denied claim, it might reasonably be inferred that the beneficiary still needs (or should be reimbursed for) the denied drug. We recognize that this would place a burden on Part D sponsors through no fault of their own, but, in these rare instances, we believe it would help ensure the beneficiaries have appropriate access to Part D drugs and applicable discounts. It would also increase the likelihood that manufacturers would be held responsible for paying discounts that should have been paid previously.

We do not believe the point-of-sale requirement was intended to exclude discount payments for claims that were not adjudicated by the Part D sponsor at point-of-sale: even though the statute

requires provision of the discount at the point-of-sale, it does not state that applicable beneficiaries are not entitled to the discount if it was not provided at the point-of-sale. Instead, we believe this requirement was meant to ensure the discount would be available at the point-of-sale when and if a claim is electronically adjudicated. However, in limited circumstances beneficiaries submit claims for reimbursement that were not adjudicated at the point-of-sale, such as when they needed to obtain a prescription from an out-of-network pharmacy. Therefore, our guidance and the Discount Program Agreement specify that Part D sponsors provide, and manufacturers reimburse, applicable discounts for applicable drugs submitted by applicable beneficiaries via paper claims, including out-of-network and in-network paper claims, if such claims are payable under Part D. In these situations, beneficiaries are still entitled to the discount and therefore, we propose to codify this requirement in § 423.2325(c).

(2) Collection of Data

Section 1860D–14A(c)(1)(C) of the Act states that we may collect appropriate data from Part D sponsors in a timeframe that allows for applicable discounts to be provided for applicable drugs. Section 423.2325(d) of the proposed rule would require Part D sponsors to provide CMS with appropriate data on the applicable discount provided by the Part D sponsors in a manner specified by CMS. In implementing the Discount Program we determined that using the existing PDE reporting process to collect the necessary data would be most efficient and least burdensome for Part D sponsors. Thus, we would require Part D sponsors to report the applicable discount that was provided at the point-of-sale as part of the PDE record in addition to the other claim-level detail that is reported on the PDE. We would also require Part D sponsors to report confirmation of payment from manufacturers during the quarterly invoice process.

(3) Other Health or Prescription Drug Coverage

Section 1860D–14A(c)(1)(A)(v) of the Act requires that applicable discounts for applicable drugs get applied before any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of applicable beneficiaries as the Secretary may specify. We propose to codify the requirement in § 423.2325(f) by specifying that an applicable discount must be applied to beneficiary cost-sharing when Part D is the primary payer before any other health or prescription drug coverage is applied. Since the Part D sponsor would provide the discount at the same time as it makes primary payment on the claim, this coordination generally would take place in real time as the claim is adjudicated by the pharmacy in accordance with existing Part D coordination of benefit requirements. We specify that this requirement would not apply to Medicare secondary payer claims because the beneficiary would not have a Medicare Part D coverage gap on the initial claim to the primary payer. However, this requirement would apply to coordination of benefit claims in which the Part D sponsor coordinates benefits post point-of-sale with another payer who paid primary in error.

(4) Supplemental Benefits

Section 1860D–14A(c)(2) of the Act provides that if an applicable beneficiary has supplemental benefits under his or her Part D plan, the applicable discounts shall not be provided until after such supplemental benefits have been applied. Supplemental benefits offered under a Part D plan would have the meaning set forth in § 423.100 (see discussion of supplemental benefits under the proposed definition ''other health or prescription drug coverage''). Section 423.2325(e)(1) would codify this requirement by specifying that an applicable discount is applied to beneficiary cost-sharing after supplemental benefits have been applied to the claim for an applicable drug, and paragraph (e)(2) would establish that no applicable discount is available if supplemental benefits eliminate the coverage gap so that a beneficiary has zero cost-sharing on a claim.

If a Part D sponsor offers a plan with supplemental benefits on applicable drugs covered between the plan's initial coverage limit and the Medicare Part D catastrophic threshold using either coinsurance or fixed copay, the value of the supplemental benefits would need to be calculated first on any claim for an applicable drug as the difference between the proposed supplemental cost-sharing and the coinsurance under the basic benefit. For example, if the supplemental benefit for an applicable drug had a 60 percent coinsurance, the value of the supplemental benefits that would need to be applied first (plan liability) would be 40 percent (100 percent coinsurance under basic minus 60 percent coinsurance) of the negotiated price of the drug. The applicable discount would then be calculated as 50 percent of the negotiated price (as defined in § 423.2305) less the supplemental benefit. Beneficiary cost-sharing would then be the remainder of the negotiated price after the plan liability and applicable discount had been applied. Thus, in the case of either a coinsurance or copay design for supplemental benefits, the amount the beneficiary pays at point-of-sale would generally be approximately 50 percent of his or her expected cost-sharing under the plan's benefit package. This amount will change over time as the coinsurance level for a beneficiary is reduced until it reaches 25 percent in 2020. Section 423.2325(e)(3) would require that the dispensing fee and the vaccine administration fee be included in the Part D sponsor liability portion of a claim with supplemental benefits. For the same reasons that we propose to require the dispensing fee and the vaccine administration fee to be applied to the portion of a claim for an applicable drug that falls below the initial coverage limit or above the annual out-of-pocket threshold, to the extent possible, on straddle claims, we believe including the dispensing fee and the vaccine administration fee in the plan liability supports the statutory goal of alleviating the burden of the coverage gap on applicable beneficiaries.

(5) Pharmacy Prompt Payment

Section 1860D–14A(c)(1)(A)(iv) of the Act requires procedures to ensure that, not later than the applicable number of calendar days after the dispensing of an applicable drug by a pharmacy or mail order service, the pharmacy or mail order service is reimbursed for an amount equal to the difference between: (1) The negotiated price of the applicable drug; and (2) the discounted price of the applicable drug. This amount would be equal to the amount of the applicable discount. The applicable number of calendar days with respect to claims for reimbursement submitted electronically is 14 days, and otherwise, is 30 days. We propose to implement this requirement in § 423.2325(g) by specifying that Part D sponsors reimburse a pharmacy or mail order service the amount of the applicable discount no later than the applicable number of calendar days after the date of dispensing an applicable drug. This requirement would apply to all network pharmacies, including but not limited to long term care pharmacies and home infusion pharmacies.

We considered using the existing prompt pay requirements in § 423.520 as the basis for implementing the discount payment prompt pay requirements because it seemed to make sense given that the discounts are included on the pharmacy claims and the timeframes are identical. However, unlike § 423.520, § 423.2325(g) does not exclude mail order or long term care pharmacies. Therefore, Part D sponsors that do not currently pay mail order or long term care pharmacies in accordance with the § 423.520 prompt pay requirements for other network pharmacies would need to establish another mechanism for reimbursing these pharmacies for discount payments in accordance with the § 423.2325(g).

Finally, we propose to add a new paragraph (24) to § 423.505(b) so that the requirements we are proposing in § 423.2325 are included in all Part D sponsor contracts with us.

g. Manufacturer Discount Payment Audit and Dispute Resolution (§ 423.2330)

(1) Third Party Administrator Audits

Section 1860D–14A(d)(3)(D) of the Act permits manufacturers to conduct periodic audits, directly or through contracts, of the data and information used by the TPA to determine discounts for applicable drugs of the manufacturer under the Discount Program. Section 423.2330(a) would codify the provisions of the Discount Program Agreement governing these audits by specifying the requirements for requesting an audit and the rights of manufacturers associated with conducting audits.

We propose in § 423.2330(a)(1) that the term periodic be defined as no more often than annually. We believe that this standard would ensure that all manufacturers have an opportunity to conduct meaningful audits within available TPA resources. The proposed definition of periodic represents a balance between frequent audits that may provide the greatest level of detail and very infrequent audits that may be less costly to implement, but may not provide needed information in a timely manner.

While we considered allowing quarterly audits, we do not believe that there will be significant quarter to quarter changes in data collection and invoice calculation procedures that would warrant such frequent audits. Given that the TPA will need to allow all participating manufacturers the opportunity to conduct audits, we believe that an annual audit strikes the right balance of providing meaningful and timely information to manufacturers that can reasonably be accommodated by the TPA.

Section 1860D–14A(d)(3)(D) of the Act requires that our contract with the TPA permit audits by manufacturers of the data and information used by the TPA to determine discounts for manufacturer's applicable drugs. Because the statute thus permits the manufacturer to audit data used by the TPA, and importantly, does not grant manufacturers a right to audit CMS or the Part D sponsors, we propose to specify in regulations that the audit right is limited to information held by the TPA and used to calculate discounts. This means that the manufacturer would not have the ability to audit CMS records or the records of Part D sponsors. We believe the data provided from the TPA provides manufacturers with appropriate and sufficient information to conduct an audit because it provides the claim-level information specified in the Discount Program Agreement that is used to calculate the discounts. We believe that defining the data available for audit also requires balancing considerations between efficiently administering the Discount Program and providing manufacturers with an appropriate level of information to validate invoices. Section 423.2330(a)(3) would establish, consistent with the Discount Program Agreement, that manufacturers may audit a statistically significant sample of the database used by the TPA to calculate gap discounts. We believe that a statistically significant sample provides a balance between allowing an audit to include: (1) All of the data, which would provide complete information, but would be unwieldy in terms of resources; and (2) a very small sample that would have insufficient information but be inexpensive to implement. Moreover, the use of a statistically valid sample meets generally accepted auditing standards, would provide sufficient data to manufacturers to reach statistically valid conclusions that could be used to dispute discount payments, and is an efficient use of audit resources.

Proposed § 423.2330(a)(3) also supports our obligation to protect the privacy of beneficiary medical information. This section proposes that, with the exception of work papers, audit data may not leave the room where the audit is conducted, which would further protect beneficiary privacy. Another measure to protect the confidentiality of beneficiary medical information is contained in proposed § 423.2330(a)(4), which would specify that the auditor may only release an opinion of the results of the audit and may not release any other information obtained from the audit, including its work papers, to its client, employer, or any other party. We believe these limitations on the distribution of data support beneficiary privacy, while addressing manufacturer need for access to data that are relevant to the calculation of the gap discounts. These regulations all would codify provisions in the current Discount Program Agreement.

(2) Manufacturer Audits

Section 1860D–14A (e)(1) of the Act specifies that each manufacturer with a Discount Program Agreement in effect shall be subject to periodic audit by CMS and we propose to codify this requirement in § 423.2330(b). Similar to the limitation in § 423.2330(a)(1), we propose to define the term periodic in § 423.2330(b)(1) as no more often than annually. In § 423.2330(b)(3) we propose that we would have the right to audit appropriate data of the manufacturer, including data related to a manufacturer's FDA-assigned labeler codes, expiration date of NDCs, utilization, and pricing information relied on by the manufacturer to dispute quarterly invoices, as well as any other data CMS determines are necessary to carry out the Discount Program.

(3) Dispute Resolution

Section 1860D–14A(c)(1)(A)(vii) of the Act requires the Secretary to establish ''a reasonable dispute resolution mechanism to resolve disagreements between manufacturers, applicable beneficiaries, and the third party with a contract * * *.''

Therefore, we propose in § 423.2330(c) a multi-stage dispute resolution process consisting of: (1) An initial dispute stage; (2) an appeals stage for manufacturers that do not accept the findings of the dispute process; and (3) a final administrator review when either a manufacturer or CMS disagree with the outcome of the initial appeals process.

Before proposing this multistage dispute resolution process, we reviewed potentially analogous appeals mechanisms, both within the Medicare program and in other, similar government programs, such as Tricare and Medicaid. Within the Medicare Part D program we reviewed the appeals process for organizations seeking to become Part D sponsors and the appeals process for Medicare beneficiaries challenging denials of benefits. We also reviewed the appeals mechanism for the Department of Defense (DoD) Tricare program and Medicaid—two existing government programs that collect rebates from pharmaceutical

manufacturers. In each instance, we found a multistage dispute resolution program. We concluded that a multi-stage process results in balanced, equitable decisions because of the multiple perspectives that are available. Therefore, we are proposing a similar multistage process for the Medicare Coverage Gap dispute resolution process.

Section 423.2330(c) would include a timetable for the three-stage approach to manage the process most efficiently and to support equal treatment of each appeal. The timetable ensures that manufacturers' disputes are resolved as quickly as possible, while allowing both parties to perform the necessary calculations and investigations to evaluate the gap discount invoice. The proposed timeframes were established by estimating the time required to analyze the data presented, by the volume of claims, and by considering the characteristics of the Discount Program compared to the other similar programs previously noted.

Specifically, we propose in § 423.2330(c)(1) that manufacturers may dispute quarterly gap discount amounts by providing notice of the dispute to the TPA within 60 days of the receipt of information that is the subject of the dispute. The information is limited to data received from the TPA, or as a result of a manufacturer's audit.

We believe that the deadline for filing disputes will result in more prompt remuneration to manufacturers receiving positive decisions and more predictable workloads for the dispute infrastructure.

Proposed § 423.2330(c)(2) also states that the notice of dispute be accompanied by supporting evidence that is material, specific, and related to the dispute. We propose this requirement because the manufacturer bears the burden of proof that the PDE data is incorrect. We also propose in § 423.2330(c)(3) to codify the Discount Program Agreement provision that manufacturers may not withhold any invoiced amounts pending dispute resolution except for invoiced amounts for applicable drugs without labeler codes provided by the manufacturer to us. The proposition to generally bar the withholding of disputed invoice amounts is justified because gap discounts are owed by manufacturers but are paid by Part D sponsors to beneficiaries at the point-of-sale; we believe that the prohibition of withholding disputed invoices will minimize the risk to Part D sponsors for these discount-related incurred liabilities without significantly increasing the financial risk to a manufacturer because of the extensive quality assurance CMS performs on PDEs submitted by Part D sponsors. The PDE data used to calculate quarterly invoices are of high quality. The PDE data are derived from claims for each prescription submitted to Part D sponsors for payment. Part D sponsors validate each claim to comply with the False Claims Act and as part of their process to reimburse pharmacies for the cost of the drug. In addition, we implement multiple edits to validate the PDE data submitted by Part D sponsors. Those edits include identification and adjustment of outlier and other inappropriate entries for variables such as discount amount, beneficiary eligibility for the gap discount, incorrect NDCs, etc. Therefore, the burden of proof is on manufacturers to demonstrate that the data used to calculate the quarterly invoice are incorrect.

Section 423.2330(c)(4) would allow manufacturers to request an additional adjudication by the Independent Review Entity (IRE), under contract with CMS, within 30 days of the receipt of an unfavorable determination from the TPA, or if no decision was received from the TPA, within 90 days of the receipt of the dispute submission. This section also proposes that the IRE be required to make a determination within ninety calendar days of receipt of the manufacturer request for an appeal.

Section 423.2330(c)(6) establishes a final administrative step to support an equitable dispute resolution process. We are proposing that both manufacturers and CMS would have the right to request a final review of the dispute by the Administrator. Since we administer the Discount Program and manufacturers have financial liability for the discounts, both parties have an interest in ensuring an equitable resolution to the dispute. We propose that this request be made within 30 days after the manufacturer receives a decision from the IRE to facilitate a timely outcome. Finally, we propose that the decision of the Administrator would be final and binding.

We propose to codify the policies as described and welcome comments on the dispute and appeals process.

h. Beneficiary Dispute Resolution (§ 423.2335)

Section 1860D–14A(c)(1)(A)(vii) of the Act requires CMS to provide a reasonable dispute mechanism to resolve disagreements between manufacturers, applicable beneficiaries, and the TPA. While § 423.2330(c) would address the disputes that could arise between the manufacturer and CMS or the TPA, § 423.2335 would provide the beneficiary dispute resolution requirements. Specifically, § 423.2335 would provide that beneficiaries shall have access to the Part D coverage determination and appeals process as described in § 423.558 through § 423.638 for disputes involving the availability and amount of applicable discounts under the Discount Program.

As previously discussed in this preamble, we have determined that the Part D sponsor is the only entity capable of accurately providing applicable discounts at the point-of-sale because of its detailed knowledge of the drug, the beneficiary, and the claim. Part D sponsors would advance applicable discounts as part of their normal process for adjudicating Part D claims. Since we consider the discounts to be a Part D benefit we propose that the existing mechanism that Part D sponsors have in place to accommodate coverage determinations and appeals related to Part D sponsor decisions on the amount of cost-sharing for a drug be used for beneficiary disputes associated with the Discount Program (see § 423.558 through § 423.638).

Although section 1860D–14A(c)(1)(A)(vii) of the Act specifies disputes that could arise between manufacturers, applicable beneficiaries and the TPA, we believe that under the Discount Program model whereby Part D sponsors provide the discounts at point-of-sale, each Part D sponsor is the appropriate party to address any beneficiary disputes that would otherwise involve manufacturers or the TPA. We believe that the beneficiary would generally contact his or her plan with any questions about any coverage gap claims, including the availability or amount of an applicable discount. Currently a beneficiary who wishes to see how his or her claim amounts were calculated, including those affected by a manufacturer discount, would consult the Explanation of Benefit (EOB) form distributed by the Part D sponsor. For 2011, we amended the model EOB to add coverage gap discounts as ''other payments'' that count toward a beneficiary's out-of-pocket costs. Beneficiaries may not know at the point-of-sale whether a manufacturer discount has been applied to their claim, or if the discount has been applied correctly. Part D sponsors direct beneficiaries to their EOBs for information about claims-payment amounts. The EOB instructs beneficiaries to contact the Part D sponsor with any remaining concerns. Maintaining this consistent process for all member benefit payments would be the easiest for the beneficiaries to understand and follow, and, we believe,

impose minimal additional burden on Part D sponsors.

Although we could establish a separate mechanism for beneficiary disputes under the Discount Program, we decline to do so because we believe it would prove duplicative and inefficient for Part D sponsors, beneficiaries, and us. It also would be potentially more confusing for beneficiaries who would be unable to rely on a single process to resolve their benefit-related inquiries. For all of these reasons, we propose to designate the existing Part D coverage determination appeals process as the mechanism for beneficiary disputes about the Discount Program.

i. Compliance Monitoring and Civil Money Penalties (§ 423.2340)

Section 1860D–14A(e)(2) of the Act requires us to impose a civil money penalty (CMP) on a manufacturer that fails to provide applicable beneficiaries applicable discounts for applicable drugs of the manufacturer in accordance with the Discount Program Agreement. The statute sets forth the formula for determining the CMP amount, which will equal the sum of the amount that the manufacturer would have paid with respect to such discounts under the agreement (which will then be used to pay the discounts which the manufacturer had failed to provide) plus 25 percent of such amount. Section 423.2340 would implement these requirements and establish the procedures for imposing and collecting the CMPs in accordance with subpart T of this part. Accordingly, we propose to revise the definition of ''affected party'' in subpart T (as defined in § 423.1002) by adding the term ''manufacturer'' (as defined in § 423.2305) to the definition and clarifying that we interpret the use of ''Part D sponsor'' throughout subpart T to be synonymous with ''affected party''. In accordance with the Discount Program Agreement and proposed § 423.2315(b)(3), manufacturers must pay each Part D sponsor within 38 calendar days of receipt from the TPA of the electronic invoice and Medicare Part D Discount Information for the applicable discounts included on the invoice except as specified in § 423.2330(c)(3). Therefore, we consider a manufacturer to have failed to provide applicable beneficiaries applicable discounts for applicable drugs of the manufacturer in accordance with the Discount Program Agreement if it fails to comply with this requirement unless such failure is due to technical or other reasons beyond the control of the manufacturer, such as a natural disaster. Consequently, we would impose a civil money penalty whenever a manufacturer fails to make full payment on its invoice within 38 calendar days of receipt of the invoice and Medicare Part D Discount Information for the applicable discount included on the invoice unless such failure is due to technical or other reasons beyond the control of the manufacturer. We plan to add this provision to the Discount Program Agreement.

Section 423.2340(c) would codify the methodology for determining the amount of the CMP as equal to the amount of applicable discount the manufacturer would have paid under the Discount Program Agreement, which will then be used to pay the applicable discount that the manufacturer had failed to provide, plus 25 percent of such amount. This amount may be reduced by any amount that the manufacturer has paid after the 38th calendar day but before the date the CMP is collected. We interpret this to mean that the CMP would be calculated based upon the outstanding invoiced amount that was not paid within 38 calendar days of receipt as required under the Discount Program Agreement and proposed § 423.2315(b)(3) irrespective of any partial or late payments. In other words, a manufacturer's failure to pay the entire invoice amount would trigger the CMP and late payments would not relieve the manufacturer of its obligation to pay an additional 25 percent of the unpaid amount from the invoice. In order to ensure consistency and transparency with the imposition of these civil money penalties, unless the exception applies (that is, the payment is late due to technical or other reasons beyond the control of the manufacturer), we would impose the additional 25 percent on all invoiced amounts not paid within 38 calendar days of receipt, even, for example, if the payment is only 1 day late.

Section 423.2340(d) specifies that if CMS makes a determination to impose a CMP, we would send a written notice of our decision to impose a CMP that includes a description of the basis for the determination, the basis for the penalty, the amount of the penalty, the date the penalty is due, the manufacturer's right to a hearing (as specified under § 423.1006) and information about where to file the request for hearing. To ensure a consistent approach to CMPs, we propose extending existing appeal procedures for CMPs in subpart T of this part to manufacturers appealing a CMP imposed under the Discount Program. We have utilized this appeals process for more than 20 years for various types of adverse agency determinations affecting an array of medical providers, MA organizations, and Part D sponsors. We therefore propose to use this well established process and infrastructure for CMP appeals from manufacturers that have contracted with the Discount Program and are delinquent in paying the discounts as required. To that end, we propose to revise the definition of ''affected party'' in § 423.1002 to include manufacturers participating in the Discount Program. Section 423.2340(e) would provide that we would initiate collection of the CMP following expiration of the timeframe for requesting an ALJ hearing, which is 60 calendar days from the CMP determination, as specified in § 423.1020 if the manufacturer did not request a hearing; and CMS would initiate collection of the CMP once the administrative decision is final if a manufacturer requests a hearing and our decision to impose the CMP is upheld.

Section 1860D–14A(e)(2)(B) of the Act states that the provisions of section 1128A of the Act (except subsections (a) and (b)) apply to CMPs under this subpart to the same extent that they apply to a CMP or procedure under section 1128A(a) of the Act. We propose to codify this requirement in § 423.2340(f). We welcome comments on this proposal.

j. Termination of Agreement (§ 423.2345)

Section 1860D–14A(b)(4)(B)(i) of the Act provides that we may terminate a Discount Program Agreement for a knowing and willful violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 30 days after the date of notice to the manufacturer of such termination and CMS shall provide, upon request, a hearing concerning such termination, and such hearing shall take place prior to the effective date of the termination with sufficient time for such effective date to be repealed if CMS determines appropriate. Section 423.2345 would codify these requirements consistent with the termination provisions in the Discount Program Agreement. For instance, § 423.2345(a)(1) would clarify that ''good cause shown'' must relate to the manufacturer's participation in the Discount Program. Our proposed regulation would further specify that we must provide the manufacturer with an opportunity to cure any ground for termination within 30 calendar days of receipt of the written termination notice. In addition, we propose, consistent with the statutory requirement as reflected in the Discount

Program Agreement, that the manufacturer may request a hearing with a hearing officer concerning such termination if requested in writing within 15 calendar days of receiving notice of the termination, and such hearing must take place prior to the effective date of termination with sufficient time for such effective date to be repealed if we determine appropriate.

In order to address potential timing issues with appeals during the termination process, we propose to clarify in § 423.2345(a)(2) that termination must not be effective earlier than 30 days after the date of notice to the manufacturer of such termination and must not be effective prior to resolution of timely appeal requests received in accordance with paragraphs (a)(4) and (a)(5) of this section. Proposed sections (a)(4) and (a)(5) state, in part, that CMS will provide a manufacturer with a hearing before the hearing officer about such termination if requested in writing within 15 calendar days of receiving notice of the termination. Further, CMS or a manufacturer that has received an unfavorable determination from the hearing officer may request review by the CMS Administrator within 30 calendar days of receipt of the notification of such determination. Therefore, a termination would not be effective until either the timeframes to pursue a hearing with the hearing officer or CMS Administrator have passed or a final decision has been issued by the hearing officer or CMS Administrator and there is no remaining opportunity to request further review.

We also propose in § 423.2345(a)(5)(i) to specify that CMS or a manufacturer that has received an unfavorable determination from the hearing officer may request review by the CMS Administrator within thirty calendar days of receipt of the notification of such determination. The Discount Program Agreement currently provides only that a manufacturer may request review of an unfavorable decision by the CMS Administrator. However, we believe that a fair appeals process must ensure that both parties have an opportunity for further review of a decision made by an independent review entity. The decision of the CMS Administrator would be final and binding on either party. We request comments on these termination requirements.

Section 1860D–14A(b)(4)(B)(ii) of the Act provides that a manufacturer may terminate the Discount Program Agreement for any reason. Such termination shall be effective as of the day after the end of the calendar year if the termination occurs before January 30 of a calendar year or as of the day after the end of the succeeding calendar year if the termination occurs on or after January 30 of a calendar year. We propose to codify these requirements in § 423.2345(b).

Section 1860D–14A(b)(4)(B)(iii) of the Act states that any termination shall not affect discounts for applicable drugs of the manufacturer that are due under the Discount Program Agreement before the effective date of the termination and we propose to codify this requirement in § 423.2345(c). However, upon the effective date of the Discount Program Agreement termination, the manufacturer's drugs would no longer be covered under Medicare Part D. In addition, § 423.2345(d) would specify that we would cease releasing data to the manufacturer except as necessary to ensure the manufacturer reimburses applicable discounts for time periods in which the Discount Program Agreement was in effect and would notify the manufacturer to destroy data files provided by us under the Discount Program Agreement.

Finally, § 423.2345(e) would restrict reinstatement of manufacturers that previously terminated their Discount Program Agreements or had them terminated by CMS to those manufacturers that pay any and all outstanding applicable discounts incurred during any previous periods under Discount Program Agreements.

2. Inclusion of Benzodiazepines and Barbiturates as Part D Covered Drugs (§ 423.100)

Section 175 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), amended section 1860D–2(e)(2)(A) of the Act to include barbiturates, when used for the medical indications of epilepsy, cancer, or a chronic mental health disorder and to include benzodiazepines. These amendments apply to prescriptions dispensed on or after January 1, 2013. Accordingly, we propose to revise the definition of Part D drug at § 423.100, by including barbiturates (when used for the previously noted medical indications) and benzodiazepines that are dispensed on or after January 1, 2013. Like any covered prescription drugs under the Part D benefit program, benzodiazepines and barbiturates must meet all other conditions as defined in § 423.100 of a Part D covered drug such as: FDA approved for safety and effectiveness as a prescription drug under section 505 of the Federal Food, Drug, and Cosmetic Act; used and sold in the United States; not otherwise covered by Medicare Part A or Part B; and used only for medically accepted indications.

We remind plans that it is their responsibility to use the tools (that is, system edits, quality assurance checks) at their disposal to ensure barbiturates are covered for the conditions specified in statute. Also, given the vulnerability of these drugs to misuse and abuse, it is recommended that Part D sponsors use their Drug Utilization Report tools to identify and prevent waste and clinical abuses/misuses.

3. Pharmacy Benefit Manager's Transparency Requirements (§ 423.501 and § 423.514)

Under section 6005 of the Affordable Care Act, Part A of Title XI of the Act was amended by inserting after section 1150 of the Act a new section: ''SEC. 1150A. Pharmacy Benefit Manager's Transparency Requirements.'' Section 1150A of the Act contains several new reporting requirements for Part D sponsors under Part D of title XVIII, qualified health benefits plans (QHBP) offered through an exchange established by a State under section 1311 of the Affordable Care Act, and entities that provide pharmacy benefits management services, referred to in this section as pharmacy benefit managers (PBMs). The purpose of these new reporting requirements is to promote transparency of financial transactions involving Part D sponsors, QHBPs, and PBMs. Under section 1150A, the information is required to be reported to the Secretary by the Part D sponsor or QHBP and, in the case of a PBM, to the Part D sponsor or QHBP. In accordance with this authority, we propose to codify various reporting requirements in our regulation at § 423.514. In addition, we propose to add a definition for ''bona fide service fees'' to our regulations at § 423.501.

Under the authority of section 1860D–15 of the Act, we collect from Part D sponsors cost data necessary to determine payments under the Part D program. Currently, we collect from Part D sponsors PDE data that provide detailed information on each drug dispensed under Part D. In addition, we collect direct and indirect remuneration (DIR) information that indicates the amount of remuneration received by the sponsor or its PBM from pharmaceutical manufacturers and other sources. Part D sponsors are required to report these cost data to CMS within 6 months of the end of the coverage year.

We propose to amend our regulations to implement the provisions of section 1150A of the Act with respect to Part D sponsors and the PBMs that manage prescription drug coverage under a contract with a Part D sponsor. The

provisions of section 1150A of the Act with respect to QHBPs and their PBMs will be addressed in separate rulemaking.

The specific information that is required to be collected and reported under Section 1150A of the Act by each Part D sponsor and PBM for a contract year is the following:

- The percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies.
- The percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate), by pharmacy type (which includes an independent pharmacy, chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medication to the general public), that is paid by the Part D sponsor or PBM under the contract.
- The aggregate amount and the type of rebates, discounts, or price concessions (excluding bona fide service fees) that the PBM negotiates that are attributable to patient utilization under the plan, the aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed.
- The aggregate amount of the difference between the amount the Part D sponsor pays the PBM and the amount that the PBM pays retail pharmacies, and mail order pharmacies, and the total number of prescriptions that were dispensed.

Under section 1150A(c) of the Act, information disclosed by a Part D sponsor or PBM is confidential and generally shall not be disclosed by the Secretary or by a plan receiving the information. Consistent with the statute as applied to Part D sponsors and PBMs that provide pharmacy benefits management services on behalf of Part D sponsors, we propose to add language listing the following exceptions, which allow the Secretary to disclose the information in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs, for the following purposes:

- As the Secretary determines necessary to carry out section 1150A or Part D of Title XVIII.
- To permit the Comptroller General to review the information provided.
- To permit the Director of the Congressional Budget Office to review the information provided.

We believe the exception allowing disclosure to States to carry out section 1311 of the Act is relevant in the context of QHBPs but is not relevant to the Part D sponsors and their PBMs. Thus, this exception will be addressed in separate rulemaking regarding the provisions of 1150A of the Act with respect to QHBPs and their PBMs.

As required by section 1150A(d) of the Act, the provisions of section 1927(b)(3)(C) of the Act shall apply to a Part D sponsor or PBM that fails to provide the required information on a timely basis or knowingly provides false information ''in the same manner as such provisions apply to a manufacturer with an agreement under that section.''

Consistent with the statute, we are implementing this new reporting requirement by updating the regulations to specify reporting requirements for pharmacy benefits manager data. Each entity that provides pharmacy benefits management services must provide to the Part D sponsor, and each Part D sponsor must provide to CMS, the data elements required by this rulemaking.

Accordingly, in § 423.514, we propose to add language requiring that each entity that provides pharmacy benefits management services must provide to the Part D sponsor, and that each sponsor of a Part D plan provide to CMS, all of the following information in a manner specified by CMS:

- The total number of prescriptions that were dispensed.
- The percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies.
- The percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate), by pharmacy type (which includes an independent pharmacy, chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medication to the general public), that is paid by the Part D sponsors or PBM under the contract.
- The aggregate amount and type of rebates, discounts, or price concessions (excluding bona fide service fees) that the PBM negotiates that are attributable to patient utilization under the plan.
- The aggregate amount of the rebates, discounts or price concessions that are passed through to the plan sponsor.
- The aggregate amount of the difference between the amount the Part D sponsor pays the PBM and the amount that the PBM pays retail pharmacies, and mail order pharmacies.

The information submitted under this regulation would be subject to the confidentiality requirements under section 1150A(c) of the Act, and the provisions of section 1927(b)(3)(C) of the Act are applicable to any Part D sponsor or PBM that fails to provide this information on a timely basis or that knowingly provides false information in the same manner as those provisions apply to a manufacturer with an agreement under section 1927 of the Act.

We believe that we already collect much of the above listed information. For example, we can tally the total number of prescription dispensed from PDE records. Other information can be collected by modifying existing reporting mechanisms. For example, the aggregate amount of the difference between the amount the Part D sponsor pays the PBM and the amount the PBM pays pharmacies (that is, the PBM spread) is available from the DIR data reported to CMS by Part D sponsors on the 2010 DIR Report for Payment Reconciliation: Summary Report. We plan to add to the DIR reporting requirements PBM spread amounts for retail pharmacies and PBM spread amounts for mail order pharmacies in order to meet section 1150A of the Act reporting requirements.

In the interests of administrative simplicity and to minimize reporting burden on Part D sponsors, we would like to further leverage existing data sources and reporting mechanisms. Thus, we solicit comment on whether any of the following data elements can be collected using existing data sources such as PDE records and/or added to existing reporting mechanisms, and whether any may require a separate reporting mechanism:

- Number of retail prescriptions.
- Number of mail order prescriptions.
- Number of prescriptions dispensed by independent pharmacies.
- Number of prescriptions dispensed by chain pharmacies.
- Number of prescriptions dispensed by supermarket pharmacies.
- Number of prescriptions dispensed by state-licensed mass merchandisers to the general public.

We note that the provisions regarding DIR under the Part D program do not mention DIR attributable to patient utilization, whereas section 1150A of the Act references rebates, discounts, and price concessions that are attributable to patient utilization. We are soliciting comments regarding whether there are differences between DIR under the Part D program and DIR attributable to patient utilization. If there are any such differences, we also seek comments regarding whether we should establish additional reporting requirements for DIR attributable to patient utilization.

Consistent with the requirement under section 1150A of the Act that plans exclude bona fide service fees when they report the aggregate amount and type of rebates, discounts or price concessions, we also propose to amend the regulations at § 423.501 to add the following definition for bona fide service fees:

Bona fide service fees means fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drugs. Bona fide service fees include, but are not limited to, distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs).

We are soliciting comment on this definition, which is taken without modification from section 1150A of the Act and is consistent with the definitions used in Medicare FFS and Medicaid. We intend to monitor the reported bona fide service fees reported by Part D sponsors to ensure compliance with program requirements.

B. Strengthening Beneficiary Protections

This section includes provisions aimed at strengthening beneficiary protections under Parts C and D. We are also considering changes under the long term care (LTC) conditions of participation. In our opinion, it is appropriate to provide for reinstatement of beneficiaries in the section 1876 cost plans from which they were disenrolled for failing to pay premiums when they can establish good cause for their failure to pay. We anticipate that this would result in uninterrupted plan coverage for eligible beneficiaries thereby improving access to healthcare for individuals such as those with chronic conditions requiring continual monitoring and medication. Similarly, we expect that requiring enrollees in MA plans to be provided with uniform ID cards that all providers can easily recognize would facilitate access to health care for those beneficiaries. We also think that calculating creditable coverage by excluding the value of additional coverage in the coverage gap and the manufacturer's discount—the standard that qualifies retiree drug coverage for the retiree drug subsidy—would mean a beneficiary receiving retiree drug coverage would be less likely to be assessed a late enrollment penalty if he or she decided to enroll in a Part D plan. Enabling health care professionals to request Independent Review Entity (IRE) reconsiderations of Part D coverage determinations on behalf of enrollees without having to obtain signed authorized representative forms would, in our opinion, lessen the burden faced by providers seeking to assist enrollees with appeals and would encourage more health care professionals to step forward and help beneficiaries access this level of the appeals process. Lastly, the various arrangements that exist involving LTC facilities, LTC pharmacies and the LTC consultant pharmacists these pharmacies provide to LTC facilities, and pharmaceutical manufacturers and/or distributors have raised concerns regarding the quality of the consultant pharmacist reviews and the potential impact on resident health and safety. We believe these concerns may be addressed by changes we are considering that would require LTC consultant pharmacists be independent of the LTC facility pharmacy, pharmaceutical manufacturers or distributors, or any affiliate of these entities. The foregoing proposals and the change under consideration are set forth in Table 2.

TABLE 2—PROVISIONS TO STRENGTHEN BENEFICIARY PROTECTIONS

Preamble section	Provision	Part 417		Part 422		Part 423		Part 483	
		Subpart	Subpart	Subpart	Section	Subpart	Section	Subpart	Section
II.B.1	Good Cause and Reinstatement into a Cost Plan.	Subpart K	§ 417.460	N/A	N/A	N/A	N/A	N/A	N/A.
II.B.2	Requiring MA Plans to Issue Member ID cards.	N/A	N/A	Subpart A	§ 422.111	N/A	N/A	N/A	N/A.
II.B.3	Determination of Actuarially Equivalent Creditable Prescription Drug Coverage.	N/A	N/A	Subpart K	§ 422.56	N/A	N/A	N/A	N/A.
II.B.4	Who May File Part D Appeals with the Independent Review Entity.	N/A	N/A	N/A	N/A	Subpart M	§ 423.600, § 423.602.	N/A	N/A.

TABLE 2—PROVISIONS TO STRENGTHEN BENEFICIARY PROTECTIONS—Continued

Preamble section	Provision	Part 417		Part 422		Part 423		Part 483	
		Subpart	Subpart	Subpart	Section	Subpart	Section	Subpart	Section
II.B.5	Independence of LTC Consultant Pharmacists.	N/A	N/A	N/A	N/A	N/A	N/A	Subpart B ..	§ 483.60.

1. Good Cause and Reinstatement Into a Cost Plan (§ 417.460)

Current regulations at § 417.460(c) specify that an HMO or competitive medical plan may disenroll a member who fails to pay premiums or other charges imposed by the HMO or competitive medical plan for deductible and coinsurance amounts. The cost plan must demonstrate that it made reasonable efforts to collect the unpaid amount (for example, attempted to contact the member by phone or mail) and sent the enrollee written notice of the proposed disenrollment (including an explanation of the enrollee's right to a hearing under the HMO's or competitive medical plan's grievance procedures). Cost plans also have the option of not disenrolling members who fail to pay their premiums or cost-sharing. Whichever policy they choose, it must be applied consistently to all members in the plan.

In the April 2011 final rule (76 FR 21511), we established rules that allowed beneficiaries disenrolled from MA and Part D plans for failure to pay premiums the ability to request reinstatement into the plan from which they were involuntarily disenrolled provided they could establish good cause and pay all arrearages. We established these rules at § 422.74 and § 423.44 not only because they were consistent with the policy for delinquent Medicare Part B premium payments, but because beneficiaries who were disenrolled from an MA or Part D plan for failure to pay premiums generally were not eligible for a special enrollment period. We believed there may be situations where individuals had extenuating circumstances that prevented them from paying their premiums timely and that reinstatement would be appropriate.

We received broad support for this regulatory change for MA and Part D plans, and stated at the time that we would consider expanding the scope of this provision to section 1876 cost enrollees in the future. Based on feedback we have received from partners, we are proposing to amend § 417.460(c) regarding disenrollment for non-payment of premiums to allow for the reinstatement of enrollment for good cause subsequent to an involuntary disenrollment associated with the failure to pay premiums or other cost-sharing amounts. In order to be eligible for reinstatement, the beneficiary would have to pay all outstanding arrearages, including premiums that accrued during the period of disenrollment. We believe this is an important protection to provide beneficiaries enrolled in cost plans because even though members of cost plans do not have the same election period restrictions as those in MA and Part D plans, a reinstatement of enrollment would remove the involuntary disenrollment and result in continuous coverage.

We propose that the requirements for reinstatement be similar to those established under Part C and Part D. That is, the reinstatement must be requested, good cause determined and payment made of all premium or cost sharing arrearages, including amounts that would have been due since the disenrollment, within 3 months of the disenrollment date. Examples of good cause would be similar to those established for individuals disenrolled from MA or Part D plans and may include, but are not limited to: (1) An unexpected, prolonged hospitalization; (2) an error by a Federal government employee or plan representative; or (3) loss of home or severe impact by fire, or other exceptional circumstance outside the beneficiary's control. We also propose that good cause would not exist if the only basis for requesting reinstatement was a change in the individual's circumstances subsequent to the involuntary disenrollment resulting in his or her ability to pay the premiums.

We would note that an individual who is involuntarily disenrolled within the same timeframe from both his or her cost plan and a separate prescription drug plan (not affiliated with the cost plan) would need to seek separate good cause determinations for reinstatement into both plans. This is because the two plans may have different grace periods and arrearage amounts.

2. Requiring MA Plans To Issue ID Cards (§ 422.111)

Pursuant to section 1860D–4(a)(1) of the Act and § 423.120(c), and consistent with standards established by CMS, Part D sponsors must issue and re-issue as appropriate a card or other technology that enrollees can use to access negotiated prices for Part D covered drugs. While we have made recommendations through sub-regulatory guidance (*http://www.cms.gov/ManagedCareMarketing/*) with respect to member identification (ID) cards for Medicare Advantage (MA) Preferred Provider Organization and Private Fee-for-Service products, we have issued no related requirements. Many MA organizations issue ID cards to their enrollees, though absent regulation, there is no way to ensure consistency of information across such documents. We believe it is important to establish requirements for the MA member ID card to ensure that information such as the plan's customer service number, link to the plan's website and member ID number are disclosed to enrollees for access to care. Specifically, we propose to require that ID cards contain the following information: (1) For an MA PPO or PPFS plan, a statement that Medicare Limiting Charges apply; (2) an address for the plan's website; (3) a customer service number; and (4) the individual identification number for each enrollee, to clearly identify that he or she is a member of the plan.

Implementation of these provisions will ensure providers have easy access to the necessary information for verifying coverage and processing claims. Therefore, under our authority at section 1852(c) of the Act to require that MA organizations disclose MA plan information upon request, as well as our authority under section 1856(b)(1) to establish standards by regulation and section 1857(e) of the Act to specify additional contractual terms and conditions the Secretary may find

necessary and appropriate, we propose to amend § 422.111 by adding a new paragraph (i) to expressly require MA plans issue and re-issue, as necessary, a card that contains certain information and enables enrollees to access all covered services. Additionally, in an effort to protect beneficiaries from misuse of personal information, we will explicitly prohibit plan sponsors from disclosing social security numbers or health insurance claim numbers on the member ID cards. We will provide further instructions in the Medicare Marketing Guidelines.

3. Determination of Actuarially Equivalent Creditable Prescription Drug Coverage (§ 423.56)

Section 1860D–22 of the Act outlines the special rules for employer-sponsored programs. Subsection 1860D–22(a) of the Act establishes that the Secretary shall provide payment to sponsors of qualified retiree prescription drug plans that provide equivalent or better coverage than the actuarial value of standard prescription drug coverage. The Affordable Care Act amended section 1860D–22(a)(2)(A) of the Act by adding a provision with regard to the actuarial equivalence of retiree prescription drug coverage to the defined standard coverage. The new provision requires that when attesting to the actuarial equivalence of the plan's prescription drug coverage to the defined standard coverage, qualified retiree prescription drug plans not take into account the value of any discount or coverage provided during the gap between the initial coverage limit during the year and the out-of-pocket threshold for the defined standard coverage under Part D. This change was intended to carve-out coverage provided during the gap when determining the actuarial equivalence of retiree prescription drug coverage for the purpose of qualifying for the retiree drug subsidy payment under section 1860D–22(a)(2) of the Act. In addition, section 1860D–14A(g)(1) of the Act expressly excludes enrollees in RDS plans from the definition of ''applicable beneficiary.'' Thus, these Part D eligible individuals are not entitled to gap coverage or any applicable discount on drugs. In accordance with these legislative changes, we revised the retiree drug subsidy calculation by amending § 423.884(d) to remove the value of any discount or coverage provided during the coverage gap from the valuation of the RDS coverage. In other words, the calculation of the actuarial value of defined standard Part D coverage for the purposes of the RDS attestation excludes discounts provided to applicable beneficiaries in the gap by the discount program under 1860D–14A of the Act and the decreases in gap coinsurance for applicable beneficiaries under 1860D–2(b) of the Act.

Section 1860D–13(b)(4) of the Act defines creditable prescription drug coverage to include coverage that at least meets the actuarial equivalence requirements in 1860D–13(b)(5)(A) of the Act. Section 1860D–13(b)(5)(A) of the Act further states that an individual's prescription drug coverage meets the actuarial equivalence requirements only if the coverage is determined (in a manner specified by the Secretary) to provide coverage of the cost of prescription drugs the actuarial value of which (as defined by the Secretary) to the individual equals to or exceeds the actuarial value of the standard prescription drug coverage (as determined under section 1860D–11(c) of the Act). The Affordable Care Act, as amended, establishes two types of standard prescription drug coverage. Specifically, the standard defined benefit now includes provisions that apply only for applicable beneficiaries (see sections 1860D–2(b)(2)(C) and (D) of the Act), while the rest of the standard defined benefit applies for other enrollees. Thus, we calculate two actuarial values for standard prescription drug coverage—one value that would apply to applicable beneficiaries, and another value for standard prescription drug coverage when establishing the low-income subsidy. As a result of these changes, we need to clarify which actuarial equivalence standard is used for the valuation of creditable prescription drug coverage when determining whether an individual is subject to the late enrollment penalty (LEP) under 1860D–13(b) of the Act.

We believe the value of the defined standard benefit, as it applies to the valuation of creditable coverage, should be consistent with the regulation change for the valuation of the retiree drug subsidy calculation. Retiree prescription drug coverage is a primary source of creditable coverage. This being the case, we are proposing to align the actuarial value calculation we use for purposes of section 1860D–13(b) of the Act with the actuarial value calculation used to determine the value of the retiree drug subsidy. By using the same value for both determinations, we will be ensuring that the individuals who are enrolled in retiree drug plans that have met and attested to the actuarial equivalence value of defined standard prescription drug coverage as provided under § 423.884(5)(iii)(C) are not subject to the LEP under § 423.46.

To this end, we are proposing to amend § 423.56(a) to exclude the value of gap discounts or coverage, so that it is consistent with the calculation of the actuarial value of qualified retiree prescription drug coverage found at § 423.884(d). We also propose to revise the reference to ''CMS actuarial guidelines'' in § 423.56(a) to read ''CMS guidelines.'' We believe this revision would allow CMS additional flexibility to provide interpretive guidance on the definition of creditable coverage for reasons beyond those relating to actuarial principles.

4. Who May File Part D Appeals With the Independent Review Entity (§ 423.600 and § 423.602)

Section 1860D–4(h) of the Act directs the Secretary to establish a Part D appeals process that is similar to the appeals process used for MA appeals. The Parts C and D appeals procedures are set forth in Subpart M of Parts 422 and 423 of our regulations, respectively. In our January 12, 2009 final rule (74 FR 1494), we amended both these sets of regulations to strengthen enrollee access to the Part C and Part D appeals process. Specifically, we amended the MA appeals regulations at § 422.582 to permit physicians to request standard plan reconsiderations of pre-service requests on behalf of MA enrollees. Consistent with section 1860D–4(g) of the Act, we made a corresponding change to the Part D regulations at § 423.580, allowing physicians and other prescribers to request standard redeterminations on behalf of enrollees. Allowing prescribers to request coverage determinations and plan level appeals on behalf of enrollees has significantly enhanced enrollee access to these processes.

Subsequent program experience has taught us that these changes to the Part D appeal process may not go far enough in terms of improving access to the Part D appeals process, as explained in this section. Consequently, we are proposing to revise the Part D regulations at § 423.600 to allow physicians and other prescribers to request Independent Review Entity (IRE) reconsiderations on behalf of enrollees. We are also proposing to make a corresponding change to the notice provisions at § 423.602(a).

Currently, the Part D IRE reports that approximately 46 percent of the cases it dismisses lack a valid appointment of representative (AOR) form, and that the overwhelming majority of these dismissed appeals (close to 90 percent) are initiated by prescribers. Such dismissals impede prescribers from assisting enrollees in obtaining timely

independent review of their cases which creates the potential for delays in prescription drug access. Furthermore, given a prescribers' ability to act on behalf of an enrollee in requesting Part D plan level appeals, prescribers frequently express dissatisfaction with not being able to also assist patients with IRE level appeals and the perceived burden associated with becoming the enrollee's appointed representative. Clearly, this proposal would significantly reduce the number of requests for review that the Part D IRE dismisses due to the lack of an AOR form. In addition, because the IRE will no longer have to seek an AOR form, it will be able to immediately initiate substantive review of these cases. Thus, we believe this change would enhance beneficiary access to the appeals process and better ensure prompt IRE decisions on whether requested drugs should be covered under Part D.

Under this proposal, the regulations would continue to require a Part D enrollee, or a prescriber acting on his/her behalf, to request an IRE review; adverse redeterminations would not be automatically forwarded to the IRE. We have considered requiring auto-forwarding of adverse redetermination requests under the Part D program, but we continue to believe that the statute supports the position that in order to obtain IRE review the enrollee (or someone acting on the enrollee's behalf) must request such review. (See the January 28, 2005 final rule (70 FR 4193) for a discussion of this issue.) Although section 1860D–4(h) of the Act states that only the Part D eligible individual shall be entitled to bring an appeal to the IRE, we do not interpret this language as precluding a prescriber from acting on a Part D enrollee's behalf in requesting IRE review. As required by section 1860D–4(h) of the Act, this proposed change makes the MA and prescription drug benefit programs' appeals processes more similar, by giving Part D prescribers a mechanism to assist enrollees in accessing IRE review. In the MA program, the regulatory requirement that adverse plan reconsiderations be auto-forwarded to the IRE essentially gives physicians acting on behalf of enrollees direct access to the IRE reconsideration process. Also, as explained in our January 2009 final rule, allowing prescribers to request IRE appeals on behalf of enrollees does not present a conflict of interest because Part D prescribers are generally not entitled to payment from the enrollee, pharmacy, or plan for the prescribed drug, and therefore, do not have a financial interest in the outcome of appeals in the same manner as physicians requesting appeals under the MA program. Furthermore, we believe that an enrollee's prescriber has already been selected by the enrollee and occupies a position of trust. A prescriber is in a good position to know whether an independent review is warranted and is in the best interest of his or her patient.

This proposal should reduce administrative burdens under the IRE appeal process by eliminating the need for prescribers to routinely obtain AOR forms from enrollees and permitting prescribers to assist their patients in the appeals process without taking on the added responsibilities attendant to being an appointed representative. In contrast to the ongoing authority of appointed representatives, this proposal would allow a prescriber to act on an enrollee's behalf on an as-needed, case-by-case basis. A completed AOR form is not necessary or advisable for prescribers who are only seeking to assist Part D enrollees in exercising their own appeal rights under the statute. Prescribers will not have the same authority as an appointed representative, such as the right to bring appeals at any level, the right to obtain information on appeals, etc. Instead, we envision that from the time of the initial IRE appeal request, the prescriber's role will remain what it has been—providing a supporting statement or the clinical information necessary to approve coverage, if appropriate. Accordingly, we believe that this proposal will promote enrollee access to the Part D appeals process, reduce the burden on the prescriber community, and allow a more efficient use of appeals resources.

We are proposing a corresponding change to § 423.602(a) to specify that the IRE is responsible for notifying the prescriber of its decision when the prescriber makes the request on behalf of the enrollee. The enrollee will receive a written decision notice from the IRE, ensuring that enrollees are fully informed about the review process and able to participate if they choose to do so. We intend to issue additional manual guidance regarding the specifics of prescriber notice requirements.

As in § 422.582 and § 423.580, we are proposing that prescribers must notify enrollees whenever they request IRE review on their behalf, and we intend to issue additional operational guidance with respect to how this requirement may be satisfied. Finally, we want to make clear that this proposal addresses only the right of a prescriber to file an appeal on behalf of an enrollee at the IRE level. Other individuals who wish to act on behalf of an enrollee in filing an appeal must continue to do so as the enrollee's representative.

5. Independence of LTC Consultant Pharmacists (§ 483.60)

Under sections 1819(b)(4) and 1919(b)(4) of the Act, long term care (LTC) facilities must provide, either directly or under arrangements with others, for the provision of pharmaceutical services to meet the needs of each resident. This requirement is codified in regulations at § 483.60, which require LTC facilities to employ or obtain the services of a licensed pharmacist to provide consultation on all aspects of the provision of pharmacy services in the facility, including a drug regimen review at least once a month for each facility resident.

In the process of performing the drug regimen reviews, if the consultant pharmacist recommends a modification of a resident's drug treatment regimen, he/she notates the resident's medical record with the recommendation to the prescribing physician. The prescribing physician must respond to the recommendation and, based on our experience, the physician generally follows it because the consultant pharmacist is considered to be an unbiased expert of pharmacology in the LTC setting. As a result of their role in LTC facilities, LTC consultant pharmacists have significant influence over the drugs that LTC facility residents receive.

In accordance with section 1860D–4(b)(1) of the Act, as codified in our regulations at § 423.120(a)(5), Part D sponsors are required to provide LTC facility residents who are plan enrollees convenient access to LTC pharmacies. We expect that each LTC facility would select one, or possibly more than one, eligible network LTC pharmacy to provide Medicare drug benefits to its residents. We have specified minimum performance and service criteria in the Medicare Prescription Drug Benefit Manual, Chapter 5 (''Benefits and Beneficiary Protections''), section 50.5.2 (available on the CMS Web site at: *http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter5.pdf).*

Commonly, nursing homes contract with a single LTC pharmacy for prescription drugs for facility residents. Very often the same LTC pharmacy then also contracts with the facility to provide consultant pharmacists for required consultation on all aspects of the provision of pharmacy services in the facility, including the monthly resident drug regimen reviews. In verbal conversations with industry representatives, we have been informed

that LTC pharmacies typically provide the consultant pharmacists to nursing homes at rates that are well below the LTC pharmacy's cost and below fair market value.

We have been concerned with the potential effect on patient safety and quality of care of various contractual arrangements involving LTC facilities, LTC pharmacies, the LTC consultant pharmacists these pharmacies provide to LTC facilities, and pharmaceutical manufacturers and/or distributors. These arrangements may take many forms. The practice of LTC pharmacies' providing consultant pharmacists to nursing homes at below cost or fair market value is one such type of arrangement. We are concerned that these arrangements may be used to entice nursing homes to enter into contracts with the LTC pharmacy for pharmacy dispensing services and the purchase of prescription drugs. We are greatly concerned with financial arrangements that involve payments from pharmaceutical manufacturers directly or indirectly to LTC pharmacies and LTC consultant pharmacists for encouraging physicians to prescribe the manufacturer's drug(s) for residents. The impact of these financial incentives is heightened when, as permitted under State law or by the State Pharmacy Board, LTC facilities sign agreements with LTC pharmacies permitting the consultant pharmacists to make medication switches. These types of arrangements may result in incentives for the LTC consultant pharmacist to make recommendations that conflict with the best interests of nursing home residents, as well as with Part D sponsors' formularies and/or drug utilization management (DUM) programs. Any such arrangements have the potential to directly or indirectly influence consultant pharmacist drug regimen recommendations. As a result, the arrangements bring into question the ability of the LTC consultant pharmacists to provide impartial reviews of the residents' drug regimens, which in turn raises concerns regarding the quality of those reviews and potential impact on resident health and safety.

Industry estimates indicate that three LTC pharmacy organizations have 90 percent of the market. Based on these estimates, the LTC pharmacy industry is highly concentrated, and we believe, therefore, these arrangements are widespread. As a result, we are concerned that the lack of independence of the consultant pharmacist from the interests of the LTC pharmacy or other LTC pharmacy-related organization may lead to recommendations that steer nursing home residents to certain drugs. This steering could result in the overprescribing of medications, the prescribing of drugs that are inappropriate for LTC residents, or the use of unnecessary or inappropriate therapeutic substitutions. Such potential outcomes can pose serious jeopardy to nursing home residents' health and safety. Although we have no evidence directly linking these arrangements to adverse outcomes, we believe a requirement under consideration that LTC consulting pharmacists be independent would be appropriate and prudent because it would ensure that financial arrangements did not influence the consultant pharmacist's clinical decision making to the detriment of LTC residents. Our concerns are not merely theoretical. We are aware of claims brought by qui tam relators under the False Claims Act alleging that, for instance, an LTC pharmacy received quarterly payments styled as rebates from the pharmaceutical manufacturer to engage in an active intervention program to convince physicians to prescribe a manufacturer's antipsychotic agent to the physicians' nursing home patients and to authorize all competitive products only after the failure of the manufacturer's product. In 2005, the Food and Drug Administration (FDA) issued warnings of the increasing death rate associated with the use of antipsychotic agents for behavioral symptoms for older persons with dementia. In reporting the results of 17 clinical trials, FDA noted an approximately 1.6 to 1.7 fold increase in mortality, compared to placebo-treated patients, in these studies.[1] Thus, any financial arrangements that encourage consultant pharmacists to prescribe these drugs to older LTC residents with dementia contrary to FDA warnings may detrimentally affect those residents' health and safety.

Recent research suggests the use of antipsychotic drugs in nursing homes remains high—higher, in fact, than the percentage of residents diagnosed with psychoses. Despite the serious safety concerns, researchers reported nearly 1 in 3 nursing home residents in the U.S. received antipsychotic drugs in 2007.[2] Prior research examining potentially inappropriate prescription drugs among nursing home residents found half of the almost 3,400 study residents were prescribed a potentially inappropriate prescription medication. Forty percent of these residents had medication that was identified as both inappropriate and generally to be avoided among older LTC residents; a third of these medications posed a potential for severe harm. The therapeutic class most prevalent was antipsychotic agents.[3]

More recently, a review by the HHS Office of Inspector General of Medicare Part D claims for atypical antipsychotics for elderly nursing home residents in the first half of 2007 found that 22 percent of those drugs were not administered in accordance with CMS standards for unnecessary drug use in nursing homes. The OIG also found a very high incidence of atypical antipsychotic prescribing for elderly nursing home patients with dementia despite the presence of an FDA black box warning that such prescribing is associated with increased mortality.

In addition to research findings, nursing home survey and certification data reported in the CMS online survey and certification reporting system indicate unnecessary drug use in nursing homes continues to be a problem. In 2006, we issued updated guidance for LTC survey and certification reviews of the use of potentially unnecessary medications.[4] The guidance, providing specific information on medications that are problematic to the nursing home population, was implemented in December 2006. In the 7 years prior to the implementation, the percent of surveys with a citation for unnecessary drug use ranged from 12.6 to 14.0 percent. Since implementation, however, the percent of surveys with these citations has increased yearly from 18.2 percent in 2007 to 19.4 percent in 2009.

The research and our survey and certification data indicate that the use of unnecessary medications, particularly antipsychotics, is problematic in LTC facilities. Although our findings do not directly connect LTC pharmacy relationships with consultant pharmacists to these research findings and survey results, we believe it is reasonable to presume that the

[1] FDA, Public Health Advisory: Deaths with Antipsychotics in Elderly Patients with Behavioral Disturbances, April 2005. Accessed online at *http://www.fda.gov/Drugs/DrugSafety/PublicHealthAdvisories/UCM053171* on May 26, 2010.

[2] Chen, Y, Briesacher, BA, Field, TS Tjia, J Lau, DT, Gurwitz, JH. Unexplained Variation across US Nursing Homes in Antipsychotic Prescribing Rates. *Archives of Internal Medicine.* 2010:170(11):89–95.

[3] Lau, DT, Kasper, JD, Potter, DE and Lyles, A. Potentially Inappropriate Medication Prescriptions among Elderly Nursing Home Residents: Their Scope and Associated Resident and Facility Characteristics. *Health Services Research.* 2004:39(5):1257–1276.

[4] CMS, Guidance for Unnecessary Drugs § 483.25(l), September 2006. Accessed online at *http://cms.gov/manuals/Downloads/som107ap_pp_guidelines_ltcf.pdf* on June 3, 2010.

incentives present in the relationships among consultant pharmacist, LTC pharmacies and drug manufacturers can influence the prescribing practices reflected in these data.

As a result, we believe requiring the independence of consultant pharmacists is necessary and appropriate and are considering making such a change. We solicit comments on our understanding in this matter, as well as on our changes under consideration discussed in this section.

We note further that, although Federal regulations at § 483.25(l) require LTC facilities to avoid unnecessary drugs, our experience indicates that this responsibility generally is delegated to the consultant pharmacist who is, for the most part, provided by the facility's contracted LTC pharmacy. According to a June 2008 report of a study by the HHS Office of Inspector General (OIG) regarding Part D drugs and LTC facility residents, about 80 percent of the 128 nursing home administrators interviewed for the study indicated the consultant pharmacists performing their facility's drug regimen reviews were employed by the nursing home's LTC pharmacy.[5] Further, this report states that 54 percent of the 79 pharmacy directors interviewed for the study reported that their pharmacy receives rebates from pharmaceutical manufacturers that are frequently based on market share or volume. However, only three of the pharmacy directors reported providing rebate information to the LTC facility. Thus, in delegating responsibility for avoiding use of unnecessary drugs to consultant pharmacists, nursing homes generally are unaware of any financial interests that can bias the pharmacist's drug recommendations.

Consultant pharmacists perform monthly drug regimen reviews for all LTC facility residents. During this review, the consultant pharmacist may recommend a medication change. In making a decision whether to accept the recommended change, prescribing physicians are likewise generally unaware of the LTC pharmacy rebate arrangements with pharmaceutical manufacturers that may influence the recommendation. In the previously cited report, the OIG noted that when a consultant pharmacist recommended a medication change during the drug regimen review, the recommendation was accepted by the prescribing physician about 74 percent of the time.[6] We believe severing the relationship between the consultant pharmacist and the LTC pharmacy, pharmaceutical manufacturers and distributors, and any affiliated entities would further protect the safety of LTC residents because it will ensure that financial arrangements do not influence the consultant pharmacist's clinical decision making to the detriment of LTC residents.

Therefore, we are considering requiring that LTC consultant pharmacists be independent of any affiliations with the LTC facilities' LTC pharmacies, pharmaceutical manufacturers and distributors, or any affiliates of these entities. For the reasons described in this section, we believe such a requirement is necessary to ensure that consultant pharmacist decisions are objective and unbiased. That is, LTC facilities must use a qualified professional pharmacist to conduct drug regimen reviews and make medication recommendations based solely on what is in the best interests of the resident. We believe this can be achieved only if the consultant pharmacist is working without the influence of conflicting financial interests that might otherwise encourage overprescribing and overutilization, which creates health and safety risks for residents. We note that some arrangements we are addressing here may also implicate the fraud and abuse laws for which the HHS OIG and the Department of Justice (DOJ) have jurisdiction.

The changes we are considering would use the authority available under sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act to require that LTC consultant pharmacists be independent. The cited statutory provision gives the Secretary authority to establish ''such other requirements relating to the health, safety, and well-being of residents * * *.''

We are considering requiring that long term care facilities employ or directly or indirectly contract the services of a licensed pharmacist who is independent. We also are considering including a definition of the term ''independence'' to mean that the licensed pharmacist must not be employed, under contract, or otherwise affiliated with the facility's pharmacy, a pharmaceutical manufacturer or distributor, or any affiliate of these entities. Our changes would also prohibit nursing homes from contracting for the provision of consultant pharmacy services with entities (such as a subsidiary of an LTC pharmacy) that have been created for the purpose of providing reorganized consultant pharmacist services.

We do not believe it necessary to define the terms ''affiliate'' or ''affiliated'' as we believe the meaning should be broadly interpreted to cover all relationships that incent overprescribing and inappropriate prescribing in LTC facilities. We do not intend, however, for any of the changes under consideration to prohibit any relationships that would be inherently free of conflict of interest. Thus, we solicit comment on the specific relationships that should be permitted.

We are aware that some Indian Tribes and Tribal organizations own LTC facilities that serve their members and that the Tribe may also own the pharmacy that serves the facility. We believe that the Tribal-owned LTC facility may employ the services of a pharmacist to provide consultation and perform drug regimen reviews who is also employed by the facility's pharmacy without violating the independence requirement. In these instances, because the LTC facility and pharmacy are commonly owned by the Tribe, the consultant pharmacist's incentives for prescribing are aligned with the best interests of not only the Tribal members who are LTC residents, but also the Tribe. We believe a similar alignment of interests would exist in Indian Health Services (IHS) owned facilities and Tribal facilities that are serviced by IHS pharmacies. We expect there are other LTC providers or systems in which the incentives for prescribing are similarly aligned to sufficiently limit the risk of conflicts of interest and ensure the best interests of the LTC residents are served. Therefore, we are thinking of including an exception for Tribal owned LTC facilities and pharmacies. We also solicit comment from the public on our interpretation that in these unique situations independence is not an issue because the risk of conflicts of interest is sufficiently limited.

We anticipate that if we were to require that LTC facilities engage independent consultant pharmacists, this would cause consultant pharmacists to reorganize to achieve independence from the parties (facility pharmacies, pharmaceutical manufacturers and distributors, and affiliated entities) with which the consultant pharmacists are currently affiliated. That is, we believe the consultant pharmacists currently assigned to LTC facilities would seek to

[5] HHS, Office of Inspector General, ''Availability of Medicare Part D Drugs to Dual-Eligible Nursing Home Residents,'' June 2008. Available online at *http://oig.hhs.gov/oei/reports/oei-02-06-00190.pdf.* Accessed on June 28, 2010.

[6] HHS, Office of Inspector General, ''Availability of Medicare Part D Drugs to Dual-Eligible Nursing Home Residents,'' June 2008. Available online at *http://oig.hhs.gov/oei/reports/oei-02-06-00190.pdf.* Accessed on June 28, 2010.

retain relationships with those facilities, either through direct employment or by banding together with other consultant pharmacists, for instance, in professional corporations. We believe that if the changes under consideration were to take effect beginning January 2013, such a time frame would provide sufficient time for implementation of the requirement. However, we recognize that there may be some areas where certain conditions or extenuating circumstances might argue for a longer implementation period. Specifically, we anticipate that LTC facilities in rural areas would face the greatest challenges in recruiting qualified consultant pharmacists, particularly if the consultant pharmacists currently serving the rural facilities do not reorganize in order to continue to provide services. Therefore, the requirements under consideration may need to be modified to assist these facilities. One way to assist would be to extend the time period for implementation. Thus, we are soliciting comment on whether to provide for a later effective date for rural facilities as opposed to other LTC facilities or to make other accommodations for the unique circumstances in which rural facilities operate. While we do not believe that any consultant pharmacist should have a conflict of interest, we are also soliciting comments on whether it would make sense to waive the independence requirement to permit alternative approaches. In describing these other approaches, comments should address the protections that would be implemented to reduce the risk of conflict of interest due to the lack of independence of the consultant pharmacists.

It is our understanding that LTC consultant pharmacists commonly perform approximately 60 drug regimen reviews in a day. We suspect that this rate may be too high given our expectation that independent consultant pharmacists would conduct more thorough drug regimen reviews, monitoring for drug side effects and efficacy. Therefore, although we are not proposing in this rule to codify changes to the drug regimen review requirements, we are soliciting public comment on best practices related to the conduct of drug regimen reviews. We will use these comments to inform possible future rulemaking regarding the drug regimen review requirements.

C. Excluding Poor Performers

This section includes three proposals designed to strengthen our ability to remove poor performers. We believe we could protect beneficiaries through the proposal that would enable us to terminate health care prepayment plans (HCPPs) whose administration does not meet specified financial, reporting, and access requirements.

A second proposal would enable us to look at the plan rating system, which we developed to provide beneficiaries with information about the quality and performance of health and drug plans to assist in plan selection during the open enrollment period. The plan ratings include process measures that focus on whether good medical care or drug care was provided, outcome measures that address the result of that care, and measures that relate to administrative processes that support and direct the provision of care. It is our view that the star rating system not only provides beneficiaries/consumers with easy-to-understand information critical for making choices among sponsors, but provides a powerful tracking tool that enables us to continue to administer the Part C and D programs with the best interests of the beneficiaries in mind.

We propose to give CMS the authority to terminate MAOs and Part D sponsors that have failed to provide, over a course of 3-years, service meriting at least 3-star ratings. A second proposal would give CMS the authority to deny applications submitted by MAOs and Part D sponsors that have performed poorly in the past. We anticipate that this proposal would directly enable us to protect beneficiaries from poor care. Both these provisions, in our opinion, would give entities that want to administer benefits to Medicare beneficiaries a strong incentive to pay attention to the star rating criteria and provide for better quality health care if they wish to stay in or join the program. See Table 3 for details of these proposals.

TABLE 3—PROVISIONS TO EXCLUDE POOR PERFORMERS

Preamble section	Provision	Part 417		Part 422		Part 423	
		Subpart	Section	Subpart	Section	Subpart	Section
II.C.1	CMS Termination of Health Care Prepayment Plans.	Subpart U	§ 417.801	N/A	N/A	N/A	N/A.
II.C.2	Plan Performance Ratings as a Measure of Administrative and Management Arrangements and as a Basis for Termination or Non-Renewal of a Medicare Contract.	N/A	N/A	Subpart K	§ 422.504 § 422.510	Subpart K	§ 423.505. § 423.509.

TABLE 3—PROVISIONS TO EXCLUDE POOR PERFORMERS—Continued

Preamble section	Provision	Part 417		Part 422		Part 423	
		Subpart	Section	Subpart	Section	Subpart	Section
II.C.3	Denial of Applications Submitted by Part C and D Sponsors with a Past Contract Termination or CMS-Initiated Non-Renewal.	N/A	N/A	N/A	§ 422.502	Subpart K	§ 423.503.

1. CMS Termination of Health Care Prepayment Plans (§ 417.801)

Section 1833(a)(10)(A) of the Act authorizes payment to HCPPs, but does not specify program requirements. Consequently, we have incorporated features of both section 1876 of the Act cost contract plan, and MA program regulations to establish benefit, enrollment, appeals, and other HCPP program features. For example, in our January 2005 final rule (70 FR 4588 through 4741), we extended fundamental features of the MA appeals process to HCPPs.

Although our current regulations at § 417.801(d) permit us to terminate a contract with an HCPP, we propose to codify specific reasons for HCPP termination in § 417.801(d) to strengthen our oversight and enforcement capability. In addition, specifying additional elements through notice-and-comment rulemaking would ensure that all HCPPs are aware that their failure to comply with such requirements may lead to termination of their contracts with us. Section 417.801(d) currently provides that we may terminate or not renew a contract with an HCPP if the HCPP: (1) No longer meets the requirements for participation and reimbursement as an HCPP; (2) is not in substantial compliance with the provisions of the agreement or applicable statutory or regulatory requirements; or (3) undergoes a change in ownership. We propose to retain the bases for termination but to modify § 417.801(d)(ii) to include three specific elements of substantial non-compliance with the CMS contract, applicable CMS regulations, or applicable provision of the Act as a basis for CMS termination of an HCPP.

First, in their agreements with us, HCPPs agree to provide adequate access to providers and to document such access. Accordingly, we would specify that failure to provide adequate access to providers, or documentation of such access, is a basis for determining that an HCPP is not in substantial compliance with applicable regulatory requirements. We propose to include this basis for termination in new paragraph (d)(1)(ii)(A). Second, HCPPs are required to provide data to us and to maintain financial records and statistics related to costs payable by CMS for CMS audit or review. This requirement is currently captured in § 417.806, which cross references financial records requirements at § 417.568, of the section 1876 cost contract plan regulations. We would specify, in new paragraph (d)(1)(ii)(B), that failure to provide such data and/or to maintain records appropriately is a basis for determining that an HCPP is not in substantial compliance. Third, HCPPs must report costs to us in addition to maintaining financial records and following other financial requirements specified at § 417.568 of the cost contract program regulations. Currently, these requirements are also referenced in HCPPs' agreements with CMS. We propose that a new paragraph at (d)(1)(ii)(C) would specify that a failure to report costs to CMS will constitute a basis for determining that an HCPP is not in substantial compliance.

2. Plan Performance Ratings as a Measure of Administrative and Management Arrangements and as a Basis for Termination or Non-Renewal of a Medicare Contract (§ 422.504, § 422.510, § 423.505, and § 423.509)

Since 2007, we have developed and published annual performance ratings for all stand-alone Medicare PDPs. In 2008, we began issuing ratings for MA plans as well. The ratings are based on measures that address a range of health and drug plan performance categories, including access to care, communication with members, and clinical quality of care. The scores in each performance category are based on data reported by MA organizations and PDP sponsors, beneficiary survey responses, and monitoring conducted by CMS and its contractors. We rate MA organizations and Part D sponsors on a 5-star scale, with the best performers receiving a rating of 5 stars. The organizations receive a score for each performance measure, a summary score each for Part C and Part D, as well as an overall rating. Under the methodology developed and applied by CMS for its star rating process, a rating of 3 or more stars is an indication of sponsors with ''average'' or better performance. By contrast, organizations receiving a summary or overall score below 3 stars are among the weakest performers in the Medicare Part C and D programs.

The Medicare regulations at § 422.503(b)(4) and § 423.504(b)(4) state that, to qualify as an MAO or Part D sponsor, an organization must have administrative and management arrangements satisfactory to CMS, including, per § 422.503(b)(4)(ii) and § 423.504(b)(4)(ii), personnel and systems sufficient for the organization to implement, control, and evaluate the activities associated with the delivery of Part C and D benefits. Once under contract with CMS as an MAO or Part D sponsor, an organization remains obligated to maintain satisfactory administrative and management arrangements, a point we propose to clarify by adding paragraphs § 422.504(a)(17) and § 423.505(b)(25) to the list of required elements in CMS' contracts with MAOs and Part D sponsors. Also, as explained later in this section, we believe that the plan ratings are a direct indicator of the ongoing effectiveness of a contracting organization's administrative and management arrangements. Therefore, we propose adding paragraphs § 422.504(a)(18) and § 423.505(b)(26) to require an organization to demonstrate that it maintains satisfactory administrative and management

arrangements by achieving a summary plan rating of at least 3 stars each year.

We also propose to establish the failure to achieve a 3-star summary rating consistently as a basis for contract termination. As the measures in the star ratings are based largely on Part C and D program requirements, and the plan ratings are a reflection of a sponsor's performance across a range of program areas, we believe that a sponsor with a low Part C or Part D summary star rating has failed in a significant way to meet its obligations as an MAO or Part D sponsor. (As we calculate the summary rating score by taking an average of the measure-level stars, sponsors can receive scores on individual measures of less than 3 stars but still achieve a summary rating of at least 3 stars.) A sponsor that fails to achieve a good rating for 3 consecutive years has demonstrated consistently that it is unable or unwilling to take corrective action to improve its Part C or D performance.

As noted previously, to qualify as an MAO or Part D sponsor, an organization must have effective administrative and management arrangements. Such arrangements involve the allocation and coordination of an organization's resources to ensure that it can fulfill the entire range of its obligations related to the delivery of Medicare benefits. Of course, the importance of these arrangements only increases once an organization has entered into an MAO or Part D sponsor contract as the quality of the arrangements is tested repeatedly by the process of actually delivering Medicare benefits in a timely and effective manner during the term of the contract. Because of the critical role administrative and management arrangements play in ensuring an organization's compliance with its Medicare obligations, we believe it is necessary to make clear, by adding to the set of required CMS contract elements, that organizations must continue to maintain effective administrative and management arrangements even after they have entered into Medicare contracts. Accordingly, we propose adding paragraphs § 422.504(a)(17) and § 423.505(b)(25) which state that the maintenance of effective administrative and management arrangements is a material term of the MAO and Part D sponsor contracts. The summary rating for a plan sponsor is calculated according to the methodologies outlined in the Plan Star Ratings technical notes, and is based on a formula that factors in a sponsor's scores on all measures pertaining to Part C to calculate the Part C summary rating and pertaining to Part D to calculate the Part D summary rating. Organizations that offer both Part C and Part D benefits receive an overall rating that combines the Part C and D star ratings results. To evaluate an organization's administration and management capabilities accurately, it is necessary to review its performance across a range of operational areas. Because the summary Plan Rating scores are based on a sponsor's performance of a wide range of Medicare requirements within each of the MA and Part D programs, the scores are a reliable measure of the quality of an organization's administrative and management arrangements. Therefore, to articulate the standard by which we would measure compliance with that obligation, we propose to establish as a requirement that organizations must achieve a summary plan rating of at least 3 stars for each of Part C and Part D each year by adding paragraph § 422.504(a)(18) and adding paragraph § 423.505(b)(26). It would not be appropriate to use the overall rating for this purpose, as organizations that offer both Part C and Part D benefits must fully meet the requirements of each program independently. It is conceivable that if we exclusively rely upon the overall measure, strong performance within one program could mask poor performance in the other program, which would not be an acceptable outcome.

The star ratings may also be used as a basis for contract enforcement actions. We have the authority under section 1857(c)(2) of the Act to terminate CMS' contract with an MAO or a Part D sponsor when we determine that the organization has failed substantially to carry out the contract or is carrying out the contract in a manner inconsistent with the efficient and effective administration of the Part C or D programs. A summary rating of less than 3 stars can be achieved only when a sponsor demonstrates poor performance across a range of measures. Therefore, we believe that sponsors that consistently achieve poor plan ratings have demonstrated a substantial failure to comply with the terms of their Medicare contracts. Also, low-rated sponsors interfere with the efficient and effective administration of the MA and Part D programs as beneficiaries rely on us to ensure that the array of plan choices only includes offerings from sponsors that have demonstrated that they can provide at least good quality services to their members.

Accordingly, we propose to amend the bases upon which CMS may terminate an MAO or Part D sponsor contract under § 422.510(a) and § 423.509(a) to include a sponsor's failure to achieve at least a 3-star summary plan performance rating for three consecutive contract years. We believe that 3 years is sufficient time for a sponsor, once it has received notice of its low star rating, to develop and implement corrective action and for improved performance to be reflected in the star ratings issued at the conclusion of the 3-year period.

We base our determinations that good plan ratings are indicative of the strength of an organization's administrative and management arrangements and that consistently poor plan ratings are a basis for contract termination on the fact that the elements of the plan ratings correlate to Part C and D requirements described in applicable statutes and regulations. While the exact measures may vary slightly from year to year, each year's plan ratings are based on similar elements from previous years, as they are developed in consultation with a workgroup of industry stakeholders and based on a review of stated Part C and D program requirements. The most recent plan ratings, issued in September 2010, provide a useful template for demonstrating the correlation between program requirements and the performance measured. (See 2011 Part C Technical Notes and 2011 Part D Plan Ratings Technical Notes: September 2010.)

The 2010 Part C plan ratings were organized into five domains—''Staying Healthy: Screenings Tests, and Vaccines''; ''Managing Chronic (Long Term) Conditions''; ''Ratings of Health Plan Responsiveness and Care''; ''Health Plan Members' Complaints and Appeals''; and ''Health Plan Telephone Customer Service.'' The Part C regulations at § 422.152(a)(2) state that MAOs must conduct quality improvement projects that can be expected to have a favorable effect on health outcomes and enrollee satisfaction and address areas identified by CMS. The Staying Healthy measures evaluated the extent to which MAOs provided screenings to their members for conditions such as breast cancer, colorectal cancer, elevated cholesterol, glaucoma, and osteoporosis, as well as providing monitoring to patients with long term medication, and flu vaccines to plan members. As these measures have been consistently included in the Part C plan ratings over a period of several years, it is fair to say that MAOs have known over that same timeframe that we would rate them on quality improvement projects designed to address the identified conditions and that they should take action to improve

their scores for this measure. Moreover, we have clearly fulfilled our obligation under § 422.152(a)(2) to identify areas that MAOs need to address for this purpose by annually publishing the methodology and results both publicly on the CMS Web site and in the form of private previews for MAOs to review their own results. As a result, an MAO's score in the ''Staying Healthy'' domain is a fair measure of the extent to which it is complying with § 422.152(a)(2).

The ''Managing Chronic (Long Term) Conditions'' domain most closely mirrors the requirements at § 422.152(a)(1) which obligate MAOs to have a chronic care improvement program that addresses populations identified by us based on a review of current quality performance. The measures in this domain concern the management of conditions such as osteoporosis, diabetes, and high blood pressure. Again, the measures have remained largely constant for a number of years, so MAOs have had effective notice that we had identified beneficiaries with those conditions as the populations for which we would expect sponsors to implement effective chronic care improvement programs. The measures related to the ''Health Plan Responsiveness and Access to Care'' domain demonstrate an MAO's compliance with its obligations under § 422.112(a)(1) to maintain a provider network sufficient to ensure its enrollees' access to covered services. The measures ''Getting Needed Care'' and ''Getting Appointments and Care Quickly'' are both based on the results of beneficiary surveys concerning their experiences in being able to get timely appointments with plan-contracted providers. The measure ''Doctors Who Communicate Well'' reflects enrollees' responses to a series of questions concerning the quality of their interaction with plan-contracted physicians, including the amount of time the physicians spent with an enrollee and the care with which the physicians conducted appointments, all of which indicate the extent to which those services are provided in a manner consistent with professionally recognized standards of health care, per § 422.504(a)(3)(iii).

In the ''Health Plan Member's Complaints and Appeals'' domain, we provide a rating of the extent to which an MAO affords its members their coverage determination appeal rights under the Part C program. The Part C regulations at Part 422, Subpart M, require MAOs to adhere to standards and timeframes for issuing timely and accurate determinations concerning the coverage of health services for their members as well as the processing of their appeals of such determinations. The ''Makes Timely Decisions about Appeals'' rating measures the extent to which an MAO meets the regulatory deadlines for issuing responses to member appeals while the ''Reviewing Appeals Decisions'' rating measures the frequency with which the MAO determinations were overturned by the Independent Review Entity (IRE). The analysis for these measures was conducted by Maximus, Inc., which we contracted as an IRE for Part C appeals. The remaining measures under this domain, ''Complaints about the Health Plan'' and ''Corrective Action Plans'' (CAPs) provide a more general view of an MAO's performance from two different perspectives. The ''Complaints'' measure is based on a calculation of the rate (that is, complaints per 1,000 members) at which we receive complaints from beneficiaries, providers, or others affected by the MAO's operations. The CAP measure reflects the number and type of findings made by us during an audit of an MAO's performance. Thus, these two measures provide a snapshot of the MAO's compliance with range of requirements from the perspective of the members it must serve as well as CMS.

The ratings in the last Part C domain, ''Health Plan Customer Service,'' are the product of a series of measures related to the requirement that MAOs operate a customer service call center that is responsive to the needs of Medicare beneficiaries. In particular, the domain rating is based on the results obtained by a CMS contractor that conducts test calls to MAO customer service lines to assess the extent to which the call centers provide accurate plan information, in languages spoken by beneficiaries residing in the plan's service area, and with limited hold times consistent with the standards stated in the Medicare Marketing Guidelines we have issued pursuant to § 422.111(g).

The four domains of the Part D Plan Ratings similarly correspond to the requirements with which Part D plan sponsors must comply. The Part D domains are ''Drug Plan Customer Service;'' ''Drug Plan Member Complaints and Medicare Audit Findings;'' ''Member Experience with the Drug Plan;'' and ''Drug Pricing and Patient Safety.'' The domain ''Drug Plan Customer Service'' includes measures concerning hold times, accuracy of information, and foreign language interpretation services are the Part D equivalents of the measures used in the Part C plan rating. They reflect the Part D sponsor's compliance with the customer service call center requirements described in the Medicare Marketing Guidelines issued in accordance with § 423.128(d)(1). The measure related to hold times for pharmacists' calls to the sponsor are evidence of the sponsor's compliance with the requirement, stated at § 423.128(d)(1) that the sponsor operate a call center to provide technical assistance to pharmacists concerning their plan operations. This domain also contains three measures related to plan performance of its obligations related to the issuance of coverage determinations and processing of members' appeal requests, per Part 423, Subpart M. The last measure in this domain indicates the extent to which a sponsor is complying with CMS processes for ensuring that the data used by pharmacists to determine a customer's Part D plan enrollment is accurate and up to date. The provision of this data, referred to as ''4Rx data'' is part of Part D sponsors' obligation, stated at § 423.505(b)(2), to process enrollments in a manner consistent with the requirements stated in Part 423, Subpart B.

The second domain, ''Drug Plan Member Complaints and Medicare Audit Findings,'' consists largely of the same kind of measures related to beneficiary satisfaction and CMS audit findings as included in the Part C plan ratings, and the discussion provided above of their bearing on a determination of a sponsor's compliance with program requirements is applicable to the Part D ratings as well.

The ''Member Experience with Drug Plan'' domain consists of measures related to plan members' experience in getting access to information about their Part D plan or getting prescriptions filled easily when using the plan. These measures provide evidence of a sponsor's compliance with the requirement, stated at § 423.128, that it disseminate information about its Part D plans, and that it provide benefits through a point of claims adjudication system (per § 423.505(b)(17)) operated through a contracted pharmacy network that meets Part D access requirements (per § 423.120).

The ''Drug Pricing and Patient Safety'' domain consists, in part, of measures related to a sponsor's ability to maintain and transmit accurate information related to its members' LIS eligibility status and the information concerning drug prices available at network pharmacies. Under this domain, CMS assesses, by comparing its data with that of Part D sponsors, the accuracy of a sponsor's records concerning the LIS status of its members, a significant part

of their obligation under § 423.800 to participate in the administration of the low-income subsidy portion of the Part D benefit program. With respect to drug pricing, we compare sponsors' data reported to us with other data sources, including prescription drug event data and data from commercially available drug pricing reference files. The remaining two measures in this domain assess the sponsor's efforts to ensure that its members are being directed away from drugs with a high risk of side effects and that those members with diabetes are treating their high blood pressure with medication appropriate for their condition. Both of these measures are indications of a sponsor's compliance with its obligation under § 423.150(c) to develop and implement drug utilization review systems that identify patterns of inappropriate care among its enrollees.

The thresholds we have established for the star ratings in each category are based on regulatory standards or our review of industry performance over several years. From that systematic review, for each regulatory standard-based measure we consider the actual contract scores in relation to a theoretical distribution of all possible measures with the regulatory standard considered a 3-star rating. (For example, in 2008 CMS announced to Part D sponsors that, after a review of industry performance during the first 2 years of the Part D program, we had established that sponsors would be required to submit 4Rx data for 99 percent of their enrollment transactions to be considered compliant with Part D enrollment processing requirements.) When an absolute performance standard has not yet been established, we look at a contract's performance on a measure relative to all other contracts' performance on the same measure. In either case we usually segment the range of the actual contract scores for each measure into one of the 5-star groupings. The segmentation of the scores into groups is based on statistical techniques that minimize the distance between scores within a grouping (or ''cluster'') and maximize the distance between scores in different groupings. There may not be clusters in each grouping, therefore there could be as many as 5 or as few as one rating in the final data. In developing that methodology, we reserved 1- and 2-star ratings for performance that was significantly below what a review of industry-wide performance would show to be acceptable and achievable by competently administered sponsors. This establishment of compliance standards through the analysis of all Medicare contractors' performance to identify outliers is consistent with our regulatory authority at § 422.504(m)(2) and § 423.505(n)(2). We have previously issued guidance (for example, CY 2012 Call Letter, page 119, issued April 4, 2011) to MAOs and Part D sponsors indicating that we considered organizations with 3 consecutive years of less than 3-star Plan Ratings to be out of compliance with Medicare program requirements. We stated there that organizations with such a Plan Rating history should expect that, prior to initiating a termination action, we would confirm that the data used to calculate the Plan Ratings did reflect an organization's substantial failure to comply with Part C or D requirements. In essence, we noted that poor Plan Rating scores were a strong indication, but not conclusive evidence, of substantial non-compliance. In applying that policy, we include Plan Ratings issued in years prior to the issuance of the guidance to identify organizations whose performance may warrant contract termination.

With the elevation of low Plan Ratings from the status of likely indicator to conclusive evidence of substantial non-compliance, we believe that the use of prospective Plan Ratings is more appropriate in our application of this authority. Therefore, we propose that we would not begin calculating the 3-year period until after organizations have received notice through the rulemaking process of the new basis for contract termination. As we plan on this proposal to be issued as part of a final rule in the spring 2012, we expect to use only those Plan Ratings issued after the publication of the final rule. That is, we would use the contract year 2013 Plan Ratings, which we expect to issue in September 2012, as the first set of ratings in the calculation of any sponsor's 3 consecutive years of Plan Ratings. We invite public comment on our proposal for identifying the first set of Plan Ratings we would use in determining whether a sponsor's performance during 3 consecutive years supported a CMS decision to terminate its Medicare contract.

3. Denial of Applications Submitted by Part C and D Sponsors With a Past Contract Termination or CMS–Initiated Non-Renewal (§ 422.502 and § 423.503)

In accordance with § 422.502(b) and § 423.503(b) applicants with current or prior contracts with CMS are subject to our denial of their applications if they fail during the preceding 14-months to comply with the requirements of the Part C or D programs even if the applications otherwise demonstrate that they meet all of the Part C or D sponsor qualifications. In the April 2011 final rule (76 FR 21432), we added provisions at § 422.502(b)(2) and § 423.503(b)(2) concerning the treatment of entities submitting applications to us when the entity has operated its contract(s) with CMS for less than 14-months at the time it submits a new application or service area expansion request. In the interest of ensuring that new entrants to the Part C or Part D programs can fully manage their current contracts and books of business before further expanding, we added a provision that in the absence of 14-months performance history, we may deny an application based on a lack of information available to determine an applicant's capacity to comply with the requirements of the Part C or Part D program, respectively.

At this time, we are proposing to further refine our intended approach to using past performance in making application determinations. Specifically, we are concerned about entities submitting applications to us when the entity has had a previous Medicare contract terminated or non-renewed by CMS. We initiate termination or non-renewal of a contract only when the MA organization or Part D sponsor has committed extremely serious violations of the Part C or Part D program. In the past, these contract actions by CMS have been rare. The bases for a termination are specified in § 422.510 and § 423.509, and include such serious violations as substantially failing to carry out the terms of its Medicare contract; committing fraud; and failing to carry out the requirements for beneficiary access to services by, for instance, not implementing required appeals and grievance processes or not establishing provider and pharmacy networks that meet our requirements. The bases for a CMS-initiated non-renewal are specified in § 422.506(b) and § 423.507(b), and include the same list of violations, plus several others. Nevertheless, despite the seriousness of termination and CMS-initiated non-renewal actions, and the underlying noncompliance that would have led to such a drastic step, the regulation is silent concerning when these organizations may re-enter the Part C and Part D programs. As such, we currently rely upon the past performance provisions in § 422.502(b)(1) and § 423.503(b)(2) to determine whether an application from a previously terminated or CMS-non-renewed organization is approvable. These provisions limit the period of time we can review for purposes of

assessing past performance to 14-months. Fourteen months is a reasonable amount of time to review the performance of organizations with current and ongoing Medicare Part C and Part D contracts. In the case of organizations whose performance was so poor as to have their contract(s) terminated or non-renewed by CMS, we believe that a 14-month look-back is an inadequate amount of time.

In contrast to the regulation's silence on a ''waiting period'' for organizations whose contracts have been terminated or non-renewed by CMS, long-standing provisions at § 422.506(a)(4), § 422.508(c), § 422.512(e), § 423.507(a)(3), § 423.508(e), and § 423.510(e) require that organizations that have voluntarily non-renewed or terminated their contracts must wait 2 years before they may reenter the program. We believe that the interval between the effective date of a contract's CMS-initiated termination or non-renewal should be no less than in the case of a voluntary termination or non-renewal. Indeed, a period of greater than 2 years is appropriate, for these entities have broken faith with the program in a more significant way than in the case of a voluntary non-renewal.

As such, we are proposing to modify the past performance review period to capture CMS-initiated terminations or non-renewals that became effective within the 38 months preceding the submission of a new application. The selection of 38 months accounts for a 3-year period, plus the 2 months of the year during which applications are being prepared for submission to CMS. Three years represents 1 additional year compared to the 2 years of waiting time for voluntary non-renewals. To make this change, we propose adding new paragraphs at § 422.502(b)(3) and at § 423.503(b)(3) to state that if CMS has terminated or non-renewed an MA organization's or Part D sponsor's contract, effective within the 38 months preceding the deadline established by CMS for the submission of contract qualification applications, we may deny an application based on the applicant's substantial failure to comply with the requirements of the Part C or Part D program even if the applicant currently meets all of the requirements of this part.

Additionally, in the April 2011 final rule, we defined ''covered persons'' for the purpose of determining which organizations are prohibited from re-contracting with CMS for the two years following a voluntary non-renewal. Specifically, we codified that the 2-year ban on new Part C or Part D sponsor contracts to which non-renewing organizations are subject under the regulation be expanded to include organizations owned or managed by an individual (referred to as a covered person) who served in a similar capacity for a previously non-renewed Part C or Part D organization. The requirement assists CMS in prohibiting and preventing each such organization from gaming the Medicare program by reapplying for a contract as a new organization during the 2-year ban, when the applying organization has common ownership and management control. In essence, this requirement helps ensure that the provisions of the 2-year application prohibition are given full effect.

For consistency and to prevent the same sort of gaming by organizations whose contracts have been terminated or non-renewed by CMS, we propose to add new paragraphs at § 422.502(b)(4) and at § 423.503(b)(4) to replicate the existing language concerning covered persons as currently exists for voluntarily-non-renewing organizations. Specifically, the newly proposed language states that in implementing the 38-month provision, we may deny an application where the applicant's covered persons also served as covered persons for the terminated or non-renewed contract. As with the voluntary non-renewal provisions, in this instance ''covered person'' would mean one of the following: (1) All owners of terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent; (2) an owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the organization; (3) a member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

The combined effect of these proposals is to ensure appropriate requirements exist concerning program re-entry subsequent to all types of terminations and non-renewals, and to strengthen the past performance review to capture the most serious types of non-compliance (resulting in CMS-initiated terminations and non-renewals) for a more reasonable period of time.

D. Improving Program Efficiencies

By reducing regulatory burdens for MA Organizations, Part D sponsors, and cost contractors, lowering transaction costs, and reducing waste and unnecessary spending, we believe we can improve program efficiency and keep costs down and improve the quality of care received by Medicare beneficiaries. Non-renewing cost contractors would save money if we eliminated the current regulatory requirement to purchase print advertising announcing their non-renewals. Implementing the hospital-acquired conditions (HACs) and present on admission indicator policy that is currently required under the Original Medicare Inpatient Hospital Prospective Payment system (IPPS) for MA plans would continue our efforts to enhance quality and efficiency of care, and promote incentives for hospitals to eliminate medical errors and reduce Medicare expenditures for poor quality or unnecessary care. MAOs and Part D sponsors that are no longer tied to particular agent/broker compensation amounts would save transaction and other costs if rules regarding agent/broker compensation were made more flexible. Cost-sharing tailored to a trial fill of a prescription drug would not only save money for each beneficiary who found that the drug did not work for him or her, but would also lessen the problems of disposal or diversion of unused drugs.

These proposals and others are outlined in Table 4.

TABLE 4—PROVISIONS TO IMPROVE PROGRAM EFFICIENCIES

Preamble section	Provision	Part 417		Part 422		Part 423	
		Subpart	Section	Subpart	Section	Subpart	Section
II.D.1	Cost Contract Plan Public Notification Requirements in Cases of Non-Renewal.	Subpart L	§ 417.492	N/A	N/A	N/A	N/A
II.D.2	New Benefit Flexibility for Fully-Integrated Dual Eligible Special Needs Plans (FIDE SNPs).	N/A	N/A	Subpart C	§ 422.102	N/A	N/A
II.D.3	Application of the Medicare Hospital-Acquired Conditions and Present on Admission Indicator Policy to MA Organizations.	N/A	N/A	Subpart C	§ 422.504	N/A	N/A
II.D.4	Clarifying Coverage of Durable Medical Equipment.	N/A	N/A	Subpart C	§ 422.100, § 422.111.	N/A	N/A
II.D.5	Broker and Agent Requirements.	N/A	N/A	Subpart V	§ 422.2274	Subpart V	§ 423.2274
II.D.6	Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse and Waste Control Program.	N/A	N/A	N/A	N/A	Subpart D	§ 423.104, § 423.153

1. Cost Contract Plan Public Notification Requirements in Cases of Non-Renewal (§ 417.492)

Section 1876 of the Act provided the Secretary with the authority to enter into contracts with HMOs on a cost basis. While section 1876(k)(1)(A) of the Act precludes the Secretary from entering into new cost contracts after the establishment of Part C, existing contracts are grandfathered, and subject to regulations, including § 417.492, which sets forth rules that apply to non-renewal of a cost contract.

In the event that such a contract is non-renewed, the cost plan or CMS must notify both the enrollees of the organization and the general public of the non-renewal. As specified in § 417.492(a)(1)(iii), public notification must include ''notice in one or more newspapers of general circulation in each community or county located in the HMO's or CMP's geographic area.'' We propose removing the current requirements at § 417.492(a)(1)(iii) and (b)(1)(iii) for non-renewing cost-contracting plans (in voluntary non-renewal situations) and for CMS (in CMS-initiated non-renewal situations) to notify the general public concerning the impending non-renewal. Our proposed removal of this requirement is motivated by the cost of newspaper advertisements and the declining rate of newspaper circulation. In addition, we believe that the requirement that cost plans provide personalized non-renewal information is sufficient to ensure adequate non-renewal notice.

2. New Benefit Flexibility for Fully-Integrated Dual Eligible Special Needs Plans (FIDE SNPs) (§ 422.102)

Congress established dual eligible SNPs (D–SNPs) under the Medicare Modernization Act of 2003 (MMA) with the intention of better integrating care for individuals eligible for both Medicare and Medicaid (''dual eligible'' beneficiaries). The Affordable Care Act created a subset of D–SNPs, fully-integrated dual eligible SNPs (FIDE SNPs), which CMS further defined in our April 2011 final rule (76 FR 21443 and 76 FR 21444) at § 422.2 as D–SNPs that: (1) Provide dual eligible beneficiaries access to Medicare and Medicaid benefits under a single managed care organization; (2) coordinate delivery of covered Medicare and Medicaid health and long-term care services; (3) possess a valid capitated contract with the State for specified primary, acute, and long-term care benefits consistent with State policy; and (4) comply with CMS and State policy regarding marketing, appeals, quality assurance, and enrollment communication procedures.

Section 2602(c) of the Affordable Care Act also charged us with making Medicare and Medicaid work together more effectively to improve patient care and lower costs. Thus, we are implementing initiatives aimed at improving quality and access to care for dual eligible beneficiaries, simplifying processes, and eliminating regulatory conflicts and cost-shifting that occurs between the Medicare and Medicaid

programs, States, and the Federal government. (For more information on this initiative, see our CY 2012 Call Letter, at *http://www.cms.gov/MedicareAdvtgSpecRateStats/Downloads/Announcement2012.pdf.*) To further these goals, we propose to give certain SNPs additional flexibility with respect to plan design, as discussed in detail later in this section. Under this proposed rule, FIDE SNPs that are currently operational, that have operated in the previous contract year, and that meet certain CMS criteria including, but not limited to, being of high-quality (as defined by CMS in the calendar year 2013 draft/final call letter), would be afforded this benefit flexibility.

Section 1852(a)(3) of the Act and our regulations at § 422.2, § 422.100(c)(1), and § 422.102 allow us considerable discretion in deciding what benefits beyond those covered under Medicare Parts A, B, or D can be offered to MA enrollees as a ''supplemental benefit'' that is included in an MA plan for every enrollee who joins the plan (other benefits may be offered at the enrollee's option). We are interested in assessing whether certain supplemental benefits could help prevent health status decline in the dual eligible population, and reduce the quantity and cost of future health care needs. To this end, and as described in this section, we propose amending our regulations at § 422.102(e) to allow certain FIDE SNPs that CMS deems eligible the flexibility to offer supplemental benefits beyond those that we currently allow for MA plans.

We currently apply the same guidance as to what can be offered as a supplemental benefit to all MA plans, regardless of plan type. In recent years, we have used guidance (see § 30.1 of Chapter 4 of the Medicare Managed Care Manual, ''Benefits and Beneficiary Protections,'' *http://www.cms.gov/manuals/downloads/mc86c04.pdf*) to clarify that supplemental benefits must be items and services that are—

- Primarily health related, meaning that an item or service is directly health-related, not for comfort or cosmetic or daily maintenance purposes, and has a use that is either national typical usage or part of a community pattern of care;
- Have a cost—that is, a non-zero direct medical cost associated with their provision; and
- Not Part A- or B-covered benefits.

This guidance was based on concerns that competitive pressures were leading some MA organizations to spend Medicare rebate dollars (MA organizations with ''bid'' amounts for covering A and B services below the A and B ''benchmark'' amount for their county may use a percentage of the difference to offer additional benefits) on items that were more focused on providing marketing and enrollment incentives than on delivering quality, cost effective health care. We also were concerned that MA organizations could attempt to offer supplemental benefits that discriminate against certain enrollees and thereby violate the anti-discrimination prohibition in section 1852(a)(3) of the Act.

While these concerns still prevail, we believe that allowing certain SNPs greater flexibility in offering supplemental benefits beginning contract year 2013 would advance our overall goal of better integrating care for dual eligible beneficiaries. In addition, by limiting benefit flexibilities to those plans that are qualified to participate in this initiative, we reduce the likelihood that States could shift costs to the Medicare program by cutting Medicaid services and benefits from their State Medicaid plans.

We propose limiting the flexibility that would be offered under this proposed rule to FIDE SNPs. Because FIDE SNPs are required to offer LTC supports and services, we believe that an approach that limits benefits flexibility to FIDE SNPs, as opposed to all D–SNP types, would be more consistent with the objective of keeping beneficiaries at risk of institutionalization in their homes, preventing health status decline that triggers additional utilization of health services, and lowering costs for the Medicaid and Medicare programs. We request comment on whether extending supplemental benefit flexibilities under our proposed § 422.102(e) to eligible SNPs that are SNP types other than FIDE SNPs could measurably reduce unnecessary utilization and improve beneficiary outcomes in an equivalent manner.

We are also proposing to further limit the benefit flexibility under this proposed rule to those qualified SNPs that serve only full-benefit dual eligible beneficiaries. We believe that dual eligible beneficiaries who receive full State Medicaid benefits would have the most to gain from fully-integrated Medicare-Medicaid plan benefit offerings that include additional Medicare supplemental benefits. Furthermore, in circumstances where a State reduces coverage of a Medicaid benefit, we believe that the ability to offer additional Medicare supplemental benefits to full-benefit dual eligible enrollees is particularly critical in order to ensure continuity of care.

We are particularly interested in assessing whether certain supplemental benefits could prevent health status decline in the dual eligible population and reduce the quantity and cost of future health care needs. Examples of benefits that could be offered under this proposed rule would include—

- Personal care services in the home;
- Non-skilled nursing activities in the home;
- Custodial care; and
- In-home food delivery for vulnerable beneficiaries. (We note that our current guidance on supplemental benefits permits in-home food delivery on a limited basis—that is, for a limited duration and only in certain circumstances.)

We would review each qualified SNP's proposed supplemental benefit offerings for conformance to the SNP's model of care (MOC), and we would approve additional supplemental benefit offerings for these qualified SNPs as we deem necessary.

We request comment on what specific categories and types of supplemental benefits we should consider for the purposes of extending benefits flexibility to qualified FIDE SNPs participating in this initiative, as well as on the circumstances under which plans should be permitted to offer these additional supplemental benefits. We also request comment on additional restrictions that should govern plans' ability to offer these additional benefits, and how we might be able to expand the scope of approved supplemental benefits in a manner that allows plans to serve their dual eligible enrollees effectively and efficiently.

We also recognize that the services, Medicare Part C premium coverage, and out-of-pocket (OOP) cost-sharing benefits that dual eligible beneficiaries receive vary according to their Medicaid eligibility category and the State where they reside. We request comments on ways to minimize this proposed provision's cost impact on dual eligible beneficiaries, while ensuring that States, SNPs, and providers can feasibly provide additional supplemental benefits to a full benefit dual eligible population.

In order to implement this proposal, we propose amending § 422.102 to add a new paragraph (e) specifying that, subject to CMS approval, and as specified annually by CMS, certain FIDE SNPs may offer additional supplemental benefits beyond those other MA plans may offer where CMS finds that the offering of such benefits could better integrate care for the dual eligible population. All such benefits would be consistent with the rules for supplemental benefits under Part 422, including § 422.2, § 422.100(c)(1), and

§ 422.102. Assuming that this proposal is finalized, we would issue guidance in our annual Call Letter and in Chapter 4 of the Medicare Managed Care Manual—to provide guidance on the applicability of this provision, as well as examples of the specific additional supplemental benefits flexibilities that could be afforded under this initiative. We solicit comments on this approach.

3. Application of the Medicare Hospital-Acquired Conditions and Present on Admission Indicator Policy to MA Organizations (§ 422.504)

We propose to require by regulation that MA organizations provide in their contracts with hospitals that they will reduce payments for Part A hospital services for serious events that could be prevented through evidence-based guidelines, in accordance with the hospital-acquired conditions (HACs) and present on admission indicator (POA) policy that is currently required for hospitals paid under the Original Medicare Acute Care Hospital Inpatient Prospective Payment System (IPPS). We believe this proposed change is necessary to bring MA requirements in line with current HAC–POA policy in the fee-for-service Medicare program, as well as—in the near future—to the Medicaid program.

Section 5001(c) of the Deficit Reduction Act of 2005 (DRA) added section 1886(d)(4)(D) of the Act to require a quality adjustment in Medicare Severity Diagnosis Related Group (MS–DRG) payments for certain hospital-acquired conditions. We have titled the provision ''Hospital-Acquired Conditions and Present on Admission Indicator Reporting'' (HAC & POA). For discharges occurring on or after October 1, 2008, IPPS hospitals do not receive the higher payment for cases when one of the selected conditions is acquired during hospitalization (that is, was not present on admission). The case is paid as though the secondary diagnosis is not present. We periodically revise the list of conditions, in consultation with the Centers for Disease Control (CDC), in accordance with the Act. There are currently 10 HAC categories, including conditions such as air embolism, blood incompatibility, various types of falls and trauma, and certain types of surgical site infections. The FY 2012 IPPS final rule (76 FR 51476) contains a full discussion of the current HAC–POA policy as well as final changes for FY 2012. The final policy includes the addition of several new ICD–9–CM diagnosis codes to current HAC categories, and a revision of one subcategory title from ''Electric Shock'' to ''Other Injuries.'' In addition, section II.F.3. of the FY 2012 IPPS final rule includes updates and findings from the Research Triangle Institute, International (RTI) evaluation on CMS' Hospital-Acquired Conditions and Present on Admission Indicator. This is an intra-agency project with funding and technical support coming from CMS, OPHS, AHRQ, and CDC. The RTI evaluation includes the impact of the Hospital-Acquired Condition-Present on Admission (HAC–POA) provisions on the changes in the incidence of selected conditions, effects on Medicare payments, impacts on coding accuracy, unintended consequences, and infection and event rates. The evaluation will also examine the implementation of the program and evaluate additional conditions for future selection. (For a complete discussion of the current HAC–POA policy, changes to the HAC–POA policy for FY 2012, and current RTI report see the FY 2012 IPPS final rule (August 18, 2011 (76 FR 51504 through 51522).)

Additionally, section 1886(d)(4)(D)(iii) of the Act requires that hospitals, effective with discharges occurring on or after October 1, 2007, submit information on Medicare claims specifying whether diagnoses were POA. Collection of POA indicator data is necessary to identify which conditions were acquired during hospitalization for the HAC payment provision as well as for broader public health uses of Medicare data. We have implemented a payment policy for the IPPS to pay the CC/MCC MS–DRGs for those HACs with POA codes indicating that the diagnosis was either present on admission or clinically undetermined if the secondary diagnosis was present on admission. We will not pay the complication/comorbidity and major complication/comorbidity (CC/MCC) MS–DRGs for those HACs coded with POA codes indicating that the secondary diagnosis was not present on admission or that it was unknown if the secondary diagnosis was present on admission (73 FR 48486 and 48487, August 19, 2008).

The HAC and POA web page at *http://www.cms.gov/HospitalAcqCond* provides further information. In addition, specific instructions for providers on how to select the correct POA indicator for each diagnosis code were included in the ICD–9–CM Official Guidelines for Coding and Reporting, available on the CDC Web site at: *http://www.cdc.gov/nchs/data/icd9/icdguide10.pdf.* Additional information regarding POA indicator reporting and original Medicare application of the POA reporting options is available on the CMS Web site at: *http://www.cms.gov/HospitalAcqCond/.*

Looking toward the future of Medicare and Medicaid, Congress set forth in the Affordable Care Act requirements to further Medicare's development of value-based purchasing programs (VBP), health care provider quality reporting, and expansion of the HAC program to encourage further incentives to improve quality and affordability of care and increase public transparency. Section 3008(b) of the Affordable Care Act requires the Secretary to undertake a study and report to Congress by January 1, 2012 on extending HAC–POA payment policy for IPPS hospitals to other facilities providing medical care to Medicare beneficiaries, such as hospital outpatient departments, non-IPPS hospitals, skilled nursing facilities, and others.

In addition, section 3008(a) of the Affordable Care Act requires us to implement for the IPPS, a rate-based payment policy to reduce payments to hospitals in the lowest quartile of performance on risk-adjusted quality measures HACs, effective beginning FY 2015. The amount of payment will be 99 percent of the amount of payment that would otherwise apply to such discharges. This section also requires us to make information available to the public regarding HACs of each applicable hospital on the Hospital Compare Internet website.

Finally, section 2702 of the Affordable Care Act requires the Secretary to identify current State practices that prohibit payment for HACs and incorporate the practices identified, or elements of such practices, which the Secretary determines appropriate for application to the Medicaid program in regulations. The new regulations will prohibit payments to States under section 1903 of the Act for any amounts expended for providing medical assistance for health care-acquired conditions specified in the regulations. In addition, section 2702 of the Affordable Care Act requires the Secretary to apply to State plans (or waivers) under title XIX of the Act the regulations promulgated pursuant to section 1886(d)(4)(D) of the Act relating to the HAC–POA payment policy, as appropriate for the Medicaid program. Final regulations implementing these requirements were published in the June 6, 2011 **Federal Register** (76 FR 32816). The final rule was effective July 1, 2011 but gives States the option to implement between July 1, 2011 and July 1, 2012.

It is important to us to continue to align these incentives between the fee-

for-service and MA programs and, as noted above, with the Medicaid program. Section 1856(b)(1) of the Act authorizes the Secretary to establish MA standards by regulation. In addition, section 1857(e)(1) of the Act authorizes the Secretary to impose additional terms and conditions found necessary and appropriate. Based on this general authority in the Act, we propose to require MA organizations to implement policies and procedures to reduce reimbursements to contracted hospitals for Part A inpatient hospital services for serious events that could be prevented through evidence-based guidelines, in accordance with the HAC–POA policy that is required for hospitals paid under the IPPS. Consistent with practice under the IPPS, MAOs should not reimburse hospitals the higher payment for cases when one of the selected conditions is acquired during hospitalization (that is, was not POA). Any such case would be paid as though the secondary diagnosis is not present. We note that MA organizations are already required to pay non-contract provider hospitals the amount that they would receive for services under Original Medicare, including any applicable reductions for HACs. This requirement is outlined in the MA Payment Guide for out of Network Payments, available at *https://www.cms.gov/MedicareAdvtgSpecRateStats/downloads/oon-payments.pdf.*

The HAC–POA policy promotes increased quality, efficiency of care, and incentives for hospitals to eliminate medical errors and reduce Medicare expenditures for poor quality or unnecessary care. It is one of several VBP tools the agency uses; others include measuring performance, using payment incentives, publicly reporting performance results, applying national and local coverage policy decisions, and enforcing conditions of participation.

We believe that with robust input and participation of MA organizations and other stakeholders, we can achieve these goals for efficiency and quality in the MA program while implementing the policies in a way that takes into account the varying models, access, and payment features of the MA program. We understand that MA organizations may pay hospitals on a capitated basis or through other payment systems that may not be similar to that of the IPPS and also may not currently incorporate the POA indicator policy. We want to allow flexibility for MA organizations to determine the best methodology within their contract structures with hospitals for reporting these serious conditions and events, determining whether the condition was present on admission or caused during the inpatient hospital stay, and paying hospitals appropriately. However, we also believe that plans already have some operational systems in place to facilitate implementation of the requirement. For example, MA organizations must already pay noncontract providers the amount that they would receive under Original Medicare, which includes reducing the payment for HACs that were not present on admission. Also, beginning January 3, 2012, MA organizations will be required to collect and submit encounter data for each item and service provided to MA enrollees in accordance with risk adjustment policies required in § 422.310(d) (Form Number: CMS–10340 (OMB#: 0938–New). We would collect the encounter data electronically from Medicare Advantage Organizations via the Health Insurance Portability and Accountability Act (HIPAA) compliant standard Health Care Claims transactions for professional data and institutional data. The HIPAA 5010 claim form used for this transaction is the same claim form that hospital providers use to submit claims under Original Medicare, including specific fields for POA information. In addition, the current MA plan rating system includes measures related to some of these serious events. Therefore, we believe that these distinct policies can be aligned to produce all of the intended results, including net savings to MA organizations and Medicare by avoiding unnecessary costs in the delivery of care.

We propose to amend § 422.504(i)(3) by adding a new paragraph (iv) to require that, beginning in CY 2013, MA organizations provide in their contracts with hospitals that payment will not be made to contracting hospitals in the case of serious preventable events and hospital-acquired conditions in accordance with section 1886(d)(4)(D) of the Act and all applicable Medicare policies. We solicit comments and recommendations on what other issues to consider in finalizing our proposal to apply the current fee-for-service HAC–POA policy to MA plans.

4. Clarifying Coverage of Durable Medical Equipment (§ 422.100 and § 422.111)

Medicare beneficiaries not enrolled in an MA plan may obtain their Medicare-covered durable medical equipment (DME) items and supplies from any Medicare-certified DME supplier. If a DME supplier does not stock a particular manufacturer's product or brand of DME, the beneficiary may obtain that product or brand from another supplier or request his or her supplier of choice order the particular product or brand he or she uses or which his or her physician has ordered. While sections 1852(a)(1)(A) and (B) of the Act require MA plans to provide Parts A and B-covered items and services (with the exception of hospice care), including DME items and supplies, network-based MA plans may maintain networks of appropriate providers sufficient to provide adequate access to covered services for their members (see § 422.112(a)(1) and § 422.114(a)). In other words, network-based MA plans may limit access to Medicare-covered items and services via networks, as long as those networks provide adequate enrollee access to services consistent with standards established by CMS.

Medicare Advantage organizations and other stakeholders have asked for our guidance with respect to limitations DME coverage that result from MA organizations limiting enrollees to specified DME providers, or to specified DME manufacturers. Specifically, some MA organizations have asked us whether they could offer lower cost-sharing for ''preferred'' DME products or brands versus ''non-preferred'' DME products or brands, as well as whether they could limit coverage of certain DME items and supplies to specific manufacturers' products or brands. In guidance in section 50.1 of Chapter 4 of the Medicare Managed Care Manual, ''Benefits and Beneficiary Protections'' (see *http://www.cms.gov/manuals/downloads/mc86c04.pdf*), we specified that, beginning in CY 2011, plans could establish several cost-sharing levels (that is, tiers) for DME items, supplies, and Part B drugs, provided that: (1) The highest cost sharing tier is at or below the relevant cost sharing threshold established by CMS for DME and Part B drugs; and (2) plans ensure access to all products through the network of providers. However, we have not specified in regulation or guidance whether network-based MA plans may, within a specified category of DME, limit coverage to specific manufacturers' DME products or brands. While we do not collect information on this type of coverage limitation in our plan benefit package (PBP) software, we are aware anecdotally that some MA organizations employ this practice to some extent. For example, one MA organization limits coverage of diabetic test strips and monitors to those manufactured by certain entities.

Although some organizations thus are already limiting DME to specific brands, we believe that our proposal would help ensure that MA organizations maximize

program efficiencies by driving enrollee utilization to specific DME products for which MA organizations may have negotiated bulk discounts. In addition, given that MA organizations are currently employing DME product or brand coverage limitations, we believe it is important to establish a regulatory framework for ensuring appropriate and adequate MA enrollee access to DME items and supplies.

Therefore, and under our authority in section 1856(b)(1) of the Act to establish MA standards by regulation and in section 1857(e)(1) of the Act to impose additional terms and conditions found necessary and appropriate, we propose to add a new paragraph (l) to § 422.100 that clarifies that MA organizations may limit coverage to specific manufacturers or brands, and imposes conditions on doing so. Specifically, in order to ensure that MA enrollees have adequate access to their DME benefits, proposed § 422.100(l) would establish requirements with respect to access and medical necessity, require transition periods, address mid-year changes to preferred DME items and supplies, appeals, and require disclosure of DME coverage limitations to enrollees.

We recognize that this is a complex issue. Therefore, we solicit comments on all aspects of these proposed changes and whether additional or strengthened beneficiary protections would be warranted under this policy. If we finalize this proposal, we intend to monitor and assess plans' compliance with the new requirements—including through review of beneficiary complaints and grievances, and appeals data—to ensure MA enrollees have appropriate and adequate access to their Part B-covered DME items and supplies.

a. Access to Preferred DME Items and Supplies

We propose requiring that MA organizations wishing to limit coverage within a specific category of DME to specific manufacturers' products or brands take necessary steps to ensure that enrollees have access to all preferred manufacturer products through their contracts with network DME suppliers. We recognize that not all DME suppliers in a network will always stock all preferred products or brands of DME items and supplies; however, we would expect contracted suppliers to make arrangements to special order products or brands of any preferred DME item or supply, as well as any non-preferred DME item or supply that is determined to be medically necessary. We would reflect this change in proposed § 422.100(l)(2)(i).

b. Medical Necessity Requirements for DME Items and Supplies

In accordance with § 422.112(a)(6)(ii), MA organizations must have established policies and procedures that allow for individual medical necessity organization determinations if there is a question about whether a service or item should be covered. MA organizations making medical necessity determinations must have a medical director, who is a physician, ensuring the accuracy of organization determinations and reconsiderations as per § 422.562(a)(4). Within Subpart M, if the MA organization's determination is contested, reconsideration by the organization, and an independent review entity of the determination are possible under § 422.578 and § 422.592, with administrative law judge and Medicare Appeal Council hearings/reviews of unfavorable reconsiderations possible under § 422.600, and § 422.608. Therefore, we propose requiring MA organizations—to the extent that they elect to limit coverage of DME items and supplies to specific manufacturers' products or brands—to provide coverage of any medically necessary DME item and supply, including DME items and supplies made by non-preferred manufacturers. We would reflect this change in proposed § 422.100(l)(2)(ii).

c. Transition Period for Coverage of Non-Preferred DME Items and Supplies

As provided under § 423.120(b)(3), MA organizations offering an MA–PD plan and Part D sponsors are required to provide for an appropriate transition process for enrollees transitioning from other coverage who are currently prescribed Part D drugs not on the new Part D plan's formulary. The purpose of this transition period is to transition the new enrollee to a therapeutically substitutable formulary drug or, alternatively, to obtain a formulary exception whereby the Part D plan would continue to cover the non-formulary drug for the remainder of the plan year for reasons of medical necessity.

Similarly, we propose requiring MA organizations to continue to ensure access to non-preferred brands of DME supplies—such as ostomy bags and diabetic test strips—for a transition period comprising the first 90 days of coverage under the plan, as specified by CMS. Similar to the Part D transition process, we expect that MA organizations would provide one refill during the 90-day transition period. We also propose requiring that, during this 90-day transition period, MA organizations cover repairs to non-preferred DME items, such as wheelchairs, feeding pumps, and hospital beds. That is, an MA organization would be required to service (including providing a loaner) DME items owned or rented by an enrollee needing repairs during the 90-day transition period. If, after the transition period ends such items needed repair, the plan could choose to pay for the repairs or instead provide its preferred brand of the item. We propose to add § 422.100(l)(2)(iii)(A) and § 422.100(l)(2)(iii) (B) to reflect this proposed requirement.

We solicit comments on the features of this transition process requirement, including whether such a transition period—modeled generally on that provided under the Part D program for non-formulary Part D drugs—is appropriate for DME items and supplies and whether there are additional transition requirements we should consider.

d. Midyear Changes to Preferred DME Items and Supplies

We propose prohibiting MA organizations from making ''negative changes,'' that is, eliminating preferred coverage of a Medicare-covered item of DME, midyear. Plans may add to their preferred DME products list—for example, to add new manufacturers' products to their coverage lists, to provide substitute DME items and supplies for products that are no longer available, or to reflect national and local coverage determinations for new DME items and supplies. We believe this proposed policy—allowing positive changes and prohibiting negative changes—strikes the appropriate balance between allowing flexibility for plans to designate preferred products, while ensuring that changes to preferred DME products are not disruptive to enrollees. We propose to reflect this change in proposed § 422.100(l)(2)(iv).

e. Appeals

While we considered establishing an exceptions process for DME under this proposed policy similar to the one established for non-formulary Part D drugs under § 423.578(b), we do not believe that adding what is essentially an additional step to the appeals process under Subpart M of Part 422 is necessary for MA organization determinations concerning coverage of specific DME brands. The Part D exceptions process was conceived as an initial means of obtaining coverage of non-formulary Part D drugs for medical necessity reasons. Once that process is exhausted, the enrollee may appeal the

decision under the rules of Subpart M of Part 423.

There is evidence that beneficiary appeals of DME coverage decisions based on products or brands are not a significant problem in the MA program. For example, since the inception of the IRE appeals process in 2006, there have been 12,500 appeals related to wheelchairs. Of these appeals, only 7 have concerned brand-specific issues. Because we have no evidence of enrollee grievances or appeals of brand-specific DME coverage issues, we believe that the current organization determination and appeals process in subpart M of part 422 is sufficient to ensure that MA enrollees have access to specific brands of DME items when medically necessary. We propose to clarify at § 422.100(l)(2)(v) that plan non-coverage of a particular manufacturer's product or brand of a DME constitutes an organization determination under § 422.566. We solicit comments on whether the organization determination and appeals process currently required in subpart M of part 422 affords MA plan enrollees with sufficient protections for ensuring appropriate and adequate access to Medicare-covered DME in MA plans that choose to limit coverage, within a specified category of DME, to specific manufacturers' products or brands. We would appreciate comments with respect to any additional protections that we should consider if we finalize this proposal.

f. Disclosure of DME Coverage Limitations

As provided under § 422.111(b)(2), MA plans must notify enrollees—at the time of enrollment and annually thereafter—of the benefits offered under the plan, including applicable conditions and limitations, premiums, and cost sharing, and any other conditions associated with receipt of benefits. This requirement has been operationalized as the annual notice of change/evidence of coverage (ANOC/EOC). We would require, under proposed § 422.100(l)(2)(vi), that MA plans that choose to limit DME coverage to preferred products or brands, be required to include, in the description of benefits required under § 422.111(b)(2) and under § 422.111(h)(2)—which requires the provision of specific information via a toll-free customer service call center, and Internet website, and in writing upon request—disclosures about these DME coverage restrictions and their rights to the Part C appeals process for requests to obtain medically necessary, non-preferred DME products or brands.

5. Broker and Agent Requirements (§ 422.2274 and § 423.2274)

Regulations setting forth agent and broker compensation promulgated in our November 10, 2008 interim final rule with comment (73 FR 67406 through 67414) required MA organizations and Part D plan sponsors (''plan sponsors'') to submit historical agent/broker compensation data from years 2006 and 2007. In addition, we requested that plan sponsors submit information in 2008 that would indicate their 2009 compensation schedules for agents selling Medicare health plans on their behalf. CMS conducted an analysis of the historical compensation information submitted by plan sponsors and published fair market value cut-off (FMV) amounts during the Spring of 2009. Later that year, plan sponsors were given the opportunity to adjust their compensation amounts to any amount at or below the FMV. These adjusted 2009 amounts became the baseline amount for compensation adjustments in future years. Subsequent to our initial compensation guidance, plan sponsors have expressed concerns about the validity of continuing to base future compensation on amounts which were selected in 2009 and based on data from 2006 and 2007. We have further heard that the current economic conditions have drastically changed local markets such that, even as adjusted, the 2009 compensation amounts do not accurately reflect the current market rates. Lastly, we have been advised by plan sponsors that have been in the market since 2009 that they are at a competitive disadvantage as compared to newly entering plans as they may set compensation rates at current-day FMV rates and are not tied to 2009 compensation amounts. Therefore, we are proposing to modify paragraph (a), and add a new paragraph (f), to § 422.2274 and § 423.2274 to allow plan sponsors to annually select their compensation amounts to reflect rates which are at or below FMV annually established by CMS. Under these proposed changes, plan sponsors would also be required to report their intentions to use independent agents and/or brokers in the upcoming plan year, along with the amounts that they will be paid, if applicable.

6. Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse and Waste Control Program (§ 423.104 and § 423.153)

Pursuant to our authority under section 1860D–4(c) of the Act, which requires PDP sponsors to have cost-effective drug utilization management and a fraud, abuse, and waste control program in place, we are proposing that Medicare Part D sponsors be required to provide their enrollees access to a daily prorated cost-sharing rate for prescriptions dispensed by a network pharmacy for less than a 30 days supply of certain covered Part D drugs that are for an initial fill of a new medication, are intended to allow the enrollee to synchronize refill dates of multiple drugs, or are dispensed in accordance with § 423.154 (which sets forth the requirements placed on Part D sponsors with respect to dispensing of prescription drugs in long-term care facilities effective January 1, 2013). If finalized as proposed, these provisions would be codified at § 423.104 and § 423.153.

Current prescribing patterns and pharmacy benefit management (PBM) payment practices result in most prescriptions for chronic medications being written by providers, and dispensed by retail pharmacies, in 30-or-more day quantities. When the full amount dispensed is not utilized by the enrollee due to adverse medication reaction or interaction, or due to failure of enrollee therapeutic adherence because of cost, inconvenience, death, or other reason for discontinuation, it comes at an unnecessary and wasteful cost to the enrollee, the Medicare program, Part D sponsors, and the environment.

We believe that if Part D enrollees and their prescribers had the option of shorter days supplies of initial fills of new prescriptions without the disincentive of the enrollee having to pay a full month's (or longer) copayment or coinsurance, a significant portion of the current costs of discontinued chronic medications could be avoided. In addition, the avoidance of unused drugs would contribute to diminishing the environmental issues [7] caused by disposal of unused medications, and opportunities for criminal activities and substance abuse [8] caused by diversion of unused

[7] See *http://www.epa.gov/ppcp* for information about Pharmaceuticals and Personal Care Products as Pollutants (PPCPs) on the website of the U.S. Environmental Protection Agency.

[8] See Office of National Drug Control Policy, 2008 ''Prescription for Danger'', January 24, 2008, and 2009 National Drug Survey on Drug Use and Health (NSDUH), September 2010, for more information on the growing problem of nonmedical use of prescription drugs in the United States, particularly among teenagers. See also *http://www.deadiversion.usdoj.gov/index.html* for more information from the Drug Enforcement Administration about the problems associated with drug abuse resulting from legitimately made controlled substances being diverted from their lawful purpose into illicit drug traffic.

medications, all of which are growing concerns in the United States.

Currently, Part D enrollees' cost-sharing is the same whether they receive a 7-, 14-, or 30-day supply of a first fill of a new medication. A daily cost-sharing rate requirement imposed on Part D sponsors would encourage enrollees and their prescribers to limit day's supplies when appropriate by also reducing the enrollees' out-of-pocket costs. More specifically, under our proposal, Part D sponsors would be required to establish and apply a daily cost-sharing rate, such that an enrollee seeking a trial fill of a prescription for a chronic medication, for example, would pay only a prorated portion of the established amount under his or her Part D benefit plan that corresponds to the actual amount of days supply that was prescribed and is dispensed, whether it be a 7- or 14-day supply, or some other quantity less than 30 days, which would be at the discretion of the prescriber. Thus, although our proposed daily cost-sharing rate requirement would be mandatory for Part D sponsors, actually taking advantage of it would be voluntary for enrollees and their prescribers. Neither sponsors nor the Federal government would determine whether an enrollee should receive a trial fill. Rather, the decision to try a new medication through a trial fill would be made by the enrollee and his or her prescriber.

Through the establishment and application of a daily cost-sharing rate requirement on Part D sponsors, we believe an enrollee would be incentivized to inquire of his or her prescriber whether a trial fill would be appropriate when first prescribed a medication. We further believe enrollees would be most likely to inquire about a trial fill when faced with higher cost sharing for a new medication, due to the expense of the drug, such as when purchasing a drug in the deductible phase of the benefit or in the coverage gap. We further believe prescribers would be most likely to concur as to the appropriateness of a trial fill when the prescription is for an initial fill of a drug that has significant side effects and/or is frequently poorly tolerated. In such a case, the prescriber could write either one prescription for the trial fill for a period at the prescriber's discretion, or two prescriptions (for example, one for the trial fill and a second prescription for a 30 or 90 day supply—the latter prescription would be utilized if the enrollee and the prescriber agreed the drug therapy should be continued after the trial period). If the medication were discontinued after use of a trial fill, the enrollee, as well as the sponsor, would have avoided the net costs associated with the unused quantity that would be dispensed under current standard practices.

Because the prescriptions could be written during one office visit, or could be refilled by the prescriber directly with the enrollee's pharmacy after a medication trial period, additional visits to the prescriber would not necessarily be required and would not need to cause a burden to the enrollee. We assume the two prescriptions option would be most convenient for the enrollee and the prescriber (when appropriate), but seek specific comment on this assumption. If an enrollee would have difficulty returning to the pharmacy, presumably he or she would not inquire about a trial fill. Furthermore, since prescribers would determine whether or not the medication being prescribed should or could be dispensed in a trial fill, we would not expect our proposal to have any adverse effects on enrollees' health.

Indeed, while we envision, as described above, enrollees primarily requesting less than a full month's supply when prescribed a drug for the first time that is known to have significant side effects and to be frequently poorly tolerated, we are not limiting the requirement for Part D sponsors to establish and apply a daily cost-sharing rate to such medications. Rather, we have identified an additional benefit which is the ability to allow for synchronization of prescriptions. More specifically, if an enrollee already takes a prescription medication that is due for a refill in 10 days, the prescriber could write an initial prescription for a new medication for a 10-day supply, so that the enrollee could refill both prescriptions on an ongoing basis in one trip to the pharmacy (assuming the new medication is continued) and perhaps also achieve better medication compliance. Similarly, enrollees who currently take multiple medications that refill on different dates could request their prescribers to write prescriptions for less than 30 days (each one likely for a different days supply), but with 30-day refills, for all but one of those medications that is due for a refill, so that the enrollee could refill all prescriptions in one trip to the pharmacy, and could refill all the prescriptions for 30 days or more in one trip to the pharmacy thereafter on an ongoing a basis.

The ability to synchronize medications should assist enrollees in adhering to prescription treatment regimens that involve multiple medications, and we note that at least one study supports this belief, and suggests intervention targeted at individuals who do not request refills of all medications. In addition, we believe the ability to synchronize medications will be convenient for both those enrollees who take advantage of it and their prescribers by enabling fewer trips to the pharmacy and fewer prescription requests of prescribers from enrollees through the ability to consolidate pharmacy trips and prescriber office visits and phone calls.

We do not expect long-term care (LTC) enrollees to request trial fills to synchronize medications, as this is not our understanding of the LTC environment with respect to prescribing, and our April 2011 final rule (76 FR 21432) requires 14 day or less dispensing in LTC facilities effective January 1, 2013. However, as noted in that rule, we expected the LTC dispensing requirements ''would likely lead to a change in copayment methodology * * * [and] anticipate[d] the implementation of particular copayment methodologies will be dependent on the billing and dispensing methodologies used, and as a result * * * copayment methodologies within the same plan may vary depending on the LTC facility where the beneficiary resides. Copayment may be collected at the first dispensing event in a month, the last dispensing event in a month, or prorated based on the number of days a Part D drug was dispensed in a month. However, due to the relatively small copayments for low-income subsidy (LIS) beneficiaries, copayments for LIS beneficiaries should be billed with the first or last dispensing event of the month.'' The current proposed requirement on Part D sponsors to establish and apply a daily cost-sharing rate would supersede this quoted guidance in the preamble of the April 2011 final rule. In other words, Part D sponsors would be required to establish and apply a prorated, uniform cost-sharing billing methodology for all their enrollees, including those in LTC facilities and those with LIS cost-sharing subsidies.

We recognize that establishing and applying a daily cost-sharing rate to the relatively small copayments for LIS enrollees would cause such copayments to be nominal. We seek specific comments as to alternatives to incentivize LIS enrollees to take advantage of trials fills and synchronize their medications when appropriate other than through the establishment and application of a daily cost-sharing rate requirement.

Daily cost-sharing rates also may permit pharmacies, as opposed to prescribers, to facilitate synchronization

of an enrollee's medications upon his or her request, and we seek specific comment as to this possibility, as well as to any issues we may need to address to facilitate this possibility. For instance, in order for sponsors to be able to monitor the prevalence and appropriateness of the dispensing of prescriptions in shorter than 30 days supply to ensure that a pharmacy does not dispense a 30-day prescription in stages in order to increase dispensing fees, we urge the industry to develop coding to be used by network pharmacies to communicate to sponsors whether a less than 30 day fill is to align refill dates, or for that matter, is an initial fill of a new medication, or in the case of the LTC setting, is to communicate the dispensing methodology employed.

We believe that realized savings from the daily cost-sharing rate requirement may be partly offset by additional dispensing fees, administrative and programming costs, and additional initial fills of more expensive drugs. We assume additional dispensing fees would result when a trial fill of a medication is dispensed and the enrollee returns to the pharmacy for the remainder of the month's supply (or more) if the medication were successful, or when an enrollee chooses to synchronize medications. Thus, over a year, there would be up to 13 dispensing events for a medication continued after a trial fill as opposed to up to 12. Part D sponsors may also incur some costs to program their systems to establish and apply a daily cost-sharing rate to prescriptions dispensed to enrollees with less than a 30-day supply, as well as administrative costs to administer the trial fill requirement we propose here. Finally, we expect some additional costs due to more initial fills of brand drugs that enrollees previously declined to try due to the cost of a full month's supply when the brand drugs are known for significant side effects and/or to be frequently poorly tolerated.

We considered proposing a requirement similar to the Fifteen Day Initial Script program introduced in Maine in the summer of 2009. In this program, specific medications that were identified by the MaineCare program with high side effect profiles, high discontinuation rates, or frequent dose adjustments, were phased in by class and must be dispensed in a 15-day initial script to ensure cost effectiveness without wasting or discarding of dispensed, but unused, medications. We have learned through representatives of the program that MaineCare has achieved overall savings for two consecutive State fiscal years with respect to both brand and generic drugs through this program, despite the additional dispensing fees. The representatives have also reported that there has been very good acceptance of the program and very little confusion upon implementation. While we acknowledge the savings benefits of the mandatory MaineCare approach, we believe that leaving the decision to obtain less than a month's supply of a prescription with the enrollee and his or her prescriber and pharmacist may be a better approach in light of the voluntary nature of the Medicare Part D program.

A previous review of 2009 PDE data by CMS suggested that just under 32 percent of approximately 78.6 million first fills for maintenance medications are not refilled by Medicare Part D enrollees. Maintenance medications are used for diseases when the duration of therapy can reasonably be expected to exceed one year, and we assume for purposes of estimating savings to the Part D program that the lack of refills indicates the prescribed medications were discontinued. The estimated total cost of these discontinued medications was approximately $1.6 billion (70 percent for brands and 30 percent for generics). However, this review did not distinguish between community and institutional settings. Thus, to estimate the costs of discontinued medications in community settings only, since the daily cost-sharing rate requirement proposed here does not further change the dispensing requirements in the long-term care setting effective January 1, 2013, we reduced the total costs by approximately 13 percent in accordance with CMS data on gross drug costs in the Part D program in 2009 in the community and institutional settings to remove a proportion representing long-term care expenses. Consequently, the adjusted total estimated cost of 2009 community-based discontinued first fills of chronic medications was estimated at roughly $1.4 billion.

Potential savings of a daily cost-sharing requirement on Part D sponsors would come from a reduction of these costs which would be offset by some additional dispensing fees. In order to estimate the savings, we must make assumptions about how many first fills will be dispensed in quantities of less than a 30-day supply, and what the average quantity of such first fills will be. It should be pointed out that these assumptions are highly uncertain, because it is very difficult to predict enrollees' behavioral response. Having noted this caveat, we assume 20 percent of first fills in 2013 will be for a supply of less than 30 days, trending to 50 percent by 2018, and that the average of such fills will be for a 15-day supply. Assuming 32 percent of these first fills are discontinued, we estimate the potential savings to the Part D program to be $180 million in 2013 alone, and over $2.5 billion by 2018.

We recognize that certain medications are universally accepted in the health care community as not suitable to be dispensed in amounts less than a 30-day supply (for example, lotions and other drugs not in solid form). Therefore, we propose to further limit the requirement that sponsors establish and apply a daily cost-sharing rate to drugs similar to those to which to the Medicare Part D long-term care dispensing requirements apply. That is, the daily cost-sharing rate requirement would apply to solid oral doses of drugs, except antibiotics or drugs which are dispensed in their original containers as indicated in the Food and Drug Administration Prescribing Information or are customarily dispensed in their original packaging to assist patients with compliance (for example, steroid dose packs). However, unlike the long-term care dispensing requirements which apply only to brand drugs, we are proposing here that the daily cost-sharing rate requirement would apply to both brand and generic drugs.

We also understand that, while there may be additional waste generated by multiple fills when medications are continued or synchronized (for example, more plastic bottles and paper inserts, additional trips to pharmacies), the harmful effects on the environment from unused drugs, particularly the biological implications, likely have a much greater impact on the environment than additional recyclables. We seek specific comments as to this assumption.

In light of the foregoing, we propose to define ''daily cost-sharing rate'' in § 423.100. ''Daily cost-sharing rate'' would mean, as applicable, the established monthly—

- Copayment under the enrollee's Part D plan divided by 30 or 31 and rounded to the nearest lower dollar amount or to another amount but in no event to an amount which would require the enrollee to pay more for a month's supply of the prescription than the enrollee would have paid if a month's supply had been dispensed; or
- Coinsurance rate under the enrollee's Part D plan applied to the ingredient cost of the prescription for a month's supply divided by 30 or 31. We solicit comment on whether we should establish specific rounding rules so that sponsors are consistently calculating

daily cost-sharing rates with respect to enrollee and plan liabilities.

In addition, we would revise § 423.104 by adding a paragraph (i) to state that a Part D sponsor is required provide its enrollees access to a daily cost-sharing rate in accordance with § 423.153(b)(4). Section 423.153(b) currently requires a Part D sponsor to establish a reasonable and appropriate drug utilization management program. We also propose to revise § 423.153(b) by adding a new paragraph (4). Paragraph (4)(i) would require a drug utilization management program to establish and apply a daily cost-sharing rate to a prescription presented by an enrollee at a network pharmacy for a covered Part D generic or brand drug that is dispensed for a supply of less than 30 days, multiplied by the days supply actually dispensed, plus any dispensing fee in the case of coinsurance. Paragraph (b)(4)(i)(A) would limit the requirement to drugs that are in the form of solid oral doses. Paragraph (b)(4)(i)(B) would further limit the requirement to a prescription that is for an initial fill of a new medication, is intended to allow the enrollee to synchronize refill dates of multiple drugs, or is dispensed in accordance with § 423.154 (which sets forth the requirements placed on Part D sponsors with respect to dispensing of prescription drugs in long-term care facilities effective January 1, 2013). Paragraph (b)(4)(ii) would state that the requirements of (b)(4)(i) would not apply to antibiotics or drugs dispensed in their original container as indicated in the Food and Drug Administration Prescribing Information or are customarily dispensed in their original packaging to assist patients with compliance.

E. Clarifying Program Requirements

We have worked with MA organizations and Part D sponsors to implement the Medicare Advantage and Prescription Drug Benefit Programs since the inception of these programs. As part of this partnership, we have implemented operational and/or policy guidance via HPMS memoranda or manual instruction to assist MA organizations and Part D sponsors in ensuring the proper and efficient administration of the Part C and D programs. We propose to codify some of that guidance and provide other definitive direction on policy issues in order to address requests from stakeholders. These proposals appear in Table 5.

TABLE 5—PROVISIONS TO CLARIFY PROGRAM REQUIREMENTS

Preamble section	Provision	Part 417		Part 422		Part 423	
		Subpart	Section	Subpart	Section	Subpart	Section
II.E.1	Technical Corrections to Enrollment Provisions.	Subpart K	§ 417.422 § 417.432	Subpart B	§ 422.60	Subpart B	§ 423.56
II.E.2	Extending MA and Part D Program Disclosure Requirements to Section 1876 Cost Contract Plans.	Subpart K	§ 417.427	N/A	N/A	N/A	N/A
II.E.3	Clarification of, and Extension to Local Preferred Provider Plans, of Regional Preferred Provider Organization Plan Single Deductible Requirement.	N/A	N/A	Subpart C	§ 422.101	N/A	N/A
II.E.4	Technical Change to Private Fee-For-Service Plan Explanation of Benefits Requirements.	N/A	N/A	Subpart E	§ 422.216	N/A	N/A
II.E.5	Application Requirements for Special Needs Plans.	N/A	N/A	Subpart K Subpart N	§ 422.500, § 422.501, § 422.502. § 422.641, § 422.660.	N/A	N/A
II.E.6	Timeline for Resubmitting Previously Denied MA Applications.	N/A	N/A	Subpart K	§ 422.501	N/A	N/A
II.E.7	Clarification of Contract Requirements for First Tier and Downstream Entities.	N/A	N/A	Subpart K	§ 422.504	Subpart K	§ 423.505

TABLE 5—PROVISIONS TO CLARIFY PROGRAM REQUIREMENTS—Continued

Preamble section	Provision	Part 417		Part 422		Part 423	
		Subpart	Section	Subpart	Section	Subpart	Section
II.E.8	Valid Prescriptions	N/A	N/A	N/A	N/A	Subpart C	§ 423.100, § 423.104
II.E.9	Medication Therapy Management Comprehensive Medication Reviews and Beneficiaries in LTC Settings.	N/A	N/A	N/A	N/A	Subpart D	§ 423.153
II.E.10	Employer Group Waiver Plans Requirement to Follow All Part D Rules Not Explicitly Waived.	N/A	N/A	N/A	N/A	Subpart J	§ 423.458
II.E.11	Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers.	N/A	N/A	N/A	N/A	Subpart C	§ 423.120

1. Technical Corrections to Enrollment Provisions (§ 417.422, § 417.432, § 422.60, and § 423.56)

In our April 15, 2011 final rule (76 FR 21442), we amended § 423.38(d) to codify changes to the Annual Coordinated Election Period (AEP) mandated by the Affordable Care Act. Specifically, section 3204 of the Affordable Care Act changed the AEP to October 15 through December 7 for 2011 and future years. In making this change, we inadvertently neglected to revise a reference to the former AEP timeframe noted in § 423.56 (Procedures to determine and document creditable status of prescription drug coverage). This section requires the disclosure of creditable coverage to beneficiaries prior to the start of the AEP and specifically references the old date (that is, November 15). To make this section consistent with the statute, we are proposing to amend § 423.56(f)(3) to remove the outdated AEP reference.

In the April 2011 final rule (76 FR 21525), we also amended our regulations at § 417.430 to permit CMS approval of alternative enrollment mechanisms for cost plans in addition to paper forms, such as electronic enrollment. In making this revision, we unintentionally overlooked other sections in this subpart that referenced enrollment mechanisms for cost plans. Specifically, § 417.422 (Eligibility to enroll in an HMO or CMP) and § 417.432 (Conversion of enrollment) specifically reference the requirement for a beneficiary signature on an enrollment form. Because it was our intent to broaden enrollment mechanisms for cost plans to go beyond paper enrollment forms, we believe we should have revised the sections above to remove requirements for signatures. Therefore, we are proposing to revise § 417.422(d) and § 417.432(d) to remove references to signatures and state that individuals must complete an application form or ''another CMS-approved election mechanism'' in order to meet enrollment requirements.

In addition, we are proposing to correct an outdated cross-reference at § 422.60(c) (Election process). This paragraph currently references marketing rules formerly located at § 422.80. These requirements were moved to § 422.2262 (Review and distribution of marketing materials) in previous rulemaking.

2. Extending MA and Part D Program Disclosure Requirements to Section 1876 Cost Contract Plans (§ 417.427)

In our April 2010 final rule (75 FR 19783 through 19785), we exercised our authority under sections 1876(c)(3)(C) and 1876(i)(3)(D) of the Act to extend the MA marketing requirements to section 1876 cost contract plans. Under section 1876(c)(3)(C) of the Act, we may regulate marketing of plans authorized under section 1876 of the Act to ensure that marketing material is not misleading. Section 1876(i)(3)(D) of the Act gives the Secretary the authority to impose ''other terms and conditions'' under contracts authorized by the statute that the Secretary finds ''necessary and appropriate.'' As a result, since contract year 2010, cost plan contractors have been required to follow all marketing requirements specified in Subpart V of Part 422, with the exception of § 422.2276, which permits an MA organization to develop marketing and informational materials specifically tailored to members of an employer group who are eligible for employer-sponsor benefits through the MA organization, as well as waives requirements to review such materials. As we noted in our April 2010 final rule (75 FR 19785) extending MA marketing requirements to cost contracts, the statutory authority under section 1857(i)(1) of the Act, which permits the Secretary to waive certain requirements for employer group plans under the MA program, does not apply to cost plans.

In extending the marketing requirements to cost contract plans in our April 2010 final rule, we neglected to extend the MA organization and Part D sponsor disclosure requirements, at § 422.111 and § 423.128, respectively, to cost contract plans. We believe that extending these provisions would also be appropriate, given the close relationship between the marketing requirements in Subpart V of Parts 422 and 423 and the disclosure requirements at § 422.111 and § 423.128. These provisions require MA organizations and Part D sponsors to

disclose to enrollees, at the time of enrollment and annually thereafter (in the form of an annual notice of change/evidence of coverage, or ANOC/EOC mailing), certain detailed information about plan benefits, service area, provider and pharmacy access, grievance and appeal procedures, quality improvement programs, and disenrollment rights and responsibilities. They also require the provision of certain information and establish requirements with respect to: (1) the explanations of benefits notice; (2) customer service call centers; and (3) internet Web sites. Thus, these requirements are closely tied to the marketing requirements of Subpart V of Parts 422 and 423. In order to ensure that cost contract plan enrollees have all the information they need about their health care benefits, we believe that cost contract plans should also be subject to all the same disclosure requirements as MA organizations and Part D sponsors. Therefore, we propose to extend the disclosure requirements in § 422.111 and § 423.128 to cost contract plans by adding a new § 417.427.

3. Clarification of, and Extension to Local Preferred Provider Plans, of Regional Preferred Provider Organization Plan Single Deductible Requirement (§ 422.101)

Section 1858(b) of the Act provides that, to the extent RPPO plans use a deductible, any such deductible must be a single deductible, rather than separate deductibles for Parts A and Part B benefits. This single deductible may be applied differentially for in-network services and may be waived for preventive or other items and services. Our regulations at § 422.101(d)(1) track the language in the statute closely. They require that RPPO plans, to the extent they apply a deductible, apply only a single deductible related to combined Medicare Part A and Part B services. They also allow the single deductible to be differential for specific in-network services and to be waived for preventive services or other items and services, at the plan's option. However, both the statute and our regulations are silent with respect to any deductible requirements for local preferred provider organization (LPPO) plans. Consequently, in practice, LPPO plans may have a variety of deductible designs, including separate in-network and out of network deductibles.

We propose to make three changes to our regulations at § 422.101(d)(1) to both clarify current requirements with respect to the application of a single deductible and to level the playing field between LPPO and RPPO plans by extending the RPPO rules to LPPOs. Specifically, we propose clarifying the application of the differential of the single deductible for in-network services, and modifying our current regulations to take into account recent rulemaking under which MA plans must provide certain Medicare-covered preventive services at zero cost sharing. We propose to rely upon our authority at section 1856(b)(1) of the Act to establish MA standards by regulation, and in section 1857(e)(1) of the Act to impose additional terms and conditions found necessary and appropriate, to extend the RPPO single deductible requirements by regulation to LPPOs. We believe that having the same rules for LPPOs and RPPOs supports transparency and comparability of options for beneficiaries when they evaluate and select plans for enrollment. In previous rulemaking, we have taken steps to align the plan design requirements for RPPOs and LPPOs. For example, in our April 2010 final rule (76 FR 21507 through 21508) that made revisions to the MA and Part D programs for CY 2012, we extended the same maximum out-of-pocket (MOOP) and catastrophic limits we had previously codified for LPPOs (75 FR 19709 through 19711) to RPPOs. In the interest of transparency, alignment in benefit design between RPPO and LPPO plans, and comparability for beneficiaries making health care coverage elections, we propose to extend to LPPOs the single deductible requirements at § 422.101(d)(1). We would clarify the rules that would now apply to both LPPO and RPPO plans as set forth late in this section.

As discussed previously, we propose to clarify at § 422.101(d)(1) that an LPPO or RPPO single deductible ''may be applied differentially for in-network services,'' as provided under section 1858(b) of the Act. We currently furnish interpretive guidance and examples of the application of the single deductible in section 50.3 of Chapter 4 of the Medicare Managed Care Manual, ''Benefits and Beneficiary Protections'' *http://www.cms.gov/manuals/downloads/mc86c04.pdf*). However, we believe there may still be confusion with respect to how these requirements are articulated in our regulations and therefore propose amending § 422.101(d)(1) to add paragraphs (i) through (iii) clarifying that an RPPO or LPPO that chooses to apply a deductible may both—

- Specify different deductibles for particular in-network Parts A and B services, provided that all of these service-specific deductibles are applied to the overall, single plan deductible; and
- Choose to exempt specific plan-covered items or services from the deductible—that is, the LPPO or RPPO may choose to always cover specific items or services at plan established cost-sharing levels whether or not the deductible has been met. For example, under our regulations, an LPPO or RPPO could establish a single combined deductible of $1,000 but limit the amount of the deductible that applies to in-network inpatient hospital services to $500, and the amount that applies to in-network physician services to $100. This RPPO could also exempt application of the deductible to particular services—for example, all home health services (in- and out-of-network).

In our April 2011 final rule (76 FR 21475 and 21476), we established a new requirement for MA organizations to provide certain in-network Medicare-covered preventive benefits at zero cost sharing. As provided under § 422.100(k), MA organizations, including those offering PPO plans, may not charge deductibles, copayments, or coinsurance for in-network Medicare-covered preventive services specified in § 410.152(l). We are therefore proposing to eliminate references to the option in both LPPO and RPPO plans to exclude preventive services from the single deductible at § 422.101(d)(1), and are proposing adding a new paragraph § 422.101(d)(1)(iv) to explicitly require LPPO and RPPO plans to exclude certain Medicare-covered preventive services (as defined in § 410.152(l)) from the single, combined deductible for each plan.

4. Technical Change to Private Fee-for-Service Plan Explanation of Benefits Requirements (§ 422.216)

In our April 15, 2011 final rule (76 FR 21504 through 21507) implementing changes to the MA and Medicare Prescription Drug Programs for Contract Year 2012, we finalized regulations at § 422.111(b)(12) giving us the authority to require MA organizations to furnish directly to enrollees, in the manner specified by CMS and in a form easily understandable to such enrollees, a written explanation of benefits, when benefits are provided under this part. We expressed our intention to work with MA organizations, Part D sponsors, and beneficiary advocates to develop an EOB for Part C benefits and to test the EOB in CY 2012 through a small, voluntary pilot program. In our April 2011 final rule (76 FR 21505), we also stated our intention to finalize a model EOB in the future, based on the results

of the pilot program and to require all MA organizations to periodically send an EOB to enrollees for Part C benefits.

We did not specifically discuss private fee-for-service (PFFS) plans in our April 2010 final rule because section 1852(k)(2)(c) of the Act and § 422.216(d)(1) already require PFFS plans to provide an EOB to enrollees. Our current regulations at § 422.216(d)(1) specify that PFFS plans must provide an appropriate EOB to plan enrollees for each claim filed by the enrollee or the provider that furnished the service. The explanation must include a clear statement of the enrollee's liability for deductibles, coinsurance, copayment, and balance billing. In the interest of consistency for beneficiaries and MA organizations, we propose to amend § 422.216(d)(1) to state that the EOB requirement for PFFS plans will be consistent with the MA EOB requirements of § 422.111(b)(12). The standard EOB that we are currently developing and piloting for most other MA plan types will include the same information as currently required for PFFS plans, as well as plan maximum out-of-pocket (MOOP) cost information. Adding this cross-reference to § 422.216(d)(1) would provide consistency in EOB requirements as well as submission and approval of marketing materials across plan types. Since the pilot program is in progress during the CY 2013 rule development cycle and we would not have finalized EOB requirements based on the pilot prior to publication of the CY 2013 final rule, we propose that PFFS plans would continue to furnish EOBs as they have been, in accordance with § 422.216(d)(1), until we finalize and implement EOB models for all MA plans.

5. Application Requirements for Special Needs Plans (§ 422.500, § 422.501, § 422.502, § 422.641, and § 422.660)

Several of the regulations implementing section 1859(f) of the Act, including § 422.101(f), § 422.107, and § 422.152(g), establish specific requirements for Special Needs Plans (SNPs). Specifically, § 422.101(f) requires that MAOs offering a SNP implement an evidence-based model of care to be evaluated by NCQA as part of the SNP approval requirement; § 422.107 requires that Dual Eligible SNPs (D–SNPs) have a contract with the State Medicaid Agencies in the States in which they operate; and § 422.152(g) requires that SNPs conduct a quality improvement program. These SNP-specific requirements have been incorporated into the MA application for MAOs that wish to offer a SNP so that these MAOs can demonstrate that they meet CMS' SNP specific requirements and are capable of serving the vulnerable special needs individuals who enroll in SNPs.

Current regulations on application procedures for MAOs, found at: § 422.500, § 422.501, and § 422.502, are specific only to an applicant that is seeking to contract as a MAO offering an MA plan, and do not specify the rights and responsibilities of an applicant that seeks to offer a SNP. Additionally, regulations on Medicare Contract Determinations and Appeals, found at § 422.641 and § 422.644, also pertain only to applicants that have been determined unqualified to enter into an MA contract, and do not provide for appeal rights to applicants who have been determined unqualified to offer a SNP. Given that every applicant that seeks to offer a SNP engages in an intensive application process to demonstrate that it meets the requirements unique to SNPs in the same manner, according to the same processes and on the same timeline as applicants seeking to contract as MAOs, we believe it is important to provide SNP applicants with the same rights and responsibilities as applicants applying to contract as MAOs. We further believe it important to clarify that each applicant that has been determined unqualified to offer a SNP has the same right to an administrative review process to each applicant that has been determined unqualified to enter into an MA contract.

Therefore, in accordance with section 1859(f) of the Act, we propose to broaden our regulations on Application Requirements and Evaluation and Determination Procedures to also apply to SNP applicants. Specifically, we propose to revise the language in § 422.500(a) and § 422.501(a) to specify that the scope of these provisions include the specific application requirements for SNPs. We also propose to add paragraph (iii) to § 422.501(c)(1) to specify the documentation SNP applicants must provide to complete an application. Furthermore, we propose to revise § 422.502(a) and § 422.502(c) to specify that our regulations on application evaluations and determinations apply to SNP applications. Additionally, in accordance with section 1859(f) of the Act, we propose to provide explicit appeal rights to each applicant that has been determined unqualified to offer a SNP for failure to meet the requirements in section 1859(f) of the Act and its implementing regulations. To do so, we propose adding a new paragraph (d) to § 422.641, a new paragraph (a)(5) to § 422.660, and a new paragraph (b)(5) to § 422.660. We believe the proposed changes would ensure that only MA organizations capable of meeting the requirements to serve Special Needs Individuals are able to target their enrollment to this vulnerable population, while also affording each MA organization that has been determined unqualified to offer a SNP the opportunity to have this decision reviewed by an impartial hearing officer.

6. Timeline for Resubmitting Previously Denied MA Applications (§ 422.501)

Section 1857(a) of the Act requires organizations that wish to participate in the MA program enter into a contract with the Secretary, under which the organization agrees to comply with applicable MA program requirements and standards. In order for us to determine whether these program requirements and standards have been met, the organization must complete an application in the manner described at Subpart K of Part 422. Section 422.501 sets forth the required elements of such an application. Under § 422.501(e), entities that are seeking to contract with the Secretary as an MA organization may not resubmit an application that has been denied by CMS for 4 months following CMS' denial. This 4-month prohibition on resubmitting a previously-denied application is obsolete and inconsistent with current agency practices. Presently, we operate on an annual application cycle whereby the established submission date for new applications (February of each year) occurs well after the specified date by which we deny the previous contract year's applications (May of the previous year). A literal reading of § 422.501(e) means that an application that is denied in May of 1 year could be resubmitted as early as September (4 months later), and well before the release of the application for the following contract year which typically occurs in December or January, in advance of the February submission deadline. In order to bring § 422.501 up to date, we propose revising paragraph (e) to clarify that every organization seeking to become an MA organization must wait until the application cycle for the following contract year to resubmit an application that has been denied in the current contract year's application cycle.

7. Clarification of Contract Requirements for First Tier and Downstream Entities (§ 422.504 and § 423.505)

The regulations at § 422.504(i) and § 423.505(i) require MA organizations and Part D sponsors to require all of the first tier, downstream, and related entities to which they have delegated the performance of certain Part C or D functions to agree to certain obligations. In particular, the regulations require sponsors to have ''contracts or written arrangements'' that provide, for example: (1) For the delegated entity to carry out its contract in a manner consistent with the sponsor's Medicare contract obligations; (2) that the sponsor may revoke the contract if the sponsor determines that the delegated entity has not performed satisfactorily; and (3) that the sponsor on an ongoing basis monitors the performance of the delegated entity. We believed it was clear that the language of § 422.504(i) and § 423.505(i) required that all contracts governing the relationships among a sponsor and all of its delegated entities (that is, those between the sponsor and its first tier entity; those between the first tier entity and any downstream entity; and those between downstream entities) contain provisions specifically addressing each of the required elements stated in the respective paragraphs. That is, each contract was required to contain ''flow down'' clauses through which each delegated entity would become legally obligated to honor the provisions of § 422.504(i) and § 423.505(i).

In the solicitations for applications for qualification of MA organizations and Part D sponsors, we instructed applicants that all contracts with delegated entities provided for our review must include language addressing all of the elements stated in § 422.504(i) and § 423.505(i). We took this position because: (1) We believed that the requirement was clearly stated in the regulation; and (2) as the sponsor cannot enforce a contract to which it is not a party (that is, it has no privity of contract with its downstream entities), the only way to give the provisions of § 422.504(i) and § 423.505(i) full effect is to require that each subcontract specifically describe the delegated entity's obligations to the sponsor.

This interpretation was challenged in 2010 by an organization whose Part D sponsor qualification application was denied when we determined, among other things, that the contract between the applicant's first tier and downstream entities incorrectly made reference to the rights of the first tier entity, rather than the applicant, in the contract sections the applicant intended to meet the requirements of § 423.505(i). While the hearing officer upheld CMS' denial of the application, in the interest of providing transparency and clarity for the healthcare industry, we have decided to amend the regulation. The changes to the regulation will help future applicants avoid confusion about the requirements related to contracts with first tier and downstream entities, thus helping to streamline the application process.

We believe that the most legally effective and direct way to ensure that the MAOs and Part D sponsors retain the necessary control and oversight over their delegated entities is by requiring all contracts among those entities to specifically reference each party's obligations to the sponsor, as enumerated in § 422.504(i) and § 423.505(i). Documents or ''written arrangements'' other than contracts can be ambiguous as to the nature of an obligation and who has agreed to perform it. They are unreliable tools for the protection of the rights of sponsors with respect to the performance of their Medicare obligations by their delegated entities. Assurances from delegated entities that they will provide necessary instructions to other downstream entities should the need arise are equally ineffective as they provide no evidence that the downstream entity could be compelled to follow such instructions. Therefore, we propose to make explicit that sponsors can fulfill the requirements of § 422.504(i) and § 423.505(i) only by providing evidence that the contract of every first tier or downstream entity contains provisions stating clearly that the parties have agreed to recognize and give effect to the sponsor's rights as listed in those subsections. Accordingly, we propose to delete the term ''written arrangements'' throughout § 422.504(i) and § 423.505(i) and in each instance replace it with ''each and every contract.''

8. Valid Prescriptions (§ 423.100 and § 423.104)

Since the inception of the Part D program, we have consistently maintained that drugs cannot be eligible for Part D coverage unless they are dispensed upon prescriptions that are valid under applicable State law. Using our authority in section 1860D–12(b)(3)(D), we propose to codify this policy to remove any doubt as to the appropriate source of law to consult when determining whether a prescription is valid.

We propose, first, to add a definition of the term ''valid prescription'' to § 423.100 to mean a ''prescription that complies with all applicable State law requirements constituting a valid prescription.'' This would make clear the need to consult State law to determine whether a prescription is valid.

We would like to underscore that we do not intend to impose any State law requirements that do not otherwise apply. Rather, our proposal is that prescriptions must comply with *applicable* State law requirements; there is no need to comply with State law requirements to the extent that they do not apply. The two following examples illustrate our intent. Some States require that insulin syringes be dispensed upon prescription only, while other States do not. We would not require prescriptions for coverage of insulin syringes under Part D in those States that do not mandate prescriptions, but would require prescriptions for Part D coverage in States that require insulin be dispensed only upon prescription. The second example involves the Indian Health Care Improvement Act (IHCIA), which: (1) Provides that licensed health professionals employed by a tribal health program need not be licensed in the State in which the program performs services; and (2) exempts specified health facilities from obtaining State licenses provided they otherwise meet State law requirements. The proposed changes would not necessitate either that these licensed professionals obtain additional State licenses or that the specified facilities obtain initial State licenses.

We also propose to add a new paragraph (h) to § 423.104 stating that, for every Part D drug that requires a prescription, Part D sponsors may only provide benefits when that drug is ''dispensed upon a valid prescription''. In tandem with the proposed definition of the term valid prescription previously discussed, these changes would ensure that, for drugs and other items that must be prescribed (including biological products and some insulin and specified associated supplies), Part D coverage would be limited to those dispensed upon valid prescriptions under applicable State law.

At this time, we are not aware of any State that requires that each electronic or written prescription include the prescriber's individual NPI in order for that prescription to be valid. But as is discussed in section II.E.11. of this proposed rule, Access to Covered Part D Drugs through Use of Standardized Technology and National Provider Identifiers, we believe that linking individual NPIs to specific prescriptions may provide law enforcement agencies

with information that could be essential to identifying and prosecuting the particular individuals committing or abetting fraud, waste, or abuse. Accordingly, we are taking this opportunity to encourage States to require that every prescription include the individual NPI of the prescriber in order to be valid under State law.

9. Medication Therapy Management Comprehensive Medication Reviews and Beneficiaries in LTC Settings (§ 423.153)

Section 1860D–4(c)(2) of the Act requires medication therapy management (MTM) programs to be designed to ensure that, with respect to targeted beneficiaries described in section 1860D–4(c)(2)(A)(ii) of the Act, covered Part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events. Section 10328 of the Affordable Care Act further amended section 1860D–4(c)(2)(ii) of the Act to require prescription drug plan sponsors to perform at a minimum, an annual comprehensive medication review that may be furnished person-to-person or via telehealth technologies. The comprehensive medication review must include a review of the individual's medications, which may result in the creation of a recommended medication action plan with a written or printed summary of the results of the review provided to the targeted individual.

In the November 2010 proposed rule, we proposed to revise the regulations at § 423.153 to require plan sponsors to offer an annual comprehensive medical review (CMR) for targeted beneficiaries, which must include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider. In response to the proposal, a commenter indicated that LTC residents with cognitive impairments may not have the ability to interact appropriately with providers or pharmacists during the CMR when using telehealth technologies. In the April 2011 final rule, we responded by agreeing that the use of telehealth technologies for conducting CMRs may not be appropriate for all beneficiaries. We also recognized and agreed that beneficiaries residing in LTC facilities who have cognitive impairments may be unable to participate in an interactive CMR. The current regulations at § 423.153(d)(1)(vii)(B) reflect this awareness by exempting sponsors from offering interactive CMRs to targeted beneficiaries in LTC settings; however, the Act, as amended by section 10328 of the Affordable Care Act, does not provide a basis for distinguishing the offering of MTM services based on settings. Since the Affordable Care Act provision for MTM programs was not effective until 2013, in the April 2011 final rule, we indicated that we would undertake further rulemaking to clarify the requirements for MTM programs to offer CMRs to targeted beneficiaries in LTC settings.

We generally agree with the commenter that it is likely that many patients in LTC settings may not be lucid enough to participate in the CMRs, nor might they be able to comprehend the resulting medication action plan that is provided as a result. However, we believe that consistent with section1860D–4(c)(2)(A)(i) all targeted beneficiaries in LTC settings must be offered the opportunity to participate in the annual CMR, since not all residents of LTC settings are cognitively impaired. We also believe that beneficiaries will still benefit from having a non-interactive CMR performed by a pharmacist or other qualified provider. Accordingly, we propose to revise the regulation at § 423.153 to require sponsors to offer the annual CMR to targeted beneficiaries in an LTC facility, but when the beneficiary cannot accept the offer to participate, the pharmacist or other qualified provider must perform the medication review without the beneficiary. This provision would give the pharmacist or provider the ability to perform the medication review without the encumbrance of attempting to communicate with a patient who cannot make decisions regarding their medical needs. In such cases, we recommend that the pharmacist, or qualified provider, reach out to the beneficiary's prescriber, caregiver, or other authorized individual such as the residents' health care proxy or legal guardian, to take part in the beneficiary's CMR.

10. Employer Group Waiver Plans Requirement To Follow All Part D Rules Not Explicitly Waived (§ 423. 458)

The Secretary has the statutory authority to waive or modify requirements that hinder the design of, the offering of, or the enrollment in, employer/union sponsored prescription drug plans (PDPs). The statutory authority, set forth in section 1860D–22(b) of the Act, provides that the provisions of section 1857(i) of the Act shall apply with respect to prescription drug plans in relation to employment-based retiree health coverage in a manner similar to the manner in which they apply to an MA plan in relation to employers, including authorizing the establishment of separate premium amounts for enrollees in a prescription drug plan by reason of such coverage and limitations on enrollment to Part D eligible individuals enrolled in such coverage.

Under this statutory authority, in order to facilitate the offering of PDPs to employer/union group health plan sponsors, we may grant waivers and/or modifications to PDP sponsors. In general, each waiver or modification that we grant is conditioned upon the PDP sponsor meeting a set of defined circumstances and complying with a set of conditions. PDP sponsors offering EGWPs must comply with all Part D requirements unless those requirements have been specifically waived or modified.

It has come to our attention that some EGWPs that provide Part D benefits to their members may not be affording their members appropriate Medicare beneficiary protections put in place by CMS regulations or guidance. Based upon discussions we have had with sponsors of EGWPs, some sponsors believe they are exempt from Part D requirements when providing Part D benefits because of the CMS waiver of the requirement that EGWP sponsors submit plan benefit packages for CMS review (see section 20.9 of Chapter 12 of the Medicare Prescription Drug Benefit Manual). Regardless of whether plan benefit packages are submitted for review, Part D sponsors of EGWPs must meet all Part D requirements (regulatory or legislative) unless such requirements are specifically waived or modified by CMS. Therefore, in order to emphasize the importance of providing EGWP members with beneficiary protections put in place by Part D requirements, we propose to revise § 423.458 to clearly state that in the absence of a CMS approved waiver, all Part D requirements apply and in the case of a CMS approved waiver that modifies the application of Part D requirements, such requirements must be met as modified by the waiver.

11. Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers (§ 423.120)

Every time a beneficiary fills a prescription under Medicare Part D, a sponsor must submit to CMS an electronic summary record called a prescription drug event (PDE). We require that Part D sponsors obtain and submit prescriber identifiers on PDE records. Every prescriber has at least one identifier that can be submitted. These identifiers include the National Provider Identifier (NPI), Drug Enforcement Administration (DEA)

number, uniform provider identification number (UPIN), or State license number. In a June 2010 report titled, ''Invalid Prescriber Identifiers on Medicare Part D Drug Claims,'' the OIG reported the findings of its review of prescriber identifiers on 2007 Part D PDE records. The OIG reported finding 18.4 million PDE records that contained 527,749 invalid identifiers, including invalid NPIs, DEA registration numbers, and UPINs. Payments by Part D drug plans and enrollees for these PDE records totaled $1.2 billion.

In light of this report, in the Announcement of Calendar Year (CY) 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Letter issued on April 4, 2011 (CY 2012 Call Letter), we stated that we will continue in 2012 to permit Medicare Part D sponsors to report on PDE records any one of the above four identifiers. However, sponsors were instructed to ensure these identifiers are active and valid, but not to reject a pharmacy claim solely on the basis of an invalid prescriber identifier in order to not impede Medicare beneficiary access to needed medications. Thus, if an active and valid prescriber ID is not included on the Part D claim for CY 2012, either the sponsor, or the pharmacy if in accordance with the contractual terms of the network pharmacy agreement, must follow up retrospectively to acquire a valid ID before the PDE is submitted to CMS. The only exception to this guidance is that a foreign prescriber identifier cannot be validated, and therefore sponsors are directed to use the license number assigned by the foreign jurisdiction and report it on the PDE without validation (when prescriptions written by such prescribers are valid under applicable State law).

We also signaled in the CY 2012 Call Letter that we were considering a regulatory change in the Part D program that would limit acceptable prescriber identifiers on claims and PDE records in 2013 to only the individual NPI. We indicated that since all practitioners who are authorized to prescribe Part D drugs under applicable U.S. State laws, which would include foreign prescribers whose prescriptions are valid in certain States, can acquire an individual NPI from HHS, we do not believe such a change would present a significant access barrier to needed Part D drugs for Medicare beneficiaries, as we explain more fully in this section of the proposed rule.

As we noted in the CY 2012 Call Letter, the consistent use of a single validated identifier would enable us to provide better oversight over possible fraudulent activities. As a measurable indicator, we know that approximately 90 percent of Medicare Part D claims as reported in prescription drugs events (PDEs) currently submitted to CMS contain valid individual prescriber NPIs—a single identifier—even though CMS permits alternate prescriber IDs at this time. Thus, while the vast majority of Medicare Part D claims contain individual NPIs, 10 percent still do not, and CMS believes it is important for prescribers to be identified in a consistent, verifiable manner in order to conduct appropriate oversight of the program.

More specifically, CMS, MEDICs, and oversight agencies would be able to more efficiently identify patterns of unusual prescribing that may be associated with fraudulent activities. When multiple prescriber identifiers, not to mention dummy or invalid identifiers, are used, authorities must take an additional step in their data analysis before even achieving a refined data set to use for further analysis to identify possible fraud. For example, having to cross-reference multiple databases that update on different schedules to be certain of the precise prescribers involved when multiple identifiers were used, would necessitate several additional steps of data pre-analysis and would also introduce potential errors in correctly matching prescribers among databases.

Pursuant to HIPAA, HHS adopted the NPI as the standard for uniquely identifying health care providers in electronic transactions in the final rule published on January 23, 2004 (69 FR 3434), which was effective May 23, 2005, the date on which all health care providers, broadly defined in 45 CFR 160.103, became eligible for NPIs. By Mary 23, 2008, all covered health care providers, defined in 45 CFR 162.402, must have obtained an NPI. Covered health care providers must disclose their NPI to other entities that need the NPI for use in standard transactions. Health care providers who are not covered entities are not required to obtain and disclose NPIs, but HHS encourages them to do so in the NPI final rule (69 FR 3445, January 23, 2004). Therefore, we believe there are very few prescribers who do not already have an individual NPI that they will disclose to Part D sponsors and/or their network pharmacies who need it for standard transactions, with the exception of foreign prescribers, whom we discuss in greater detail later in this section of the proposed rule. In addition, for those health care providers who do not already have an NPI, obtaining one is not a burdensome endeavor and is free of charge.

In light of the foregoing, we propose to amend § 423.120(c) to require, effective January 1, 2013, that Part D sponsors must submit an active and valid individual prescriber NPI on any PDE record submitted to CMS. This requirement would enhance our efforts to use claims data to identify fraud in furtherance of section 1893 of the Act, which established the Medicare Integrity Program and the Secretary's obligations with respect thereto. In addition to supporting CMS fraud and abuse activities, accurate data on prescriptions through the consistent use of valid NPIs on PDEs allows CMS to serve beneficiaries when using data in various initiatives whose purpose is to foster higher quality and more efficient coordination of care for individuals and groups of individuals.

In this regard, we are also proposing to codify our current guidance that sponsors may not reject a pharmacy claim solely on the basis of the lack of a valid prescriber NPI, unless the issue can be resolved at point-of-sale, in order to not impede Medicare beneficiary access to needed medications. In other words, Part D sponsors may not reject pharmacy claims at point of sale without prompt follow-up to ensure that the claim has been resubmitted with a corrected and valid individual prescriber NPI, or new information has been otherwise received to correct the sponsor's information. Once a prescriber's NPI is obtained and used in a Part D claim, it will be in the Part D sponsor's and/or network pharmacy's patient information database for ongoing use, so any efforts needed to obtain corrected or missing NPIs will decrease over time.

Our proposal means that if a correct and valid individual prescriber NPI is not included in the pharmacy claim, and it is determined that the prescriber does not have one and the claim is otherwise payable (for example, no indication of fraud, the prescription is not written by a provider excluded from the Medicare program, or no question regarding coverage), the sponsor must pay the claim, but cannot submit the PDE to CMS. Thus, if an active and valid prescriber ID is not included on the Part D claim, either the sponsor, or the pharmacy if in accordance with the contractual terms of the network pharmacy agreement, must follow up retrospectively to acquire an active and valid ID before the PDE may be submitted to CMS. As noted previously, we believe prescribers' NPIs will be widely available to Part D sponsors.

We remind Part D sponsors that the requirements proposed here are on sponsors, whose responsibility it would be to be able to submit PDEs to CMS with individual prescriber NPIs. Therefore, we would expect that pharmacies will be permitted to correct any invalid data before payment for a claim is reversed whether or not a negotiated contract delegates any sponsor duties in this regard to the pharmacy. Additionally, we would expect that any requirement by a plan sponsor or its contracted PBM for a pharmacy to acquire and utilize its own automated validation capability will be arrived at only through mutual agreement, since such a requirement may be unaffordable for many smaller pharmacy organizations.

With respect to requests for reimbursement submitted directly by Medicare beneficiaries, sponsors were instructed in the CY 2012 Call Letter that payment to a beneficiary could not be made dependent upon the sponsor's acquisition of the prescriber ID itself. We are proposing to codify this guidance, so that requests for reimbursement from Medicare beneficiaries are handled in the same manner by Part D sponsors as claims from pharmacies. Thus, if the sponsor is unable to retrospectively acquire an active and valid NPI in connection with a request for reimbursement submitted by a beneficiary, the sponsor may not seek recovery of the payment from the beneficiary solely on that basis, unless there is an indication of fraud.

We have learned from stakeholders through a contractor to CMS that a key barrier to improved NPI reporting on Part D PDEs is that CMS does not currently require NPI reporting, and this proposal is thus responsive to those observations. In addition, some pharmacy representatives have offered that certain States require or accept other prescriber identifiers, which impede NPI reporting at the pharmacy level. It is unclear to us whether the latter observation was in the context of States as regulators of prescriptions or as payers of claims or both, and which alternate identifiers are required or accepted by these States. For instance, it is our understanding that the Drug Enforcement Administration (DEA) has discouraged the use of DEA numbers as prescriber identifiers, and not every prescriber has one anyway. Therefore, we seek specific comment on this issue to assist us in understanding and confirming any State-imposed barriers to the standardization of prescriber identifiers to the individual NPI for the Medicare Part D program.

We considered exercising the discretionary authority granted pursuant to section 6405(c) of the Affordable Care Act so that prescriber NPIs would be required on Part D claims and PDEs. However, such an approach would require prescribers to also enroll in the Medicare program, which is a provider credentialing process. Thus, we are concerned that requiring such enrollment could impede Part D beneficiary access to needed medications, because the process involves more effort on the part of prescribers, who are not reimbursed for prescriptions, compared to obtaining an NPI, which involves a 3-page application form that primarily seeks only identifying and location information and is free of charge. While we know that prescribers will also be concerned about beneficiary access to medications, we believe virtually all prescribers who do not already have an NPI would actually obtain one, but we are not certain this would be the case with respect to Medicare enrollment.

Regarding foreign prescribers, we understand that seven States (Arizona, Florida, Maine, North Dakota, Texas, Vermont, and Washington) currently permit pharmacies to fill prescriptions from foreign prescribers, to varying degrees. We believe that foreign prescribers may not have sufficient incentives in terms of patient base or familiarity with health care reimbursement in the United States, particularly with respect to the Medicare program and Part D benefits, to obtain individual NPIs. Thus, unlike our guidance in the CY 2012 Call Letter, and unlike our proposal here with respect to non-foreign prescribers, we are not proposing to require drugs dispensed pursuant to prescriptions of foreign prescribers to be covered by Part D sponsors when the foreign prescribers decline to obtain an individual NPI if they do not already have one. The motivation for our individual prescriber NPI proposal stems in large part from our need for consistent data to conduct better oversight over possible fraudulent activities in the Medicare Part D program. Since the Federal government has no jurisdiction over foreign prescribers, we are proposing an exception to our proposal that the sponsor must pay a claim for a prescription, but cannot submit the PDE to CMS without an individual prescriber NPI, when the claim involves a foreign prescriber who does not have an individual NPI. Thus, a Part D sponsor could reject a claim involving a foreign prescriber who does not have an NPI at point-of-sale.

In fact, in light of our lack of jurisdiction over foreign prescribers and our motivation to conduct better oversight over possible fraudulent activities, we are considering whether this proposal with respect to foreign prescribers is broad enough and whether we should instead revise the Medicare Part D rules to prohibit sponsors from paying claims that involve prescriptions written by foreign prescribers, regardless of whether the foreign prescribers obtain an individual NPI. In other words, while certain prescriptions of foreign prescribers may be valid under some State laws, medications dispensed pursuant to prescriptions written by foreign prescribers would not be payable under the Medicare Part D program. Such a policy would also be consistent with the direction we have taken with respect to medical directors, that is, that Part D sponsors must employ a physician with a current and unrestricted license to practice medicine in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia. We note that we are not making such a proposal at this time, but solicit specific comments on foreign prescribers and the Part D program.

Section 423.120(c) sets forth the responsibilities of Part D plan sponsors with regard to the use of standardized technologies and compliance with the HIPAA standards at 45 CFR 162.1102. We are proposing to add a new paragraph (5)(A) which would require Part D plan sponsors to submit to CMS only PDE records that contain an active and valid individual prescriber NPI. However, new paragraph (c)(5)(B) would codify current guidance and require that a Part D plan sponsor not reject a claim from a network pharmacy solely on the basis that it does not contain an active and/or valid NPI unless the issue can be resolved at point-of-sale, there is an indication of fraud, or the claim involves a prescription written by a foreign prescriber (where permitted by State law). New paragraph (5)(C) would prohibit a Part D sponsor, with respect to requests for reimbursement submitted directly by Medicare beneficiaries, from making payment to the beneficiary dependent upon the sponsor's acquisition of the prescriber NPI and would further prohibit a Part D sponsor from seeking recovery of the payment from the beneficiary solely on the basis that the sponsor was unable to retrospectively acquire an active and valid individual prescriber NPI, unless there is an indication of fraud.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

The following sections of this document contain paperwork burden but not all of them are subject to the ICRs under the PRA for reasons noted.

A. ICRs Regarding the Coverage Gap Discount Program (§ 423.100, § 423.505(b), § 423.1002, and Part 423 Subpart W)

Section 1860D–14A (d)(6) of the Act exempts this section from PRA requirements.

B. ICRs Regarding the Inclusion of Benzodiazepines and Barbiturates as Part D Drugs (§ 423.100)

In accordance with section 175 of MIPPA, which amended section 1860D–2(e)(2)(A) of the Act, we propose to revise the definition of Part D drug at § 423.100, to include barbiturates when used for the medical indications of epilepsy, cancer, or a chronic mental health disorder, and benzodiazepines, effective January 1, 2013.

Under this proposal, Part D plan sponsors would be required to submit information in their formulary files indicating that they will cover these drugs. The collection of information burden on Part D sponsors imposed by this proposed regulation is negligible. Any burden associated with the requirement on sponsors relates to the required data entry in the formulary file software, and would be included in the PRA package entitled, Formulary Submission for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP) for Contract Year (CY) 2013 (OCN 0938–0763).

C. ICRs Regarding Pharmacy Benefit Manager's Transparency Requirements (§ 423.514)

Consistent with the statutory requirements, our proposal adds an additional data element to the DIR data reporting: Aggregate amount of the difference between the amount the Part D sponsor pays the PBM and the amount the PBM pays retail and mail order pharmacies. This data element is already available to plans as they are aware of the amounts they pay to their contracted PBMs and they currently report to CMS the amounts paid to retail and mail order pharmacies on the PDE records. We do not believe that our proposal imposes any additional substantive burden on Part D sponsors and PBMs, and, therefore, have not incorporated a burden increase.

We are soliciting comment on whether any of the following data elements can be collected using existing data sources, thereby alleviating additional reporting burden on Part D sponsors and PBMs:

- Number of retail prescriptions.
- Number of mail order prescriptions.
- Number of prescriptions dispensed by independent pharmacies.
- Number of prescriptions dispensed by chain pharmacies.
- Number of prescriptions dispensed by supermarket pharmacies.
- Number of prescriptions dispensed by state-licensed mass merchandisers to the general public.

D. ICRs Regarding Good Cause and Reinstatement Into a Cost Plan (§ 417.460)

Our proposal in § 417.460 extends reinstatement rights currently in place for members of MA and Part D plans to members of cost plans. Because good cause determinations would be made by CMS (or its contractor), we believe that this proposal would not impose any new information collection requirements.

E. ICRs Regarding Requiring MA Plans Issuance of Member ID Cards (§ 422.111)

Under our authority at section 1852(c) of the Act to require that MA organizations disclose MA plan information upon request, as well as our authority under section 1857(e) of the Act to specify additional contractual terms and conditions the Secretary may find necessary and appropriate, we propose to expressly require MA plans issue and re-issue as necessary a MA member ID card that enables enrollees to access all covered services. While this requirement is subject to the PRA, we believe this burden is exempt as defined in 5 CFR 1320.3(b)(2). That is, the time, effort, and financial resources necessary to comply with the requirement would be incurred by MA organizations in the normal course of their business activities.

F. ICRs Regarding Determination of Actuarially Equivalent Creditable Prescription Drug Coverage (§ 423.56)

Since we are proposing to amend a calculation at § 423.56 to be consistent with the calculation of the actuarial value of qualified retiree prescription drug coverage found at § 423.884(d) and to change the term ''CMS actuarial guidelines'' to read ''CMS guidelines'' to allow CMS further flexibility in issuing interpretive guidance on these requirements, there is no new information collection burden on organizations.

G. ICRs Regarding Who May File Part D Appeals With the Independent Review Entity (§ 423.600 and § 423.602)

The information collection requirements referenced in this section are exempt from the PRA in accordance with 5 CFR 1320.4(a)(2) which excludes collection activities during the conduct of administrative actions, such as redeterminations, reconsiderations, and/or appeals.

H. ICRs Regarding CMS Termination of Health Care Prepayment Plans (§ 417.801)

This section does not impose any new information collection requirements.

I. ICRs Regarding Termination or Non-Renewal of a Medicare Contract Based on Consistent Poor Plan Performance Ratings (§ 422.510 and § 423.509)

It is our position that 3 years' worth of low-star ratings constitutes a sufficient basis for us to terminate a sponsor's Part C or D contract under our authority under section 1857(c)(2) of the Act. The regulation has been changed to reflect that.

Regarding ICRs, we are not imposing any new reporting requirements. We are merely harnessing and putting to use internal data that has already been collected. We do not believe that our proposal would result in an additional burden; therefore, we have not incorporated a burden increase.

J. ICRs Regarding Denial of Applications Submitted by Part C and D Sponsors With a Past Contract Termination or CMS-Initiated Non-Renewal (§ 422.502 and § 423.503)

We have modified the past performance review period described in § 422.502(b) and § 423.503(b) (by adding new paragraphs at § 422.502(b)(3) and at § 423.503(b)(3) as well as § 422.502(b)(4) and at § 423.503(b)(4)) to include among the factors that may support a CMS denial of a contract application those CMS-initiated terminations or non-renewals that became effective within the 38 months preceding the submission of a new application.

We are not imposing any new reporting requirements. We are merely further refining our intended approach to using past performance in making application determinations. We do not believe that our proposal would result in an additional burden; therefore, we have not incorporated a burden increase.

K. ICRs Regarding New Benefit Flexibility for Fully Integrated Dual Eligible Special Needs Plans (FIDE SNPs) (§ 422.102)

Under proposed § 422.102(e) we would allow certain FIDE SNPs participating in the Medicare-Medicaid Integration Initiative, the flexibility to offer supplemental benefits beyond those that we allow for all other MA plans. We would review each qualified SNP's proposed supplemental benefit offerings as part of our review of plan bids, and we would approve additional supplemental benefit offerings for these qualified SNPs as we deem necessary. The burden associated with this proposed requirement is the time and effort necessary for SNPs to submit their benefit designs, including cost-sharing amounts, via the PBP software. While this proposed requirement is subject to the PRA, the burden associated with it is currently approved under OCN 0938–0763 with a March 31, 2012 expiration date.

L. ICRs Regarding Clarifying Payment to Providers in Instances of Hospital-Acquired Conditions (HACs) (§ 422.504)

We propose to require MAOs provide in their contracts with hospitals that payments for Part A hospital services will be reduced for serious events that could be prevented through evidence-based guidelines, in accordance with the HACs and POA policy that is currently required for hospitals paid under the Original Medicare IPPS. We believe that plans already have some operational systems in place to facilitate implementation of the requirement. For example, MAOs are already required to pay non-contract provider hospitals the amount that they would receive for services under original Medicare, including any applicable reductions for HACs. Also, beginning January 3, 2012, MA plans would be required to collect and submit encounter data for each item and service provided to MA enrollees in accordance with risk adjustment policies required in § 422.310(d). This information is collected using the HIPAA 5010, which already in use by hospital providers for FFS claims and contains fields for POA indicator reporting. While this proposed requirement is subject to the PRA, the diagnosis, POA indicator information, and other claims information are already collected as part of the encounter data collection process, and this burden is currently approved under OCN 0938–1054.

Additionally, we believe that hospitals will already be familiar with POA reporting and would not require additional education. Therefore, the burden associated with this provision would be the time and effort necessary for MA plans to modify their claims processing to recognize the POA indicators, if they do not already do so, and to adjust payment to contracted hospitals for the HAC events accordingly. Plans usually update their claims processing systems regularly for changes such as, payment logic for new national and local coverage determinations, updating HCPCS code information, and other changes to their payment calculations. Therefore, we believe this burden is exempt from the PRA as defined in 5 CFR 1320.3(b)(2), because the time, effort, and financial resources necessary to comply with this requirement would be incurred by plans in the normal course of their business activities.

M. ICRs Regarding Clarifying Coverage of Durable Medical Equipment (§ 422.101(a) and § 422.112(a))

Under § 422.100(l) we propose to permit MA plans to limit coverage of DME to specific manufacturers' products or brands. Furthermore, in order to ensure that MA enrollees have adequate access to their DME benefits, our proposed regulatory changes establish requirements with respect to access, midyear changes to preferred DME items and supplies, appeals, and disclosure of DME coverage limitations to enrollees. The burden associated with this requirement is the time and effort necessary for MA organizations to submit their benefit designs via the PBP software. While this requirement is subject to the PRA, the burden associated with it is currently approved under OCN 0938–0763. With respect to disclosing DME coverage limitations, this requirement is captured in the burden associated with the annual notice of coverage/evidence of coverage which must be completed at the time of the beneficiary's enrollment and at least annually thereafter. The MA program disclosure requirement is at § 422.111 and the burden associated with it is currently approved under OCN 0938–0753.

N. ICRs Regarding Broker and Agent Requirements (§ 422.2274 and § 423.2274)

At § 422.2274 and § 423.2274, we are proposing that plans can choose any agent/broker compensation amount at or below the fair market value amount annually. We require MA organizations to submit and/or update and attest to their compensation amount (or range) in the HPMS. This web-based system in HPMS allows new plans to submit information and, for existing plans, automatically updates, based on changes in MA payment rates, organization compensation information. We are proposing to allow plans to annually adjust their base compensation rates to reflect fair market value. Plans would continue to be required to annually submit and attest to this information to CMS through HPMS. While this proposed requirement is subject to the PRA, it does not impose any new information collection requirement on plans. The burden associated with the proposed requirement currently approved under OMB control number (OCN) 0938–0753.

O. ICRs Regarding the Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse and Waste Control Program (§ 423.153)

In accordance with section 1860D–4(c) of the Act, we propose revising § 423.153 at paragraph (b)(4) to provide that a Medicare Part D sponsor's drug utilization management program must establish and apply a daily cost-sharing rate to a prescription presented by an enrollee at a network pharmacy for a covered Part D generic or brand drug that is dispensed for a supply of less than 30 days. Under this proposal, the enrollee and his or her prescriber generally would decide if a medication supply of less than 30 days would be appropriate, and if so, the cost-sharing for the medication would be prorated by the Part D sponsor based on the days supply dispensed.

The collection of information burden on Part D sponsors imposed by this proposed regulation is negligible. Any burden associated with this proposal on sponsors related to the required data entry in the PBP software would be included in the revised PRA package entitled Plan Benefit Package (PBP) and Formulary Submission for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP) for Contract Year (CY) 2013 (OCN 0938–0763). Since obtaining a supply of a medication for less than 30 days is optional for the enrollee and his or her prescriber, there is no collection of information burden imposed by these proposed regulations on either Part Medicare D enrollees or their prescribers.

P. ICRs Regarding Technical Corrections to Enrollment Provisions (§ 417.422, § 417.432, § 422.60, and § 423.56)

At § 417.422, § 417.432, § 422.60, and § 423.56 we are proposing technical changes that correct cross-references that should have been updated in previous rulemaking. These proposals do not establish any new rules or requirements for cost or Part D plans. They merely update regulatory cross-references that were overlooked in previous rulemaking. As a result, this proposal does not impose any new information collection requirements.

Q. ICRs Regarding Applying MA and Part D Disclosure Requirements to Cost Contract Plans (§ 417.427)

We are proposing to extend the disclosure requirements in § 422.111 and § 423.128 to cost contract plans. Our regulations at § 422.111 and § 423.128 require MA organizations and Part D sponsors to disclose to enrollees, at the time of enrollment and annually thereafter (in the form of an annual notice of change/evidence of coverage, or ANOC/EOC mailing), certain detailed information about plan benefits, service area, provider and pharmacy access, grievance and appeal procedures, quality improvement programs, and disenrollment rights and responsibilities. Sections 422.111 and 423.128 also require the provision of certain information about requests and establish requirements with respect to dissemination of explanations of benefits, customer service call centers, and Internet websites.

The burden associated with this requirement is the time and effort associated with completing an ANOC/EOC at the time of a beneficiary's enrollment and at least annually thereafter, as specified in § 422.111(a)(2) of the MA program regulations and § 423.128(a)(3) of the Part D program regulations. For each entity, we estimate that it will take 12 hours to develop and submit the required information. This includes 1 hour to read CMS' published instructions, 6 hours to generate the standardized document, 1 hour to submit the materials, 4 hours to print and disclose to the beneficiaries. This package is currently approved under OCN 0938–0753 with a November 30, 2011 expiration date to account for this burden as detailed in Table 6. We estimate 20 cost contractors would be affected annually by this requirement, resulting in a total annual burden of 240 hours. We estimate, based on a hourly wage of $29.88 (hourly salary for a compliance officer/cost estimator according to Bureau of Labor Statistics) plus 48 percent for fringe benefits and overhead, that this requirement will result in a total annual burden of $10,613 (240 burden hours multiplied by $44.22 per hour). We are revising the PRA package currently approved under OCN 0938–0753 with a November 30, 2011.

R. ICRs Regarding Clarification of and Extension of Regional Preferred Provider Organization Plan Single Deductible Requirements to Local Preferred Provider Plans (§ 422.101)

This section does not impose any new information collection requirements.

S. ICRs Regarding Modifying the Current PFFS Plan Explanation of Benefits (EOB) Requirements (§ 422.216(d)(1))

Section 1852(k)(2)(c) of the Act and § 422.216(d)(1) require PFFS plans to provide an EOB to enrollees for each claim filed by the enrollee or the provider that furnished the service. In the interest of consistency for beneficiaries and MA organizations, we propose to amend § 422.216(d)(1) to state that the EOB requirement for PFFS plans would be consistent with the MA EOB requirements of § 422.111(b)(12). The standard EOB that we are currently developing and piloting in CY 2012 for most other MA plan types would include the same information as currently required for PFFS plans, as well as plan MOOP cost limit information. Adding this cross-reference to § 422.216(d)(1) would provide consistency in EOB requirements and submission and approval of marketing materials across plan types. Since the pilot program is in progress and we would not have finalized EOB requirements during this rulemaking, we propose that PFFS plans would continue to furnish EOBs as they have been, in accordance with § 422.216(d)(1), until we finalize and implement EOB models for all MA plans. While this proposed requirement is subject to the PRA, the information collection has been approved under CMS form CMS–10349, the information collection approved for the Part C EOB at § 422.111(b)(12).

T. ICRs Regarding Authority To Deny SNP Applications and SNPs Appeal Rights (§ 422.500)

Our proposed amendments to § 422.500(a), § 422.501(a), § 422.501(c)(1)(iii), § 422.502(a) and § 422.502(c) would give CMS the authority to deny SNP applications that fail to demonstrate that the MAO meets the requirements of § 422.2, § 422.4(a)(1)(iv); § 422.101(f); § 422.107, if applicable; and § 422.152(g). The burden associated with this requirement is the time and effort required by an MAO offering a SNP to complete a SNP application. While these requirements are subject to the PRA, we do not expect the burden to change from the existing burden estimate, as currently approved under OCN 0938–0935, with a January 31, 2012 expiration date.

Our proposed amendments to § 422.641 provide the procedures for making and reviewing certain contract determinations while our proposed amendments to § 422.660 establish the circumstances under which an MA organization may request a hearing before a CMS hearing officer. We are proposing these amendments to our existing regulations so that each applicant that we determine not to be qualified to offer a SNP has the right to request an administrative review of CMS' determination. The burden associated with these requirements is the time and effort of the SNP applicant in developing and presenting their case to a CMS hearing official, and ultimately the CMS Administrator, to demonstrate that they qualify to offer a SNP.

We expect the burden associated with this provision to be incurred by the small number of SNP applicants that we expect would receive application denials, and the small percentage of denied applicants that we expect would appeal our denial decision. We estimate that the total annual hourly burden for developing and presenting a case for us to review is equal to the number of organizations likely to request an appeal multiplied by the number of hours for the attorneys of each appealing SNP to research, draft, submit, and present their arguments to CMS. Based on SNP application denials from contract year 2012, out of the approximately 400 SNP applications received, 8 of these applications were denied and all 8 denials were appealed. In contract year 2011, 8 SNP applications were denied

and none of these denials were appealed. Taking the average of the last 2 years, we estimate that approximately 4 denied applicants would appeal the denial of the SNP application. We further estimate that one attorney working for 8 hours could complete the documentation to be submitted for each application denial, resulting in a total burden estimate of 32 hours (8 hours x 4 SNP application denials = 32 hours). The estimated annual cost to an MA organization that has been denied to offer a SNP associated with this provision (assuming an attorney billing $250 per hour) is $8,000 (32 hours x $250 = $8,000) as detailed in Table 6. We are revising the PRA package currently approved under OCN 0938–0935, with a January 31, 2012 expiration date, to account for this burden.

U. ICRs Regarding Timeline for Resubmitting Previously Denied MA Applications (§ 422.501)

This section does not impose any new information collection requirements.

V. ICRs Regarding Contract Requirements for First Tier and Downstream Entities (§ 422.504 and § 423.505)

We proposed to modify the regulations at § 422.504(i) and § 423.505(i) by deleting the term ''written arrangements'' throughout and in each instance replacing it with ''each and every contract,'' thus ensuring that the MAOs and Part D sponsors retain the necessary control and oversight over their delegated entities by requiring that all contracts among those entities specifically reference their obligations to the sponsor.

Regarding ICRs, we are not imposing any new reporting requirements. We are simply clarifying a requirement with which MAOs and Part D sponsors must already comply concerning their contracts with first tier and downstream entities. We do not believe that our proposal would result in an additional burden; therefore, we have not incorporated a burden increase in the PRA section.

W. ICRs Regarding Valid Prescriptions (§ 423.100 and § 423.104)

Our proposed definition of ''valid prescription'' in § 423.100 and requirement of a ''valid prescription'' in § 423.104 would codify our longstanding policy of deferring to State laws when applicable to determine whether a prescription is valid such that the drug may be eligible for Part D coverage. We are not imposing any new reporting requirements. Prescribers and pharmacies remain subject to applicable State laws regarding valid prescriptions. Furthermore, private contracts regarding Part D drugs (such as those between MAOs or Part D sponsors and pharmacies) likely also require valid prescriptions. Given these realities, we do not believe that codifying our practice of limiting Part D coverage to items dispensed upon applicable State law requirements for valid prescriptions could necessitate any more action than that already required on the part of stakeholders—be they prescribers taking steps to ensure they write valid prescriptions or MAOs, Part D sponsors, PBMs, or pharmacies trying to ascertain that prescriptions are valid.

X. ICRs Regarding Medication Therapy Management Comprehensive Medication Reviews and Beneficiaries in LTC Settings (§ 423.153)

Our current regulation requires that the comprehensive medication review must include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider, and may result in a recommended medication action plan. The proposed change to § 423.153 permits the sponsor to allow the pharmacist or other qualified provider to perform the medication review without the beneficiary in cases when the beneficiary is in an LTC facility and cannot accept the sponsor's offer of a comprehensive medication review.

The burden associated with the comprehensive medication reviews was reflected in the approved 0938–0964 which is due to expire September 30, 2012. We believe this minor revision to § 423.153(d)(1)(vii)(B) has no effect on that burden estimate.

Y. ICRs Regarding Coordination of Part D Plans with Other Prescription Drug Coverage (§ 423.458)

Since we are proposing a change to simply strengthen our policy regarding EGWP sponsor responsibilities, there is no additional burden on the part of sponsors or other entities associated with the proposed regulation. This section does not impose any new information collection.

Z. ICRs Regarding Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers (§ 423.120)

Currently, Part D sponsors report any one of four prescriber identifiers on PDE records. However, the inconsistent use of identifiers that have not been validated has hindered efforts to combat fraud and abuse. Therefore, we proposed to require that effective January 1, 2013, Part D sponsors must include valid, individual prescriber NPIs as identifiers in PDEs submitted to CMS. Since Part D sponsors are already required to include a prescriber identifier on Part D PDEs submitted to CMS, there is no new collection of information burden imposed by this proposed regulation. Furthermore, this proposed regulation does not impose any new collection of information burden on Medicare beneficiaries enrolled in the Part D program with respect to requests for reimbursement they may submit.

TABLE 6—ESTIMATED FISCAL YEAR REPORTING RECORDKEEPING AND COST BURDENS

Regulation sections	OMB Control no.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost ($)	Total capital/ maintenance costs ($)	Total cost ($)
§ 417.427	0938–0753	20	20	12	240	44.22	10,613	N/A	10,613
§ 422.500	0938–0935	4	4	8	32	250.00	8,000	N/A	8,000
Total	.....	24	24	.....	272	.....	.....	N/A	18,613

Note: Estimates of costs and savings reflect scoring by the Centers for Medicare and Medicaid Services, Office of the Actuary, and 2010 wage data from the U.S. Department of Labor, Bureau of Labor Statistics.

Additional Information Collection Requirements

This proposed rule imposes collection of information requirements as outlined in the regulation text and specified above. However, this proposed rule also makes reference to associated information collection requirements that are not discussed in the regulation text contained in this document. The following is a discussion of these information collection requirements.

Independence of LTC Consultant Pharmacists

As discussed in Section II.B.5, we are considering changes which would require each LTC facility to employ or obtain the services of a licensed pharmacist to provide consultation on all aspects of pharmacy services in a facility. These changes would further require an LTC facility to employ or directly or indirectly contract with a licensed pharmacist who was independent of the pharmacy located in or under contract with the facility.

The changes under consideration would require an independent licensed pharmacist to review the drug regimen of each resident at least once a month and define independent to mean that the licensed pharmacist must not be employed, under contract, or otherwise affiliated with the facility's pharmacy, a pharmaceutical manufacturer or distributor, or any affiliate of these entities

LTC facilities commonly contract with an LTC pharmacy for consultant pharmacist services. Because the changes under consideration would specifically require LTC facilities to employ or directly or indirectly contract with licensed pharmacists who are independent of the pharmacy located in or under contract with the facility, any other pharmacy-related organization, or pharmaceutical manufacturer or distributor, each facility would need to engage an independent consultant pharmacist. The annual burden associated with this requirement would relate to developing and executing contracts with independent consultant pharmacists. Although all 15,713 LTC facilities would need to provide the services of an independent consultant pharmacist, factors, such as the existence of nursing home chains and group purchasing organizations (GPOs), would affect the actual number of entities that would be engaged in the process of employing or contracting the LTC consultant pharmacists. For purposes of determining the fiscal year burden, we will assume that LTC facilities would have a contract with one consultant pharmacist.

Based on our experience with LTC facilities, we expect that complying with the requirement under consideration would primarily require the involvement of the LTC facility's administrator with the assistance of a facility physician, and the director of nursing. We expect also that the facility's attorney would assist with drafting the contract and reviewing any revisions. We estimate that complying with this requirement would require 16 annual burden hours for each facility to execute a contract with an independent consultant pharmacist at an estimated cost of $1,466. Thus, although we expect that many contracts will be negotiated by the facilities' parent organizations or through GPOs, were each LTC facility to directly engage in the contracting process, it would require 251,408 burden hours per fiscal year (16 annual burden hours per LTC facility × 15,713 LTC facilities) for all 15,713 LTC facilities to comply with this requirement at an estimated cost of $23,035,258 ($1,466 estimated cost per LTC facility × 15,713 LTC facilities).

After the first fiscal year, we estimate that continued compliance with the requirement under consideration would require 2 annual burden hours (1 hour each for the facility administrator and attorney) for each facility to review the contract and, if necessary execute an updated contract with an independent consultant pharmacist at an estimated cost of $192. Thus, it would require 31,426 burden hours per fiscal year (2 annual burden hours per LTC facility × 15,713 LTC facilities) for all 15,713 LTC facilities to comply with this requirement at an estimated cost of $3,016,896 ($192 estimated cost per LTC facility × 15,713 LTC facilities).

In addition to the LTC facility costs associated with the direct compensation of consultant pharmacists, facilities with existing LTC pharmacy contracts that include the pharmacy's provision of consultant pharmacist services would potentially need to amend these contracts. However, we do not know and cannot estimate the number of LTC facilities that would need to amend their LTC pharmacy contracts. We believe that our consultant pharmacist contracting cost estimates are likely to be sufficiently overstated to cover these costs as well.

Although it is currently common for LTC consultant pharmacists to perform approximately 60 drug regimen reviews in a day, we suspect that this rate may be too high given our expectation that independent consultant pharmacists would conduct more thorough drug regimen reviews, monitoring for drug side effects and effectiveness. Therefore, in the preamble, we are soliciting public comment on best practices related to the conduct of drug regimen reviews.

Pending public response to our request for comment, we have estimated the following costs related to the requirement under consideration based on an average time of 20 minutes to perform a drug regimen review. Based on the total number of LTC facilities (15,713) and total beds (1.5 million), the average LTC facility would have 100 residents. Therefore, we anticipate that it would take each facility's consultant pharmacist 2,000 minutes (20 minutes per review × 100 residents) or 33 hours each month to perform the residents' drug regimen reviews. Using an hourly rate of $51.53 for independent consultant pharmacist that includes fringe benefits, we estimate 396 (33 hours per month × 12) annual burden hours per facility at an annual cost of $20,406 (396 × $51.53) for a total cost of $320,637,592 ($20,406 per facility × 15,713 LTC facilities). (Hourly rate according to May 2010 wage data from Bureau of Labor Statistics estimates from the Occupational Employment Statistics Survey).

V. Regulatory Impact Analysis

A. Statement of Need

The purpose of this final rule is to make revisions to the MA Part C and Part D programs to implement provisions specified in the statute and make other changes to the regulations based on our continued experience in the administration of the Parts C and Part D programs. The proposed rule would—(1) implement statutory provisions; (2) strengthen beneficiary protections; (3) exclude plan participants that perform poorly; (4) improve program efficiencies; and (5) clarify program requirements.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and

benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This proposed rule has been designated an ''economically significant'' rule under section 3(f)(1) of Executive Order 12866. Accordingly, we have prepared a regulatory impact analysis that details the anticipated effects (costs, savings, and expected benefits), and alternatives considered by proposed requirement. Details regarding the burden associated with the requirements of this proposed regulation are located in the Collection of Information section of this rule.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.0 million to $34.5 million in any 1 year). Individuals and States are not included in the definition of a small entity. This proposed rule does not directly impact, health care providers, suppliers and State governments since it amends the current requirements for MA organizations and Parts D sponsors, and adds requirements for pharmaceutical manufacturers consistent with the statutory requirements of the new manufacturer drug discount program. Although this proposed rule requires MA organizations to extend the IPPS policy regarding non-payment for HACs from non-contracted provider hospitals to contracted and hospitals, we do not expect this requirement to significantly impact total hospital costs or revenues. Part D sponsors and pharmaceutical manufacturers, the entities that will largely be affected by the provisions of this rule, are not generally considered small business entities. Part D sponsors must meet minimum enrollment requirements (5,000 in urban areas and 1,500 in nonurban areas) and because of the revenue from such enrollments, these entities are generally above the revenue threshold required for analysis under the RFA. We determined that there were very few Part D sponsors that fell below the size thresholds for ''small'' businesses established by the Small Business Administration (SBA). Currently, the SBA size threshold is $7 million in total annual receipts for health insurers (North American Industry Classification System, or NAICS, Code 524114) and CMS has confirmed that most Part D sponsors have Part D receipts above the $7 million threshold. We also determined that there were very few pharmaceutical manufacturers participating in the Medicare prescription program drug discount program that fell below the size thresholds for small businesses using the SBA size threshold of 750 employees (NAICS code 32541). Total jobs data for manufacturers support the fact that the pharmaceutical industry is dominated by large businesses.

While the NAICS lists 1,555 business in the United States that represent the pharmaceutical and medicine manufacturing industry only 237 brand manufacturers currently participate in the program, and most exceed the 750 employee threshold. The majority of smaller manufacturers are either generic or specialty pharmaceutical manufacturers that are unlikely to participate in the Medicare discount program. We reviewed some of the employment statistics for the smaller specialty pharmaceutical manufacturers that participate in the discount program, and found that the number of employees typically exceeds the SBA threshold.

While a very small rural plan could fall below the threshold, we do not believe that there are more than a handful of such plans. Similarly, manufacturers are not normally considered small business entities. However, there are manufacturers that have minimal revenue, primarily because their emphasis is on the development of products rather than sales or they are not focused on large markets. A fraction of MA organizations and sponsors are considered small businesses because of their non-profit status. HHS uses as its measure of significant economic impact on a substantial number of small entities, a change in revenue of more than 3 to 5 percent. We do not believe that this threshold would be reached by the proposed requirements in this proposed rule because this proposed rule would have minimal impact on small entities. Therefore, an analysis for the RFA will not be prepared because the Secretary has determined that this proposed rule would not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector of $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately $136 million. This proposed rule is expected to reach this spending threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Based on CMS Office of the Actuary estimates, we do not believe that this proposed rule imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

In Table 7, we estimate total costs to the Federal government, States, Part D sponsors, MA organizations, pharmaceutical manufacturers and other private sector entities as a result of various provisions of this proposed rule. The provisions with the most significant costs (costs greater than $100 million from FY 2013 through FY 2018) in this proposed rule are the Medicare Coverage Gap Discount Program, and the Inclusion of Benzodiazepines, and Barbiturates as Covered Part D drugs.

The total costs of the Medicare Coverage Discount Program for the periods beginning FY 2013 through FY 2018 are estimated to be $32.7 billion, and the total costs of the inclusion of benzodiazepines and barbiturates is $1.9 billion.

Tables 8, 9, and 10 detail the costs by cost-bearing entity. Specifically, Table 8 describes costs and savings to the Federal government, Table 9 describes costs to MA organizations and/or PDP sponsors and third party entities, Table 10 describes costs to pharmaceutical manufacturers, Table 11 describes savings to States, and Table 12 describes costs to LTC facilities.

As a result, when considering both the costs and savings associated with the provisions of this proposed rule, we conclude with a net cost estimate of $32.5 billion for FY 2013 through FY 2018.

C. Anticipated Effects

1. Medicare Coverage Gap Discount Program

a. Required Payment of Gap Discounts

We believe there is a cost to manufacturers to pay the discounts to beneficiaries who are in the coverage gap. We estimate that aggregate discounts from pharmaceutical manufacturers would be $31.3 billion during FY 2013 through FY 2018. That estimate is based upon historical patterns of claims dispensed during the coverage gap and the dollar amount of those claims trended forward by enrollment growth and price increase.

In addition, the Discount Program will increase Medicare costs by additional use of more expensive brand name drugs because of improved beneficiary adherence as a result of the lower out-of-pocket costs and increased use of brand name rather than generic drugs. We estimate that the Discount Program would increase Medicare costs by $1.4 billion during FY 2013 through FY 2018.

Note that these estimated Medicare costs do not include costs related to the ACA provisions that revised the Part D benefit structure to close the coverage gap. These provisions revised the coinsurance amount and reduced the growth in the annual out-of-pocket threshold. The costs to the Federal government associated with these provisions, as scored in the April 15, 2011 final rule (76 FR 21432), were estimated to total $3.6 billion during FY 2011 through FY 2016.

b. Other Manufacturer Costs

We believe that manufacturers would incur costs as a result of the Agreement's requirements for manufacturers. For example, manufacturers would need to analyze and pay quarterly invoices, notify CMS about labeler code changes, notify FDA about NDC changes and maintain records for potential audit by CMS. However, manufacturers already have existing systems and perform these activities as a result of their experience with Medicaid and Tricare. We estimate that analyzing and paying the quarterly invoices would require 0.5 FTEs. We estimate that the cost to manufacturers would be $73,380 (annual salary for a Pharmaceutical Manufacturing Compliance Officer according to Bureau of Labor Statistics) plus 48 percent for fringe benefits and overhead × 0.5 FTE × 240 manufacturers × 6 years for a total cost of $78.2 million over the complete period FY 2013 through FY 2018.

2. Payment Processes for Part D Sponsors

We believe that there would be a minor impact on Part D sponsors from receiving and reconciling estimated rebates advanced by CMS with subsequent payments by manufacturers. Part D sponsors have experience and existing systems to accept and reconcile funds with CMS, including a LICS subsidy and a reinsurance subsidy. We believe that there would be a marginal increase in resources focused on accounting and computer system operations and maintenance. We estimate that the additional resources required would be 0.5 FTEs, on average, per Part D sponsor. We estimate that the total cost to Part D sponsors would be $63,360 (annual salary for insurance carrier compliance officer according to Bureau of Labor Statistics) plus 48 percent for fringe benefits and overhead × 0.5 FTE per Part D sponsor × 270 Part D sponsors × 6 years for a total of $76.0 million over the complete period FY 2013 through FY 2018.

3. Provision of Applicable Discounts for Applicable Drugs for Applicable Beneficiaries

We believe that there would be a minor impact on Part D sponsors as a result of this provision. Part D sponsors already implement systems to adjudicate pharmacy claims. With the exception of calculating and accounting for gap discounts, those systems include similar, if not identical, tasks as the requirements in the proposed rule. Further, we believe that the carrying cost of distributing the discounts to beneficiaries would be offset by prospective payments from us as previously described.

We believe that the additional workload associated with this proposed regulation would involve modifications to existing computer programming to account for the differences between the Discount-related systems and the traditional Part D program. In addition, we expect there to be additional reporting and recordkeeping. We estimate that Part D sponsors would increase resources the equivalent of 0.5 additional FTEs to accomplish these tasks. We estimate the cost to Part D sponsors would be at $63,360 (annual salary for insurance carrier compliance officer according to Bureau of Labor Statistics) plus 48 percent for fringe benefits and overhead × 270 Part D sponsors × 6 years for a total cost of $76.0 million over the complete period FY 2013 through FY 2018.

4. Manufacturer Discount Payment Audits and Dispute Resolution

The proposed regulation would permit manufacturers to undertake audits of the data used to calculate quarterly invoices and to dispute the invoices themselves. We believe that the activities necessary for disputing invoices and conducting data audits would be accommodated by the additional resources that we earlier linked to the Medicare Coverage Gap Agreement. Therefore, we are not estimating an additional economic impact to manufacturers from this provision.

5. Beneficiary Dispute Resolution

The proposed rule would create the right of beneficiaries to dispute gap discounts using preexisting Part D sponsor beneficiary dispute resolution mechanisms. We believe that the potential increase in beneficiary dispute volume would not require additional Part D sponsor resources. We have made significant efforts to ensure that the data used to calculate the discounts are accurate. We believe that the accuracy of the data, coupled with the automation of the dispute calculation, would result in accurate discounts that would generate few beneficiary appeals and would be accommodated within existing resources.

6. Compliance Monitoring and Civil Money Penalties

The proposed regulations would allow CMS to impose penalties if a manufacturer does not pay gap discounts that are owed according to the terms of the Agreement. We believe that, in general, manufacturers would pay the quarterly invoice according to the terms within the agreement and other guidance. Therefore, we believe that there would be few instances where manufacturers are levied a civil money penalty. We assume that monetary penalties could be levied on approximately 0.03 percent of discounts with $9.64 million of penalties over the period FY 2013 through FY 2018.

7. Termination of Discount Program Agreement for Part D Program

We believe that we would rarely find it necessary to terminate an agreement. Upon termination, covered Part D drugs of the manufacturers would be excluded from the Part D program and the manufacturer potentially would suffer a significant reduction in revenue. We have experience with similar programs and believe that the potential reduction of revenue would encourage manufacturers to resolve our concerns. This would tend to avoid terminations and the associated fiscal effects. Consequently, we estimate that there would be no material costs to manufactures due to potential agreement terminations during the period FYs 2013 through 2018.

8. Inclusion of Benzodiazepines and Barbiturates as Part D Drugs

In accordance with section 175 of the MIPPA that amended section 1860D–2(e)(2)(A) of the Act (42 U.S.C. 1395w–102(e)(2)(A)),we propose to revise the definition of Part D drug at § 423.100, by including barbiturates when used for the medical indications of epilepsy, cancer, or a chronic mental health disorder, and benzodiazepines class drugs as covered under Part D effective January 1, 2013.

Under this proposal, Part D plan sponsors would be required to submit information in their formulary files indicating that they would cover these drugs. We estimate that the cost to the Federal Government to be $1.9 billion over the 2013 through 2018 period. We assumed the cost of benzodiazepines and barbiturates as 0.4 percent of total drug cost, and that the inclusion of both these drugs would increase proportional to the current overall Part D level.

9. Good Cause and Reinstatement Into a Cost Plan

At § 417.460(c)(3) we are proposing to allow beneficiaries enrolled in cost plans the opportunity to be reinstated into their plan if they can establish good cause for nonpayment of cost-sharing. CMS (or its contractor) would evaluate cost-plan enrollees' requests for reinstatement based on good cause and make the ''good cause'' determinations. We anticipate that there would be no cost impact on cost plans.

10. Determination of Actuarially Equivalent Creditable Prescription Drug Coverage

We are proposing to clarify our regulations at § 423.884 to ensure that other insurers or organizations providing creditable prescription drug coverage to their members calculate the actuarial value in accordance with the RDS actuarial value calculation. Since this requirement is a clarification to an existing calculation already being utilized by organizations providing creditable coverage, we anticipate that there would be no cost impact on these organizations.

11. Who May File Part D Appeals With the Independent Review Entity

The proposed changes to § 423.600 would allow prescribing physicians and other prescribers to request IRE reconsiderations on behalf of Part D plan enrollees and the corresponding proposed change to § 423.602(a) specifies that the IRE must also notify the prescribing physician or other prescriber of its decision when the prescriber makes the request on behalf of the enrollee. The quantifiable burden associated with these provisions is the cost of processing Part D reconsiderations (which includes providing notice of the decision). While this provision is expected to increase the number of reconsiderations processed and completed by the IRE, it would also significantly reduce the number of appeals that have to be dismissed because the AOR form would no longer be required in cases when a prescriber is requesting a reconsideration on behalf of an enrollee. In 2010, the IRE dismissed approximately 2,500 reconsideration requests submitted by prescribers due to the lack of a properly executed AOR form, at an estimated cost of $215,000. We estimate the cost of issuing a substantive reconsideration decision in cases that are currently subject to dismissal to be $540,000, assuming an estimated cost of about $216 per case. However, this added cost would be offset by the reduction in dismissed cases, for an estimated annual cost increase of $325,000 ($540,000 less $215,000).

We also believe that eliminating the AOR requirement will result in about a 15 percent increase in the total number of IRE reconsiderations requests. Based on the percentage of plan level appeals currently filed by prescribers on behalf of enrollees (approximately 85 percent), we estimate an increase in prescriber-initiated IRE appeals, which would be partially offset by a decrease in enrollee-initiated IRE appeals. Based on 2010 reconsideration data, we estimate there would be an additional 3,000 reconsideration requests, with an estimated increase in annual costs of about $648,000. The estimated increased cost associated with issuing substantive reconsideration decisions (as opposed to dismissals) and the increased cost associated with the increase in the reconsideration workload, results in total estimated annual increased costs to the Federal government of approximately $973,000 or a total of $5.84 million from FYs 2013 through 2018.

The increase in reconsideration requests would result in additional costs to plan sponsors based upon additional time and effort to assemble case files and documentation associated with these requests and shipping to the IRE for processing. We assume a cost of approximately $25.00 per reconsideration to print, copy, compile, and mail the case file to the IRE. This results in an additional annual cost to plan sponsors of approximately $75,000, or a total of $450,000 from FYs 2013 through 2018.

12. Termination for Continued Lower-Than-3-Star-Ratings

We have the authority under section 1857(c)(2) of the Act to terminate contracts with a MAOs or a Medicare PDP sponsor when we determine that the organization has failed substantially to carry out the contract or is carrying out the contract in a manner inconsistent with the efficient and effective administration of the Part C or D program. We believe that a sponsor that fails to achieve a good rating for 3 consecutive years has demonstrated consistently that it is unable or unwilling to take corrective action to improve its Part C or D performance. Therefore, we are proposing to revise the regulation to reflect our position that 3 years' worth of low star ratings constitutes a sufficient basis for CMS to terminate a sponsor's Part C or D contract.

The changes made to this regulation would not result in any additional costs. MA organizations and Part D sponsors already incur costs as a result of needing to be in compliance with existing regulatory requirements. This change merely clarifies our authority to use sustained poor performance rating results (which are already being produced annually) as a basis for termination.

13. Exclusion for Sponsors of Contracts Terminated for Cause

We have modified the past performance review period described in § 422.502(b) and § 423.503(b) (by adding new paragraphs at § 422.502(b)(3) and at § 423.503(b)(3) as well as § 422.502(b)(4) and at § 423.503(b)(4)) to include among the factors that may support a CMS denial of a contract application those CMS-initiated terminations or non-renewals that became effective within

the 38 months preceding the submission of a new application.

The changes made to this regulation would not result in any additional costs since we are not imposing any new requirements. Rather, we are merely extending the period of time that we can review for purposes of application qualification determinations when an organization has had a prior contract terminated or non-renewed by CMS. Thus, there are no additional costs involved.

14. Independence of Long Term Care Consultant Pharmacists

LTC facilities commonly contract with an LTC pharmacy for consultant pharmacist services, and it is our understanding that LTC pharmacies typically have been providing consultant pharmacists to LTC facilities at rates below fair market value. Because the changes we are considering would specifically require LTC facilities to employ or directly or indirectly contract with independent licensed pharmacists, each facility would need to engage an independent consultant pharmacist at market rates. We understand that the subsidized rates are typically $1 per resident per month for the conduct of each resident's drug regimen review. The cost for the independent consultant pharmacists, therefore, would be substantially higher that the subsidized rates LTC facilities currently pay to the LTC pharmacies. As a result, the cost associated with complying with the requirement under consideration would be the increase in cost for the LTC facility to pay the full market value for an independent consultant pharmacist.

However, the increased costs would be offset by the amount currently paid by the 15,713 facilities to the LTC pharmacies for the provision of consultant pharmacist services. Based on the rate of $1 per resident per month and 1.5 million beds, we estimate the total annual savings to be $18 million.

We estimate that although all 15,713 LTC facilities would need to provide the services of an independent consultant pharmacist, factors, such as the existence of nursing home chains and GPOs, would affect the actual number of entities that would be engaged in the process of employing or contracting the LTC consultant pharmacists. For purposes of determining the impact, we will assume that LTC facilities would have a contract with one consultant pharmacist.

Based on our experience with LTC facilities, we expect that complying with the requirement under consideration would primarily require the involvement of the LTC facility's administrator with the assistance of a facility physician, and the director of nursing. We expect also that the facility's attorney would assist with drafting the contract and reviewing any revisions. We estimate that complying with this requirement would require 16 annual burden hours for each facility to execute a contract with an independent consultant pharmacist at an estimated cost of $1,466. Thus, although we expect that many contracts would be negotiated by the facilities' parent organizations or through GPOs, were each LTC facility to directly engage in the contracting process, it would require 251,408 burden hours per fiscal year (16 annual burden hours per LTC facility × 15,713 LTC facilities) for all 15,713 LTC facilities to comply with the requirement under consideration at an estimated cost of $23,035,258 ($1,466 estimated cost per LTC facility × 15,713 LTC facilities).

After the first fiscal year, we estimate that continued compliance with this requirement would require 2 annual burden hours (1 hour each for the facility administrator and attorney) for each facility to review the contract and, if necessary execute an updated contract with an independent consultant pharmacist at an estimated cost of $192. Thus, it would require 31,426 burden hours per fiscal year (2 annual burden hours per LTC facility × 15,713 LTC facilities) for all 15,713 LTC facilities at an estimated cost of $3,016,896 ($192 estimated cost per LTC facility × 15,713 LTC facilities).

In addition to the LTC facility costs associated with the direct compensation of consultant pharmacists, facilities with existing LTC pharmacy contracts that include the pharmacy's provision of consultant pharmacist services would potentially need to amend these contracts. However, we do not know and cannot estimate the number of LTC facilities that would need to amend their LTC pharmacy contracts. However, we believe that our consultant pharmacist contracting cost estimates are likely to be sufficiently overstated to cover these costs as well.

Further, although it is currently common for LTC consultant pharmacists to perform approximately 60 drug regimen reviews in a day, we suspect that this rate may be too high given our expectation that independent consultant pharmacists would conduct more thorough drug regimen reviews, monitoring for drug side effects and effectiveness. Therefore, earlier in the preamble, we solicited public comment on best practices related to the conduct of drug regimen reviews.

Pending public response to our request for comment, we have estimated the following costs related to the requirement under consideration based on an average time of 20 minutes to perform a drug regimen review. Based on the total number of LTC facilities (15,713) and total beds (1.5 million), the average LTC facility would have 100 residents. Therefore, we anticipate that it would take each facility's consultant pharmacist 2,000 minutes (20 minutes per review × 100 residents) or 33 hours each month to perform the residents' drug regimen reviews. Using an hourly rate of $51.53 for independent consultant pharmacist that includes fringe benefits, we estimate 396 (33 hours per month × 12) annual burden hours per facility at an annual cost of $20,406 (396 × $51.53) for a total cost of $320,639,478 ($20,406 per facility × 15,713 LTC facilities). (Hourly rate according to May 2010 wage data from Bureau of Labor Statistics estimates from the Occupational Employment Statistics Services). As noted previously, we expect that this amount would be reduced by the $18 million that the facilities would no longer pay to the LTC pharmacies for consultant pharmacist services. We recognize the limitations associated with these estimates and solicit public comment on more detailed costs for this provision.

We expect that requiring independent consultant pharmacists would result in more appropriate prescribing, leading to reductions in all of the following: absolute number of drugs prescribed; unnecessary use of high price, brand name drugs; and use of antipsychotics and other drugs that should be generally avoided among older LTC residents. One outcome of the use of fewer drugs and fewer brand name drugs would be lower drugs costs for LTC residents. For residents whose cost of care is covered by Medicare Part A per diem payments, the lower drug costs would result in direct savings to the facility. For LTC residents whose drug costs are covered by Medicaid, the savings from lower drug costs would accrue to the Medicaid programs for drug costs reimbursed on a fee-for-service basis and/or to the facility if drug costs are included in the LTC per diem payment. For those residents enrolled in a Medicare Part D prescription drug plan, the savings would be realized by the Part D sponsors and Medicare.

To estimate the potential savings, we used a comparison of the risk-adjusted costs for community and LTC beneficiaries. We found that LTC beneficiary costs were 23 percent higher than the costs for beneficiaries in the community. We believe some of the cost

differential is related to factors, such as differences in dosage forms, which would contribute to legitimately higher LTC costs. However, we estimate that 50 percent of the difference in cost is attributable to the overprescribing and unnecessary use of higher cost, brand name drugs resulting from the contractual arrangements between the LTC pharmacies and pharmaceutical manufacturers. An analysis of 2008 Part D data shows LTC beneficiary drug costs in that year averaged $4520.[9] Using the 23 percent differential, this average would be $845 higher than the average cost for a community beneficiary. We expect the regulatory change we are considering would reduce LTC costs by 50 percent of the differential or $423 per beneficiary per year for a total reduction of $360,396,000 ($423 per beneficiary × 852,000 LTC beneficiaries).

Lower LTC drug costs would result in lower LTC pharmacy revenues. We would likewise expect that the LTC pharmacies would experience a reduction in rebates from the pharmaceutical manufacturers; however, we cannot quantify this loss.

We believe it is reasonable to presume that the incentives present in non-independent relationships with pharmacies can influence prescribing practices. As a result, we expect the independent drug regimen reviews under consideration would decrease unnecessary use of antipsychotic drugs and, therefore, save lives, although we cannot quantify the number of lives that would be saved. In addition to saving lives, we expect more appropriate prescribing and improved medication oversight would lead to fewer hospitalizations and treatments for drug-related problems (such as confusion, balance disorders and complications caused by pharmacological interactions), as well as improved quality of life for LTC facility residents. We cannot quantify the number of hospitalizations or treatments that would be averted or the associated savings that would be realized. However, we believe the benefits to Medicare, Medicaid, other payers, and the LTC residents that would result from these changes are clear. Although the specific information to reliably quantify the all the costs and savings associated with this requirement is not available, we believe the benefits and costs are offsetting. Again, given the uncertainty surrounding these estimates, we are soliciting comment regarding more detailed information on the costs and savings associated with this provision.

15. New Benefit Flexibility for Fully Integrated Dual Eligible Special Needs Plans (FIDE SNPs) (§ 422.102)

We estimate that our proposal proposed at § 422.102(e) to allow certain FIDE SNPs to offer additional supplemental benefits beyond those other MA plans—subject to CMS approval, and as specified annually by CMS—will result in aggregate savings to both States and the Federal government of approximately $19.0 million between FY 2013 and FY 2018. These Federal and State savings estimates are based on our assumption that based on the eligibility standards CMS establishes approximately 34 FIDE SNPs will qualify to participate in this initiative, representing a total of approximately 115,000 enrollees in 2011.

While we acknowledge that § 1859(f)(1) of the Act extends the authority for all SNPs, including FIDE SNPs, to restrict enrollment to special needs individuals through the 2013 MA contract year, to be consistent with our scoring of other provisions in this rule, we report the impact of this proposed provision from FYs 2013 through 2018. We note that this impact may vary depending on Congressional action.

We are basing our analysis of the potential cost impacts of the FIDE SNP benefit flexibility initiative on our experience with HMO integrated care model demonstrations for Medicare-Medicaid dual eligibles and on our observation of enrollment increases that resulted from these demonstrations.

From 1997 through 2006, we conducted demonstrations that pooled Medicare and Medicaid payments to the Minnesota Senior Health Options (MSHO), Wisconsin Health Partnership Program (WPP) and Massachusetts Senior Care Organization (MSCO) HMOs to deliver Medicare and Medicaid-covered primary, acute, and long-term care services to voluntarily enrolled elderly dual eligibles. The plans participating in the demonstration were responsible for delivering Medicaid community care services, developing managed care coordination models, and arranging for the delivery of the full range of acute and long-term care services and developing care coordination models—characteristics that we believe are essential for the provision of comprehensive, integrated care. The demonstrations also used Medicaid funds to cover community care services (for example, personal care, homemaking, transportation, personal emergency response systems, home-delivered meals, adaptive equipment, home modifications, incontinence supplies, and respite care that support independence and avoid inappropriate institutionalization). At the start of the demonstrations, concern that marketing additional supplemental benefit offerings would attract a significant number of new enrollees-led us to cap enrollment in the demonstration. However, States in the demonstration never came close to reaching this enrollment cap. The only major enrollment increase was in 2006, when the demonstration programs were converted to D–SNPs, and the D–SNPs were able to passively enroll enrollees.

The MSHO program, the most extensively analyzed integrated care demonstration program for dual eligible enrollees, received a Medicare and a Medicaid capitation payment for the provision of acute and long-term care services, but reimbursed providers directly for nursing home services on a fee-for-service basis. Therefore, Federal and State government costs under this capitated program were not related to actual utilization, with the exception of fee-for-service nursing home costs. Utilization data from the MSHO demonstration show that MSHO enrollees had significantly fewer short-stay nursing home admissions as compared to dual eligibles both within and outside of the MSHO demonstration area.

We believe that plans have incentives to generate higher rebates to fund these extra supplemental benefits and have assumed that they will reduce their margins by 1 percent. Taking into account expected growth rates in bids and benchmarks, and projected rebate shares, we expect that FIDE SNPs will reduce their bids by 2 percent on average—1 percent medical and 1 percent margin—as a result of our proposed changes to § 422.102(e). Applying the per-capita savings to the projected FIDE SNP enrollment, we project $17.1 million savings to the Medicare program for the 6-year period between FY 2013 and FY 2018.

We also believe that, when delivered in a prudent manner, the additional benefits that FIDE SNPs would be permitted to offer under our proposed changes to § 422.102(e) would allow some high risk patients to remain in their home and out of institutions. We estimate that the new flexibility will generate modest reductions in Medicare program expenditures, due to a 1 percent savings of Medicare-covered medical benefits stemming from these enhanced flexibilities.

Additionally, based on the evidence from the studies in Massachusetts,

[9] CMS, March 18, 2010 Part D Data Symposium Presentations, LTC Pharmacy Price Index. Accessed online at: *http://www.cms.gov/PrescriptionDrugCovGenIn/09_ProgramReports.asp#TopOfPage* on June 17, 2010.

Minnesota, and Wisconsin demonstrations, we believe that the flexibility for FIDE SNPs to offer additional supplemental benefits will modestly impact nursing facility utilization rates and Medicaid costs. Our assumptions regarding the effectiveness of these services in preventing nursing facility entry are consistent with assumptions we have used for other legislative and regulatory proposals aimed at reducing nursing facility use and encouraging home and community based long term care. Applying the per-capita savings to the projected FIDE SNP enrollment, we estimate Federal and State Medicaid savings of $1.79 million for the 6-year period between FY 2013 and FY 2018 as a result of this proposed provision.

16. Application of the Medicare Hospital-Acquired Conditions and Present on Admission Indicator Policy to MA Organizations (§ 422.504)

We propose to require MAOs to reduce reimbursements for Part A hospital services for contract provider hospitals for serious events that could be prevented through evidence-based guidelines, in accordance with the HACs and POA policy that is currently required for hospitals paid under the Original Medicare IPPS. MA organizations are already required to pay non-contract provider hospitals the amount that they would receive for services under Original Medicare, including any applicable reductions for HACs. This requirement is outlined in the MA Payment Guide for Out of Network Payments. We do not believe that extending this requirement would impose any new administrative burden on MA plans because plans already have the operational systems in place that would facilitate implementation of the requirement. In the FY 2009 IPPS final rule, published August 19, 2008 (73 FR 49075), we estimated a total savings for Medicare of $21 million for FYs 2009, 2010 and 2011, and $22 million for FYs 2012 and 2013. These estimates already included savings that would accrue to the MA program as a result of reductions in annual MA payment rates. We do not expect a significant amount of new savings to be derived as a result of the requirements under this proposed rule. Therefore, we estimate that this provision would have negligible impact.

17. Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse, and Waste Control Program

A previous review of 2009 PDE data suggested that just under 32 percent of approximately 78.6 million first fills for maintenance medications are not refilled by Medicare Part D enrollees. Maintenance medications are used for diseases when the duration of therapy can reasonably be expected to exceed 1 year, and we assume for purposes of estimating savings to the Part D program that the lack of refills indicates the prescribed medications were discontinued. The estimated total cost of these discontinued medications was approximately $1.6 billion (70 percent for brands and 30 percent for generics). However, this analysis did not distinguish between community and institutional settings. Thus, to determine the costs of discontinued medications in community settings only, we reduced the total costs by approximately13 percent in accordance with CMS data on gross drug costs in the Part D program in 2009 in the community and institutional settings to remove a proportion representing long-term care expenses. Consequently, the adjusted total estimated cost of 2009 community-based discontinued first fills of chronic medications was estimated at roughly $1.4 billion.

In light of the cost of discontinued medications, and in accordance with section 1860D–4(c) of the Act, we are proposing to revise § 423.153(b)(4) to provide that a Medicare Part D sponsor's drug utilization management program must establish and apply a daily cost-sharing rate . Under this proposal, the enrollee and his or her prescriber generally would decide if a medication supply of less than 30 days would be appropriate, and if so, the copayment for the medication would be prorated by the Part D sponsor based on the days supply dispensed.

Specifically, we propose to define ''daily cost-sharing rate'' in § 423.100. ''Daily cost-sharing rate'' would mean, as applicable, the established monthly—

- Copayment under the enrollee's Part D plan divided by 30 or 31 and rounded to the nearest lower dollar amount or to another amount but in no event to an amount which would require the enrollee to pay more for a month's supply of the prescription than the enrollee would have paid if a month's supply had been dispensed; or
- Coinsurance rate under the enrollee's Part D plan applied to the ingredient cost of the prescription for a month's supply divided by 30 or 31.

In addition, we are specifically proposing to revise § 423.104 by adding a paragraph (i) to state that a Part D sponsor is required to provide its enrollees access to daily cost-sharing rate in accordance with § 423.154(b)(4). We also propose adding paragraph (4)(i) to § 423.153(b) to require a Part D sponsor to establish and apply a daily cost-sharing rate to a prescription presented by an enrollee at a network pharmacy for a covered Part D generic or brand drug that is dispensed for a supply of less than 30 days, multiplied by the days supply actually dispensed, plus any dispensing fee in the case of coinsurance. We further propose adding paragraph (4)(i)(A) to limit the requirement to drugs that are in the form of solid oral doses paragraph (b)(4)(i)(B) would further limit the requirement to a prescription that is for an initial fill of a new medication, is intended to allow the enrollee to synchronize refill dates of multiple drugs, or the prescription is dispensed in accordance with § 423.154 (which sets forth the requirements placed upon Part D sponsors with respect to dispensing of prescription drugs in long-term care facilities effective January 1, 2013). Paragraph (b)(4)(ii) would state that the requirements of (b)(4)(i) would not apply to antibiotics or drugs dispensed in their original container as indicated in the Food and Drug Administration Prescribing Information or are customarily dispensed in their original packaging to assist patients with compliance.

Potential savings of a daily cost-sharing rate requirement on Part D sponsors would come from a reduction of the estimated $1.4 billion in costs previously noted which would be offset by some additional dispensing fees. In order to estimate the savings, we must make assumptions about how many first fills would be dispensed in quantities of less than a 30 day supply, and what the average quantity of such first fills would be. It should be pointed out that these assumptions are highly uncertain because it is very difficult to predict the beneficiaries' behavioral response. Having noted this caveat, we assume 20 percent of first fills in 2013 will be for a supply of less than 30 days, trending to 50 percent by 2018, and that the average of such fills would be for a 15 day supply. Assuming 32 percent of these first fills are discontinued, we estimate the potential savings to the Part D program to be $140 million in 2013 alone, and over $2.4 billion by 2018.

The additional dispensing fees previously noted are associated with medications that begin with a trial fill and are continued therapeutically. For instance, an enrollee who receives less than a month's supply, but continues taking the medication, would be expected to obtain ongoing refills of 30 to 90 days. Over the course of a year, the expectation is that there will be up to 13 dispensing events over a period of 1

year of refills related to such enrollee with respect to the medication initially begun with a trial fill. However, for those enrollees who discontinue a medication, there will be savings for the enrollee by not having paid the full monthly copayment for that particular medication, as well as for sponsors and the Federal government to the extent that a full month's supply of medication was not covered by the Part D program. With respect to more initial fills of brand drugs, we believe there may be additional but less significant costs for more initial fills of brand drugs that enrollees previously declined to try due to the cost of a full month's supply, when the brand drugs are known for significant side effects and/or to be frequently poorly tolerated.

Aside from these additional costs, we expect the other regulatory impact costs imposed by the proposed provisions to be the one-time costs for the industry to reprogram PBM systems to apply a daily cost-sharing rate. In this regard, we estimate that the number of hours for 28 PBMs and 12 plan organizations to reprogram their systems to establish and apply a daily copayment rate is 80 hours per processor or plan organization, for a total one-time burden of 3,200 hours (40 × 80). The estimated cost associated with such reprogramming is the estimated number of hours multiplied by the estimated hourly rate of $145.37, which equals $465,184.

18. Technical Corrections to Enrollment Provisions

We are proposing technical changes that correct cross-references that should have been updated in previous rulemaking. These proposals are technical corrections and do not represent a burden for small businesses, rural hospitals, States, or the private sector.

19. MA and Part D Disclosure Requirements to Cost Contract Plans

We are proposing to extend the disclosure requirements in § 422.111 and § 423.128 to cost contract plans. Our regulations at § 422.111 and § 423.128 require MA organizations and Part D sponsors to disclose to enrollees, at the time of enrollment and annually thereafter (in the form of an annual notice of change/evidence of coverage, or ANOC/EOC mailing), certain detailed information about plan benefits, service area, provider and pharmacy access, grievance and appeal procedures, quality improvement programs, and disenrollment rights and responsibilities. They also require the provision of certain information about request and establish requirements with respect to dissemination of explanations of benefits, customer service call centers, and Internet websites.

For each entity, we estimate that it will take 12 hours to develop and submit the required information. This includes 1 hour to read CMS' published instructions, 6 hours to generate the standardized document, 1 hour to submit the materials, and 4 hours to print and disclose information to the beneficiaries. We estimate 20 cost contractors would be affected annually by this requirement, resulting in a total annual burden of 240 hours. We estimate, based on an hourly wage of $29.88 (hourly salary for a compliance officer/cost estimator according to Bureau of Labor Statistics) plus 48 percent for fringe benefits and overhead, that this requirement would result in a total annual burden of $10,613 rounded, approximately $0.01 million per year.

20. Denials of SNP Applications and SNP Appeal Rights

We estimate that this proposed provision would have a minimal impact resulting from administrative costs incurred by the small number of SNP applicants that we expect will receive application denials and the small percentage of denied applicants that we expect would appeal our denial decision. For those organizations that do appeal the denial of their SNP application, a minimal number of professional staff working over a short period of time would be required to prepare and present the organization's appeal.

We estimate that the total annual hourly burden for developing and presenting a case for us to review is equal to the number of organizations likely to request an appeal multiplied by the number of hours for the attorneys of each appealing SNP to research, draft, submit, and present their arguments to CMS. Based on SNP application denials from contract year 2012, out of the approximately 400 SNP applications received, 8 of these applications were denied and all 8 denials were appealed. In contract year 2011, 8 SNP applications were denied and none of these denials were appealed. Taking the average of the last two years, we estimate that approximately 4 denied applicants would appeal the denial of the SNP application. We further estimate that 1 attorney working for 8 hours could complete the documentation to be submitted for each application denial, resulting in a total burden estimate of 32 hours (8 hours × 4 SNP application denials). The estimated annual cost to an MA organization that has been denied to offer a SNP associated with this provision (assuming an attorney billing $250 per hour) is $8,000 (32 hours × $250) or when rounded, to approximately $ 0.01 million per year.

21. Contract Requirements for First Tier and Downstream Entities in Subcontracts

The regulations at § 422.504(i) and § 423.505(i) require MA organizations and Part D sponsors to require all of the first tier, downstream, and related entities to which they have delegated the performance of certain Part C or D functions to agree to certain obligations. We believe that the most legally effective and direct way to ensure that the MAOs and Part D sponsors retain the necessary control and oversight over their delegated entities is by requiring all contracts among those entities to specifically reference each party's obligations to the sponsor, as enumerated in § 422.504(i) and § 423.505(i). Thus, the regulation has been changed to address this need. Specifically, we deleted the term ''written arrangements'' throughout § 422.504(i) and § 423.505(i) and in each instance replace it with ''each and every contract.''

The proposed changes would not result in any additional costs since these types of contracts are already in use and required by regulation. Thus, the strengthening of the language to ensure that the sponsor is responsible for downstream entities is merely clarifying an existing requirement and eliminating potential loopholes.

22. Valid Prescriptions

In the § 423.100 proposed definition of ''valid prescription'' and the § 423.104 requirement of a ''valid prescription,'' we would codify our longstanding policy of deferring, when applicable, to State law to determine whether a prescription is valid such that the prescribed drug may be eligible for Part D coverage.

The changes made to this regulation would not result in any additional costs. Not only have we expected that prescriptions would be valid under applicable State law since the beginning of the Part D program, but also prescribers and pharmacies remain subject to applicable State laws regarding valid prescriptions. Furthermore, private contracts regarding Part D drugs (such as those between MAOs or Part D sponsors and pharmacies) likely also require valid prescriptions. In light of the above realities, it is not unreasonable to presume that MAOs, Part D sponsors, PBMs, and pharmacies are already

taking steps to write prescriptions that are valid under applicable State law. Accordingly, we do not believe codifying the valid prescription requirement would change current practices.

23. Medication Therapy Management Comprehensive Medication Reviews and Beneficiaries in LTC Settings

Current regulations require that unless a beneficiary is in an LTC setting, the comprehensive medication review must include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider, and may result in a recommended medication action plan. Section 10328 of the Affordable Care Act amended section 1860D–4(c)(2) of the Act to require that all targeted beneficiaries be offered an interactive CMR. Accordingly, the proposed change to § 423.153 permits the sponsor to allow the pharmacist or other qualified provider to perform the medication review without the beneficiary in cases when the beneficiary is in an LTC facility and is cognitively impaired and thus, cannot accept the sponsor's offer of an interactive CMR . We anticipate that the impact of this proposed revision will clarify the CMR process for sponsors by allowing pharmacists and other qualified providers to ascertain whether the patient is willing and able to participate in an interactive CMR before administering it. We do not anticipate any costs or savings associated with this change.

24. Coordination of Part D Plans With Other Prescription Drug Coverage

The proposed regulation would be explicit that sponsors, when providing Part D benefits to enrollees of EGWPs, are subject to the same requirements as sponsors providing Part D coverage in the individual market unless such requirements are explicitly waived. Since this change is being made to clarify an existing policy, we do not anticipate any effect on costs or savings on any specific entity.

25. Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers (NPIs)

The inconsistent use of identifiers by prescribers on Part D claims has hindered some of our efforts to combat fraud and abuse activities. Therefore, we propose to require, effective January 1, 2013, that Part D sponsors include only valid, individual prescriber NPIs as identifiers in PDEs submitted to CMS. Specifically, § 423.120(c) sets forth the responsibilities of Part D plan sponsors with regard to the use of standardized technologies and compliance with the HIPAA standards at 45 CFR 162.1102. We propose to add a new paragraph (5)(A) that would require Part D plan sponsors to submit PDE records to CMS that contain an active and valid individual prescriber NPI. Proposed new paragraph (c)(5)(B) would also codify current guidance and require that a Part D plan sponsor not reject a claim from a network pharmacy solely on the basis that it does not contain an active and/or valid NPI. With respect to requests for reimbursement submitted directly by Medicare beneficiaries, proposed paragraph (5)(C) would prohibit a Part D sponsor from making reimbursement payment to the beneficiary dependent upon the sponsor's acquisition of the prescriber NPI, and would further prohibit a Part D sponsor from seeking recovery of the payment from the beneficiary if the sponsor were unable to retrospectively acquire an active and valid individual NPI.

The impact associated with these proposed regulations is: (1) the annual cost for PBMs and plan organizations to conduct or contract with a commercial vendor or with network pharmacies to provide prescriber ID validation services; or (2) the annual cost required for PBMs and plan organizations to build their own databases of current, valid prescriber NPIs, and to recontract with network pharmacies to support retroactive review of the prescription to obtain the current, valid prescriber ID. We estimate a one-time burden for an estimated 28 PBMs and 12 plan organizations to negotiate and execute a contract with a commercial vendor to provide prescriber ID validation services to be negligible, particularly since PBMs and plan organizations typically have in-house counsel or law firms on retainer. The estimated annual cost of such a contract is $160,000, which is the mid-point of estimates we have seen for such a contract. Therefore, the estimated annual cost of such a contract for 40 PBMs and plan organizations is $6,400,000 (40 × 160,000). However, preliminary results of an analysis of 2011 PDEs submitted to date conducted by a contractor to CMS indicate that approximately 90 percent contain valid individual NPIs. Therefore, this estimation should be reduced to reflect that a certain amount of cost associated with prescriber ID validation has already been absorbed by the industry. Therefore, we assume that 80 percent of the industry needs to acquire additional prescriber ID validation capacity in order to submit only PDEs that contain active and valid individual prescriber NPIs to CMS. Thus, the estimated annual cost to PBMs and plan organizations of a contract with a commercial vendor to perform prescriber NPI validation services is $5,120,000 (6,400,000 × 0.8).

With respect to PBMs and plan organizations that decide to contract with network pharmacies for prescriber validation services or build their own databases of valid prescriber NPIs, we assume that they will only do so if the cost is equal to or less than contracting with a commercial vendor for such services, and therefore, no estimation of the costs to do so is necessary.

Since approximately 90 percent of PDEs currently submitted to CMS already contain valid individual NPIs, and an estimated 95 percent of physicians have an NPI, we estimate negligible costs associated with any PDE that cannot be submitted to CMS for lack of an NPI.

TABLE 7—ESTIMATED AGGREGATED COSTS TO THE HEALTH CARE SECTOR BY PROVISION FOR FISCAL YEARS 2013 THROUGH 2018

Provision(s)	Regulation section(s)	Fiscal year ($ in millions)						Total ($ in millions) FYs 2013–2018
		2013	2014	2015	2016	2017	2018	
Medicare Coverage Gap Agreement.	§ 423.2315 ...	3,990.00	4,520.00	5,090.00	5,710.00	6,350.00	7,050.00	32,710.00
Payment Processes for Part D Sponsors.	§ 423.2320 ...	12.66	12.66	12.66	12.66	12.66	12.66	75.96
Provision of Applicable Discounts	§ 423.2325 ...	12.66	12.66	12.66	12.66	12.66	12.66	75.96
Compliance and Civil Money Penalties.	§ 423.2340 ...	1.18	1.32	1.48	1.67	1.88	2.11	9.64

TABLE 7—ESTIMATED AGGREGATED COSTS TO THE HEALTH CARE SECTOR BY PROVISION FOR FISCAL YEARS 2013 THROUGH 2018—Continued

Provision(s)	Regulation section(s)	Fiscal year ($ in millions)						Total ($ in millions) FYs 2013–2018
		2013	2014	2015	2016	2017	2018	
Other Manufacturer Costs	§ 423.2315	13.03	13.03	13.03	13.03	13.03	13.03	78.18
Inclusion of Benzodiazepines and Barbiturates as Part D Covered Drugs.	§ 423.100	200.00	280.00	310.00	340.00	370.00	410.00	1,910.00
Who May File Part D Appeals with the Independent Review Entity.	§ 423.600	1.05	1.05	1.05	1.05	1.05	1.05	6.30
Benefit Flexibility for Fully Integrated Dual Eligible Special Needs Plans (FIDE SNPs).	§ 422.102	−5.97	−3.48	−2.30	−2.41	−2.32	−2.41	−18.89
Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse and Waste Control Program.	§ 423.104 § 423.153.	−139.50	−240.00	−330.00	−430.00	−550.00	−690.00	−2,379.50
Add language specific to SNP applications to give CMS the clear authority to deny SNP applications and to give SNPs appeal rights.	§ 422.500	0.01	0.01	0.01	0.01	0.01	0.01	0.06
Apply MA and Part D disclosure requirements to cost contract plans.	§ 417.427	0.01	0.01	0.01	0.01	0.01	0.01	0.06
Access to covered Part D drugs through the use of standardized technology and NPIs.	§ 423.120	5.12	5.12	5.12	5.12	5.12	5.12	30.72
Developing and executing contracts with independent consultant pharmacists.	§ 483.60	23.03	3.02	3.02	3.02	3.02	3.02	38.13
Total Impact ($ in millions)		4,113.28	4,605.40	5,116.74	5,666.82	6,217.12	6,817.26	32,536.62

Note: Estimates of costs and savings reflect scoring by the Centers for Medicare and Medicaid Services, Office of the Actuary, and 2010 wage data from the U.S. Department of Labor, Bureau of Labor Statistics.

TABLE 8—ESTIMATED COSTS AND SAVINGS TO THE FEDERAL GOVERNMENT BY PROVISION FOR FYS 2013 THROUGH 2018

Provision(s)	Regulation section(s)	Fiscal year ($ in millions)						Total ($ in millions) (FYs 2013–2018)
		2013	2014	2015	2016	2017	2018	
Medicare Coverage Gap Agreement.	§ 423.2315	180.00	200.00	230.00	270.00	280.00	280.00	1,440.00
Inclusion of Benzodiazepines and Barbiturates as Part D Covered Drugs.	§ 423.100	200.00	280.00	310.00	340.00	370.00	410.00	1,910.00
Who May File Part D Appeals with the Independent Review Entity.	§ 423.600	0.97	0.97	0.97	0.97	0.97	0.97	5.84
Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse and Waste Control Program.	§ 423.104 § 423.153.	−140.00	−240.00	−330.00	−430.00	−550.00	−690.00	−2,380.00
Benefit Flexibility for Fully Integrated Dual Eligible Special Needs Plans (FIDE SNPs).	§ 422.102	−5.85	−3.36	−2.17	−2.28	−2.18	−2.28	−18.12
Total ($ in millions)		235.12	237.61	208.8	178.69	98.79	−1.31	957.7

Note: Estimates of costs and savings reflect scoring by the Centers for Medicare and Medicaid Services, Office of the Actuary, and 2010 wage data from the U.S. Department of Labor, Bureau of Labor Statistics.

TABLE 9—ESTIMATED COSTS TO MA ORGANIZATIONS AND PART D SPONSORS BY PROVISION FOR FYS 2013 THROUGH 2018

Provision(s)	Regulation section(s)	Costs per fiscal year ($ in millions)						Total (FYs 2013–2018) ($ in millions)
		2013	2014	2015	2016	2017	2018	
Payment Processes for Part D Sponsors.	§ 423.2320 ...	12.66	12.66	12.66	12.66	12.66	12.66	75.96
Provision of Applicable Discounts	§ 423.2325 ...	12.66	12.66	12.66	12.66	12.66	12.66	75.96
Who May File Part D Appeals with the Independent Review Entity.	§ 423.600	0.08	0.08	0.08	0.08	0.08	0.08	0.48
Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse and Waste Control Program.	§ 423.104 § 423.153.	0.5	0	0	0	0	0	0.5
Apply MA and Part D Disclosure Requirements to Cost Contract Plans.	§ 417.427	0.01	0.01	0.01	0.01	0.01	0.01	0.06
Add language specific to SNP applications to give CMS the clear authority to deny SNP applications and to give SNPs appeal rights.	§ 422.500	0.01	0.01	0.01	0.01	0.01	0.01	0.06
Access to covered Part D drugs through the use of standardized technology and NPIs.	§ 423.120	5.12	5.12	5.12	5.12	5.12	5.12	30.72
Total ($ in millions)	.....	31.04	30.54	30.54	30.54	30.54	30.54	183.74

Note: Estimates of costs and savings reflect scoring by the Centers for Medicare and Medicaid Services, Office of the Actuary, and 2010 wage data from the U.S. Department of Labor, Bureau of Labor Statistics.

TABLE 10—ESTIMATED COSTS TO MANUFACTURERS BY PROVISION FOR FISCAL YEARS 2013 THROUGH 2018

Provision(s)	Regulation section(s)	Cost per fiscal year ($ in millions)						Total (FYs 2013–2018) ($ in millions)
		2013	2014	2015	2016	2017	2018	
Medicare Coverage Gap Agreement.	§ 423.2315 ...	3,810.00	4,320.00	4,860.00	5,440.00	6,070.00	6,770.00	31,270.00
Other Manufacturer Costs	§ 423.2315 ...	13.03	13.03	13.03	13.03	13.03	13.03	78.19
Compliance and Civil Money Penalties.	§ 423.2340 ...	1.18	1.32	1.48	1.67	1.88	2.11	9.64
Total ($ in millions)	.....	3,824.31	4,334.35	4,874.51	5,454.70	6,084.91	6,785.14	31,357.83

Note: Estimates of costs and savings reflect scoring by the Centers for Medicare and Medicaid Services, Office of the Actuary, and 2010 wage data from the U.S. Department of Labor, Bureau of Labor Statistics.

TABLE 11—ESTIMATED SAVINGS TO STATES BY PROVISION FOR FISCAL YEARS 2013 THROUGH 2018

Provision(s)	Regulation section(s)	Savings per fiscal year ($ in millions)						Total Savings (FYs 2013–2018) ($ in millions)
		2013	2014	2015	2016	2017	2018	
Benefit Flexibility for Fully Integrated Dual Eligible Special Needs Plans.	§ 422.102	0.12	0.12	0.13	0.13	0.14	0.13	0.77

Note: Estimates of costs and savings reflect scoring by the Centers for Medicare and Medicaid Services, Office of the Actuary, and 2010 wage data from the U.S. Department of Labor, Bureau of Labor Statistics.

TABLE 12—ESTIMATED COSTS TO LTC FACILITIES BY PROVISION FOR FISCAL YEARS 2013 THROUGH 2018

Provision(s)	Regulation section(s)	Cost per fiscal year ($ in millions)						Total (FYs 2013–2018) ($ in millions)
		2013	2014	2015	2016	2017	2018	
Developing and executing contracts with independent consultant pharmacists.	§ 483.60	23.03	3.02	3.02	3.02	3.02	3.02	38.13

Note: Estimates of costs and savings reflect scoring by the Centers for Medicare and Medicaid Services, Office of the Actuary, and 2010 wage data from the U.S. Department of Labor, Bureau of Labor Statistics.

D. Expected Benefits

1. Medicare Coverage Gap Discount Program Agreement

The proposed agreement would codify many of the operational parameters of the Discount Program. The intention of the agreement and the parameters within is to guide the distribution of an approximately 50 percent discount in beneficiary OOP cost for prescriptions filled while the beneficiary is in the coverage gap. We believe that a well-implemented Discount Program would increase beneficiary adherence to medication regimens that can improve their health and lower their pharmaceutical costs.

2. Payment Processes for Part D Sponsors

The proposed rule would require CMS to facilitate distribution of the gap discount to beneficiaries by requiring that CMS provide an interim discount payment to Part D sponsors. That interim discount payment would be subsequently reconciled against manufacturer payments for discounts provided to beneficiaries. This provision would help Part D sponsors maintain operations with minimal, if any, effect on cash flow. This would help Part D sponsors distribute the gap discount to beneficiaries.

3. Provision of Applicable Discounts on Applicable Drugs for Applicable Beneficiaries

The proposed rule would require Part D sponsors to calculate the discount that should be provided to beneficiaries in the coverage gap. Beneficiaries would, therefore, have minimal need to determine when they qualify for the gap discount and when they are no longer in the gap. In addition, Part D sponsors would likely automate discount calculations, potentially reducing errors and the need for beneficiaries to file an appeal that challenges the discount amount.

4. Manufacturer Discount Payment Audits and Dispute Resolution

We believe that the audit and dispute programs would both contribute to the stable operation of the Discount Program. Both programs are intended to provide an equitable means to resolve manufacturer concerns, enhance program integrity and, therefore, program stability. A predictable discount program would help beneficiaries plan their finances and health care costs over time.

5. Beneficiary Dispute Resolution

The traditional Medicare program provides a means for beneficiaries to challenge Medicare decisions to ensure they receive needed benefits. We believe that beneficiaries would gain the same benefit from a dispute resolution program associated with the Discount Program. Further, extending the existing Part D beneficiary dispute resolution process to the Discount Program would reduce the need for beneficiaries to learn a new set of dispute procedures.

6. Compliance Monitoring and Civil Money Penalties

Our expectation is that manufacturers would generally comply with the terms of the agreement and the Discount Program. We understand that manufacturers may still err and that such errors can disrupt program operations. Our intention is to use compliance actions, including penalties, to encourage reduced manufacturer errors and maintain a predictable program for beneficiaries.

7. Termination of Agreement

We believe that CMS' ability to terminate the Agreement upon extreme non-compliance by manufacturers will likely encourage manufacturers to address issues quickly. We believe that prompt resolution of significant concerns would create minimal disruption to the program and inconvenience of beneficiaries.

8. Inclusion of Benzodiazepines and Barbiturates as Part D Covered Drugs

Part D coverage of Benzodiazepines and Barbiturates potentially improves beneficiary access to these drugs and reduces beneficiary out-of-pocket costs for non-Part D covered drugs. In addition, State costs are reduced in those States that have been paying for these drugs.

9. Determination of Actuarially Equivalent Creditable Prescription Drug Coverage

By changing the actuarial value calculation for creditable coverage to not include the additional value of gap coverage consistent with the RDS actuarial value, this provision protects Medicare beneficiaries from being subject to a LEP when they leave RDS and other forms of prescription drug coverage and enroll into a Part D plan.

10. Who May File Part D Appeals With the Independent Review Entity

The proposed changes to § 423.600 would allow physicians and other prescribers to request IRE reconsiderations on behalf of Part D plan enrollees. This provision would reduce the burden on enrollees and their prescribers because they will no longer have to submit a properly executed AOR form in cases where the prescriber wishes to request a reconsideration on behalf of a Part D plan enrollee. Additionally, physicians and prescribers are in the best position to anticipate and provide the appropriate medical documentation needed to support coverage for Part D enrollees' medications. We believe that by allowing a physician or other prescriber to request a reconsideration on the enrollee's behalf, it will further improve an enrollee's access to the Part D appeals process and assist enrollees in obtaining coverage of medically necessary medications.

11. Termination for Lower-Than-3-Star-Performance Ratings

The benefit of this change is that we would leverage the annual performance ratings to remove from the MA and Part D programs poor performing organizations, thereby strengthening the programs and protecting Medicare beneficiaries.

12. Exclusion for Sponsors of Contracts Terminated for Cause

The benefit of this change is that we would ensure that organizations that demonstrated extremely poor performance have their performance history reviewed as part of the application process for an appropriate amount of time, thereby strengthening the programs and protecting Medicare beneficiaries.

13. Independence of Long Term Care Consultant Pharmacists

The various contractual arrangements that are common among LTC facilities, LTC pharmacies, LTC consultant pharmacists these pharmacies provide to nursing facilities, and pharmaceutical manufacturers and/or distributors may create incentives for the LTC consultant pharmacist to recommend overprescribing, thus creating health and safety risks for residents. We expect that an LTC consultant pharmacist who is independent of any affiliations with the nursing facilities' LTC pharmacies, pharmaceutical manufacturers and distributors, or any affiliates of these entities would be better able to comply with the changes we are considering that would require objective and unbiased consultant pharmacist monitoring and evaluation. That is, nursing facilities would use a qualified professional pharmacist to conduct drug regimen reviews and make medication recommendations based solely on what

is in the best interests of the resident. We believe the change under consideration—severing the relationship between the consultant pharmacist and the LTC pharmacy, pharmaceutical manufacturers and distributors, and any affiliated entities—would protect the safety of all LTC residents and improve the quality of their care and their well being.

We expect that the Medicare program, State Medicaid programs, as well as other payers, would realize savings as a result of independent pharmacists performing drug regimen reviews that would be uncompromised by any financial incentives. By reducing overprescribing and unnecessary use of high cost brand name drugs, the requirement we are considering would result in lower drug costs to Medicare, Medicaid and other payers. We anticipate that this requirement would likewise curb the use of drugs that are inappropriate and should generally be avoided among older LTC residents, leading to further savings to all payers from fewer hospitalizations and treatments for drug-related problems, such as pharmacologic interactions.

14. Benefit Flexibility for Fully Integrated Dual Eligible Special Needs Plans (FIDE SNPs)

Part D-SNPs that fully integrate all Medicare and Medicaid covered services, including long-term care services, can enable dual eligible beneficiaries to remain in their homes and avoid Medicaid-financed stays in LTC institutions. We believe that allowing certain FIDE SNPs to offer supplemental benefits beginning contract year 2013 would advance our overall goal of better integrating care for dual eligible beneficiaries, keeping beneficiaries at risk of institutionalization in their homes, lowering dual eligible beneficiaries' utilization of health services, and lowering costs for the Medicaid and Medicare programs.

15. Application of the Medicare Hospital-Acquired Conditions and Present on Admission Indicator Policy to MA Organizations

Although we do not expect a significant amount of new savings to result from this requirement under this proposed rule, the benefit for Medicare Advantage enrollees and to Medicare will come from increased quality, efficiency of care, and continued incentives for hospitals to eliminate medical errors and reduce Medicare expenditures for poor quality or unnecessary care.

16. Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse, and Waste Control Program

Requiring Part D sponsors to establish and apply a daily cost-sharing rate as previously described facilitates the ability of Medicare Part D enrollees to obtain trial fills of medications, particularly those with higher cost-sharing and that are known to frequently be poorly tolerated. As noted previously, we believe trial fills would result in the avoidance of unused drugs, reduce drug costs, diminish the environmental issue caused by disposal of unused medications, and reduce opportunities for criminal and substance abuse caused by diversion of unused medications, all of which are growing concerns in the United States. While there may be additional waste generated by multiple fills when medications are continued after a trial fill or synchronized (for example, more plastic bottles and paper inserts, additional trips to pharmacies), we believe the harmful effects on the environment from unused drugs, particularly the biological implications, likely have a much greater impact on the environment than additional recyclables.

With respect to synchronization of medication refills specifically, we also note that at least one study supports the notion that synchronization may assist enrollees in adhering to prescription treatment regimens that involve multiple prescriptions. In addition, we believe the ability to synchronize medications would be convenient for those enrollees who take advantage of the opportunity and their prescribers, by enabling fewer trips to the pharmacy and fewer prescription requests of prescribers by enrollees through the ability to consolidate pharmacy trips and prescriber office visits and phone calls.

17. Apply MA and Part D Disclosure Requirements to Cost Contract Plans

We believe that our requirement that cost contract plans disclose to enrollees, at the time of enrollment and annually thereafter (in the form of an annual notice of change/evidence of coverage, or ANOC/EOC mailing), certain detailed information about plan benefits, service area, provider and pharmacy access, grievance and appeal procedures, quality improvement programs, and disenrollment rights and responsibilities, and an explanation of benefits would ensure that the beneficiaries have information to help them make best choices for their health care needs.

18. Denial of SNP Applications and SNPs Appeal Rights

Our intent in proposing this provision is to give us the explicit authority to deny SNP applications that demonstrate that the applicant does not meet the requirements to operate a SNP, which have been incorporated into the MA application. This proposed change would ensure that the only MAOs that are able to offer a SNP are those that meet CMS' SNP specific requirements and are capable of serving the vulnerable special needs individuals who enroll in SNPs, thereby strengthening the program and protecting Medicare beneficiaries. Additionally, to ensure a fair and comprehensive review of these SNP applications, we propose to allow applicants who have been determined unqualified to offer a SNP the right to an administrative review process.

19. Clarification of Contract Requirements for First Tier and Downstream Entities

This clarification ensures that the MAOs and Part D sponsors retain the necessary control and oversight over their delegated entities, thereby strengthening the programs and protecting Medicare beneficiaries.

20. Valid Prescriptions

By removing any doubt as to the appropriate source of law to consult when determining whether a prescription is valid, this regulation would benefit federal law enforcement agencies. We do not believe, however, that there is a quantifiable monetary value to easing prosecutions in this manner.

21. Medication Therapy Management Comprehensive Medication Reviews and Beneficiaries in LTC Settings

The expected benefits of the proposed revisions to § 423.153 are that Part D sponsors will continue to be required to offer all targeted beneficiaries in LTC facilities the opportunity to participate in an interactive CMR, but in the event the beneficiary is cognitively impaired and unable either to respond to the offer or to participate in an interactive CMR, the pharmacist or qualified provider may proceed with a CMR that is informative for the beneficiary's prescriber and/or caregiver without interacting with the beneficiary .

22. Coordination of Part D Plans With Other Prescription Drug Coverage

We are clarifying the regulation at § 423.458 regarding the application of waivers to EGWPs. We expect that this clarification will benefit Medicare beneficiaries enrolled in such plans by ensuring the same protections as those Medicare beneficiaries enrolled in individual market Part D plans where such protections have not been explicitly waived.

23. Access to covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers (NPIs)

In addition to supporting our fraud and abuse activities, accurate data on prescriptions through the consistent use of valid NPIs on PDEs allows us to serve beneficiaries when using data in various initiatives whose purpose is to foster higher quality and more efficient coordination of care for individuals and groups of individuals.

E. Alternatives Considered

1. Affordable Care Act and MIPPA Provisions

We did not consider alternatives for the following provisions, as their implementation was mandated by the Affordable Care Act and MIPPA:

- Inclusion of Benzodiazepines and Barbiturates
- Pharmacy Benefit Manager's Transparency Requirements

2. Coverage Gap Discount Program

The Affordable Care Act mandated implementation of the Coverage Gap Discount Program and further specified that the associated manufacturer discounts had to be made available at point-of-sale. An alternative model for point-of-sale administration of the discount would involve a third party administrator directly adjudicating the discount payment to pharmacies. In this model, the pharmacy would submit the Part D claim to the Part D sponsor and receive information on the response that would direct the pharmacy to bill the third party for applicable claims. However, while this model initially showed promise, neither the current HIPAA electronic pharmacy claims billing standard nor the next HIPAA approved version of the billing standard could support the transfer of information from the Part D sponsor that would be necessary to specify the appropriate claims and appropriate discount amounts to be billed to the third party administrator, or allow for accurate coordination of benefits among payers.

3. Determination of Actuarially Equivalent Creditable Prescription Drug Coverage

The alternative would be to continue to calculate the actuarial value of creditable prescription drug coverage including the value of additional coverage provided in the coverage gap. However, this approach would mean Medicare beneficiaries enrolled in programs receiving RDS may be subject to a late enrollment penalty because the value of their RDS coverage would be less than the actuarial value of creditable coverage that includes the value of additional coverage in the gap.

4. Who May File Part D Appeals With the Independent Review Entity

As previously mentioned, the proposed changes to § 423.600 and § 423.602 would allow physicians and other prescribers to request IRE reconsiderations on behalf of Part D plan enrollees. We considered maintaining the status quo, which would require physicians and other prescribers to obtain an AOR form in order to request a reconsideration with the IRE on behalf of their enrollees. However, given our program experience since the inception of the Part D program, we realize that this approach results in an undue burden on both enrollees and their physicians or prescribers and can create an unintended barrier to enrollees accessing the appeals process. Consequently, we are proposing the change previously highlighted in this proposed rule.

5. Termination or Non-Renewal of a Medicare Contract Based on Poor Plan Performance Ratings

We did not consider alternatives for this regulation since it is necessary to ensure compliance.

6. Exclusion for Sponsors of Contracts Terminated for Cause

We considered keeping the look-back period at 14 months, but we determined it would be insufficient to accomplish our needs and thus a longer look-back period was necessary. We also considered longer look-back periods, but we deemed them to be to excessive.

7. New Benefit Flexibility for Fully Integrated Dual Eligible Special Needs Plans (FIDE SNPs)

We considered whether limiting the application of the flexibilities afforded under our proposed § 422.102(e) to FIDE SNPs would be the most appropriate way of implementing this proposed benefits flexibility, or whether we should extend the additional supplemental benefit flexibility to other SNP types. Because FIDE SNPs are required to offer LTC supports and services, a regulatory approach that limits benefits flexibility to FIDE SNPs, as opposed to all D–SNP types, may be more consistent with the objective of keeping beneficiaries in their homes and lowering costs for the Medicare and Medicaid programs. We also considered whether we should consider extending these flexibilities to all qualified FIDE SNPs, or whether we should limit these flexibilities to those qualified FIDE SNPs that currently enroll only full-benefit dual eligible beneficiaries. We believe that dual eligible beneficiaries who receive full State Medicaid benefits would have the most to gain from fully-integrated Medicare-Medicaid plan benefit offerings that include additional Medicare supplemental benefits.

8. Establishment and Application of Daily Cost-Sharing Rates as Part of Drug Utilization Management and Fraud, Abuse, and Waste Control Program

We considered proposing a requirement similar to the Fifteen Day Initial Script program introduced in Maine in the summer of 2009. In this program, specific medications that were identified by the MaineCare program with high side effect profiles, high discontinuation rates, or frequent dose adjustments, were phased in by class and must be dispensed in a 15-day initial script to ensure cost effectiveness without ''wasting'' or ''discarding'' of used medications. We have learned through representatives of the program that MaineCare has achieved overall savings for the two consecutive state fiscal years with respect to both brand and generic drugs through this program, despite the additional dispensing fees. The representatives have also reported that there was very good acceptance of the program and very little confusion upon implementation. While we acknowledge the savings benefits of the MaineCare approach, we believe that leaving the decision to obtain less than a month's supply of a prescription with the enrollee and his or her prescriber and pharmacist may be better suited for the Medicare Part D program, but we seek specific comment on this belief.

9. Clarification of Contract Requirements for First Tier and Downstream Entities

We did not consider alternatives for this regulation since it is necessary to ensure compliance and is the most effective ''no-cost'' means to achieving it.

10. Valid Prescriptions

We did not consider alternatives for this regulation as it reflects existing State laws.

11. Medication Therapy Management Comprehensive Medication Reviews and Beneficiaries in LTC Settings

The alternative to this revision would be to have the pharmacist or provider attempt to perform an interactive CMR with an LTC resident who is not capable of participating. However, by requiring an interactive CMR to be offered to all targeted beneficiaries residing in LTC our proposal gives these beneficiaries, who typically have chronic conditions that are managed by medication, the opportunity to participate in the CMR and comprehend the medication action plan as a result of the CMR. In cases when the beneficiary is unable to accept the offer of a non-interactive CMR, the beneficiary will still benefit from having a non-interactive CMR performed by a pharmacist or other qualified provider.

12. Coordination of Part D Plans with Other Prescription Drug Coverage

We considered the alternative, which was to remain silent in regulation. However, we believe that in order to facilitate beneficiary protections it is better to be clear that, unless waived, the same Medicare rules apply to sponsors of EWGPs as they do to sponsors of individual market plans. This ensures Medicare beneficiaries enrolled in EGWPs receive the same patient protections as beneficiaries enrolled in individual market plans.

13. Access to Covered Part D drugs Through Use of Standardized Technology and National Provider Identifiers (NPIs)

We considered requiring prescribers to enroll in Medicare in order for their prescriptions to be covered by the Part D program, but are concerned about the potential impact of such a requirement on enrollee access to needed medications. We also considered permitting any 1 of 4 types of prescriber identifiers to be submitted on PDEs, but we believe this option as not in line with Congressional intent regarding the use of NPIs as provider identifiers.

F. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table 13, we have prepared an accounting statement showing the classification of the expenditures, costs, and savings associated with the provisions of this proposed rule for FY 2013 through 2014.

TABLE 13—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS AND SAVINGS, FROM FY 2013 TO FY 2018

[$ in Millions]

Category	Year dollar	Units discount rate		Period covered
		7%	3%	
TRANSFERS				
Annualized Monetized Transfers	2011	$168.6	$163.6	FYs 2013–2018.
From Whom To Whom?	Federal Government to MA Organizations and Part D Sponsors			
Annualized Monetized Transfers	2011	−$0.1	−$0.1	FYs 2013–2018.
From Whom To Whom?	States to MA Organizations			
COSTS (All other provisions)				
Annualized Costs to MA organizations and Part D Sponsors	2011	$26.4	$25.9	FYs 2013–2018.
Annualized Costs to Manufacturers	2011	4,162.1	4,126.6	FYs 2013–2018.
Annualized Costs to LTC Facilities	2011	6.9	6.6	FYs 2013–2018.

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget reviewed this proposed rule.

List of Subjects

42 CFR Part 417

Administrative practice and procedure, Grant programs-health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs-health, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and record keeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

1. The authority citation for part 417 continues to read as follows:

Authority: Sec. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e–5, and 300e–9), and 31 U.S.C. 9701.

Subpart K—Enrollment, Entitlement, and Disenrollment under Medicare Contract

2. Section § 417.422 is amended by revising paragraph (d) to read as follows:

§ 417.422 Eligibility to enroll in an HMO or CMP.

* * * * *

(d) During an enrollment period of the HMO or CMP, completes the HMO's or CMP's application form or another CMS-approved election mechanism and gives whatever information is required for enrollment;

* * * * *

3. Subpart K is amended by adding a new § 417.427 to read as follows:

§ 417.427 Extending MA and Part D Program Disclosure Requirements to Section 1876 Cost Contract Plans.

(a) The procedures and requirements relating to disclosure in § 422.111 and § 423.128 apply to Medicare contracts with HMOs and CMPs under section 1876 of the Act.

(b) In applying the provisions of § 422.111 and § 423.128, references to part 422 and part 423 of this chapter must be read as references to this part, and references to MA organizations and Part D sponsors as references to HMOs and CMPs.

4. Section 417.432 is amended by revising paragraph (d) to read as follows:

§ 417.432 Conversion of enrollment.

* * * * *

(d) *Application form.* The individual who is converting must complete an application form or another CMS-approved election mechanism as described in § 417.430(a).

* * * * *

5. Section 417.460 is amended by adding new (c)(3) and (c)(4) to read as follows:

§ 417.460 Disenrollment of beneficiaries by an HMO or CMP.

* * * * *

(c) * * *

(3) *Good cause and reinstatement.* When an individual is disenrolled for failure to pay premiums or other charges imposed by the HMO or CMP for deductible and coinsurance amounts for which the enrollee is liable, CMS may reinstate enrollment in the plan, without interruption of coverage, if the individual shows good cause for failure to pay and pays all overdue premiums within 3 calendar months after the disenrollment date. The individual must establish by a credible statement that failure to pay premiums was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

(4) *Exception for reinstatement.* A beneficiary's enrollment in the plan will not be reinstated if the only basis for such reinstatement is a change in the individual's circumstances subsequent to the involuntary disenrollment for non-payment of premiums.

* * * * *

Subpart L—Medicare Contract Requirements

§ 417.492 [Amended]

6. Section 417.492 is amended as follows:

A. In paragraph (a)(1)(i) the ''; '' is removed and a ''; and'' is added in its place.

B. In paragraph (a)(1)(ii) the ''; '' is removed and a ''.'' is added in its place.

C. Removing paragraph (a)(1)(iii).

D. Removing paragraph (b)(1)(iii).

Subpart U—Health Care Prepayment Plans

7. Section 417.801 is amended by revising paragraph (d)(ii) to read as follows:

§ 417.801 Agreements between CMS and health care prepayment plans.

* * * * *

(d) * * *

(ii) The HCPP is not in substantial compliance with the provisions of the agreement, applicable CMS regulations, or applicable provisions of the Medicare law, including the following:

(A) Provision and documentation of adequate access to providers.

(B) Compliance with CMS requirements concerning provision of data and maintenance of records.

(C) Compliance with financial requirements specified at § 417.806; or

* * * * *

PART 422—MEDICARE ADVANTAGE PROGRAM

8. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart B—Eligibility, Election, and Enrollment

§ 422.60 [Amended]

9. In § 422.60, paragraph (c)(1) is amended by removing the cross-reference ''§ 422.80'' and adding in its place the cross-reference ''§ 422.2262''.

Subpart C—Benefits and Beneficiary Protections

10. Section 422.100 is amended by adding a new paragraph (l) to read as follows:

§ 422.100 General requirements.

* * * * *

(l) *Coverage of DME.* MA organizations—

(1) Must cover and ensure enrollees have access to all categories of DME covered under Part B; and

(2) May, within specific categories of DME, limit coverage to certain preferred DME products or brands, provided the MA organization ensures all of the following:

(i) Its contracts with DME suppliers ensure that enrollees have access to all preferred DME products or brands.

(ii) Its enrollees have access to all medically necessary non-preferred DME products or brands.

(iii) It provides for an appropriate transition process for new enrollees during the first 90 days of their coverage under its MA plan, during which time the MA organization will do the following:

(A) Ensure the provision of a transition supply of non-preferred DME-supplies.

(B) Provide for the repair of non-preferred DME-items.

(iv) It makes no negative changes to its preferred DME products or brands during the plan year.

(v) It treats denials of non-preferred DME products or brands as organization determinations subject to § 422.566.

(vi) It discloses DME coverage limitations and beneficiary appeal rights in the case of a denial of a non-preferred DME product or brand as part of the description of benefits required under § 422.111(b)(2) and § 422.111(h).

11. Section 422.101 is amended by revising paragraph (d)(1) to read as follows:

§ 422.101 Requirements relating to basic benefits.

* * * * *

(d) * * *

(1) *Single deductible.* MA regional and local PPO plans, to the extent they apply a deductible as follows:

(i) Must have a single deductible related to all in-network and out-of-network Medicare Part A and Part B services.

(ii) May specify separate deductible amounts for specific in-network Medicare Part A and Part B services, to the extent these deductible amounts apply to the single deductible amount specified in paragraph (d)(1)(i) of this section.

(iii) May waive from the single deductible described in paragraph (i) for other plan-covered items and services.

(iv) Must waive from the single deductible described paragraph (d)(1)(i) all Medicare-covered preventive services (as defined in § 410.152(l)).

* * * * *

12. Section 422.102 is amended by adding a new paragraph (e) to read as follows.

§ 422.102 Supplemental benefits.

* * * * *

(e) *Supplemental benefits for certain fully-integrated dual eligible special needs plans.* Subject to CMS approval, and as specified annually by CMS, certain fully-integrated dual eligible special needs plans may offer additional supplemental benefits, consistent with the requirements of this part, beyond those other MA plans may offer where CMS finds that the offering of such benefits could better integrate care for the dual eligible population.

13. Section 422.111 is amended by adding a new paragraph (i) to read as follows:

§ 422.111 Disclosure requirements.

* * * * *

(i) *Provision of information required for access to covered services.* MA plans must issue and reissue (as appropriate) a member identification card that its enrollees may use to access covered services under the plan. The card must comply with standards established by CMS, and must include, at a minimum the following:

(1) For a MA PPO or PPFS plan, a statement that Medicare Limiting Charges apply.

(2) Web link to plan's website.

(3) Customer service number.

(4) Individual identification number for each enrollee, to clearly identify that they are a member of the plan.

Subpart E—Relationships with Providers

14. Section 422.216 is amended by revising paragraph (d)(1) to read as follows:

§ 422.216 Special rules for MA private fee-for-service plans.

* * * * *

(d) * * *

(1) *General information.* An MA organization that offers an MA private fee-for-service plan must provide to plan enrollees, an appropriate explanation of benefits consistent with the requirements of § 422.111(b)(12).

* * * * *

Subpart K—Application Procedures and Contracts for Medicare Advantage Organizations

15. Section 422.500 is amended by revising paragraph (a) to read as follows:

§ 422.500 Scope and definitions.

(a) *Scope.* This subpart sets forth application requirements for entities seeking a contract as a Medicare organization offering an MA plan, including MA organizations offering a specialized MA plan for special needs individuals. MA organizations offering prescription drug plans must, in addition to the requirements of this part, follow the requirements of part 423 of this chapter specifically related to the prescription drug benefit.

* * * * *

16. Section 422.501 is amended as follows:

A. Revising paragraph (a).

B. In paragraph (c)(1)(ii) removing ''; or'' and adding in its place ''.''.

C. Adding new paragraph (c)(1)(iii).

D. Revising paragraph (e).

The addition and revision read as follows:

§ 422.501 Application requirements.

(a) *Scope.* This section sets forth application requirements for entities that seek a contract as an MA organization offering an MA plan and additional application requirements for MA organizations seeking to offer a Specialized MA Plan for Special Needs Individuals.

* * * * *

(c) * * *

(1) * * *

(iii) For Specialized MA Plans for Special Needs Individuals, documentation that the entity meets the requirements of § 422.2; § 422.4(a)(1)(iv); § 422.101(f); § 422.107, if applicable; and § 422.152(g) of this part.

* * * * *

(e) *Resubmittal of an application.* An application that has been denied by CMS for a particular contract year may not be resubmitted until the beginning of the application cycle for the following contract year.

* * * * *

17. Section 422.502 is amended as follows:

A. In paragraph (a)(1), removing the phrase ''MA contract solely'' and adding in its place the phrase ''MA contract or for a Specialized MA Plan for Special Needs Individuals solely''.

B. In paragraph (b)(1), removing the phrase ''If an MA organization'' and adding in its place ''Except as provided in paragraphs (b)(2) through (b)(4) of this section, if an MA organization''.

C. Adding paragraphs (b)(3) and (b)(4).

D. In paragraph (c) introductory text, removing the phrase ''MA contract under this part'' and adding in its place the phrase ''MA contract or to be designated a Specialized MA Plan for Special Needs Individuals under this part''.

E. Revising paragraphs (c)(2)(i) through (iii).

F. Revising paragraph (c)(3)(i).

The additions and revision read as follows:

§ 422.502 Evaluation and determination procedures.

* * * * *

(b) * * *

(3) If CMS has terminated, under § 422.510, or non-renewed, under § 422.506(b), an MA organization's contract, effective within the 38 months preceding the deadline established by CMS for the submission of contract qualification applications, CMS may deny an application based on the applicant's substantial failure to comply with the requirements of the Part C program even if the applicant currently meets all of the requirements of this part.

(4) During the same 38-month period as specified in (b)(3) of this section, CMS may deny an application where the applicant's covered persons also served as covered persons for the terminated or non-renewed contract. A ''covered person'' as used in this paragraph means one of the following:

(i) All owners of terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(iii) A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

(c) * * *

(2) *Intent to deny.* (i) If CMS finds that the applicant does not appear to be able to meet the requirements for an MA organization or Specialized MA Plan for Special Needs Individuals, CMS gives the applicant notice of intent to deny the application for an MA contract or for a Specialized MA Plan for Special Needs Individuals a summary of the basis for this preliminary finding.

(ii) Within 10 days from the intent to deny, the applicant must respond in writing to the issues or other matters that were the basis for CMS' preliminary finding and must revise its application to remedy any defects CMS identified.

(iii) If CMS does not receive a revised application within 10 days from the date of the notice, or if after timely submission of a revised application,

CMS still finds that the applicant does not appear qualified or has not provided CMS enough information to allow CMS to evaluate the application, CMS will deny the application.

(3) * * *

(i) That the applicant is not qualified to contract as an MA organization under Part C of title XVIII of the Act and/or is not qualified to offer a Specialized MA Plan for Special Needs Individuals;

* * * * *

17. Section 422.504 is amended as follows:

A. Adding new paragraphs (a)(17), (a)(18), and (i)(3)(iv).

B. Revising paragraphs (i)(3) introductory text and (i)(3)(iii), (i)(4)(i) through (iv), and (i)(5).

The additions and revisions red as follows:

§ 422.504 Contract provisions.

* * * * *

(a) * * *

(17) To maintain administrative and management capabilities sufficient for the organization to organize, implement, and control the financial, marketing, benefit administration, and quality improvement activities related to the delivery of Part C services.

(18) To maintain a Part C summary plan rating score of at least 3 stars. A Part C summary plan rating is calculated by taking an average of a contract's Part C performance measure scores.

* * * * *

(i) * * *

(3) Each and every contract governing MA organizations and first tier, downstream, and related entities, must contain the following:

* * * * *

(iii) A provision requiring that any services or other activity performed by a first tier, downstream, and related entity in accordance with a contract are consistent and comply with the MA organization's contractual obligations.

(iv) A provision requiring that payment will not be made to hospitals for serious preventable events and hospital-acquired conditions in accordance with section 1886(d)(4)(D) of the Act and all applicable Medicare policies.

* * * * *

(4) * * *

(i) Each and every contract must specify delegated activities and reporting responsibilities.

(ii) Each and every contract must either provide for revocation of the delegation activities and reporting requirements or specify other remedies in instances where CMS or the MA organization determine that such parties have not performed satisfactorily.

(iii) Each and every contract must specify that the performance of the parties is monitored by the MA organization on an ongoing basis.

(iv) Each and every contract must specify that either—

* * * * *

(5) If the MA organization delegates selection of the providers, contractors, or subcontractor to another organization, the MA organization's contract with that organization must state that the CMS-contracting MA organization retains the right to approve, suspend, or terminate any such arrangement.

* * * * *

Subpart K—Application Procedures and Contracts for Medicare Advantage Organizations

18. Section 422.510 is amended by adding a new paragraph (a)(14) to read as follows:

§ 422.510 Termination of contract by CMS.

(a) * * *

(14) Achieves a Part C summary plan rating of less than 3 stars for 3 consecutive contract years. Plan ratings issued by CMS before September 1, 2012 are not included in the calculation of the 3-year period.

* * * * *

Subpart N—Medicare Contract Determinations and Appeals

19. Section 422.641 is amended by adding a new paragraph (d) to read as follows:

§ 422.641 Contract determinations.

* * * * *

(d) A determination that an entity is not qualified to offer a Specialized MA Plan for Special Needs Individuals as defined in § 422.2 and § 422.4(a)(1)(iv).

20. Section § 422.660 is amended by adding new paragraphs (a)(5) and (b)(5) to read as follows:

§ 422.660 Right to a hearing, burden of proof, standard of proof, and standards of review.

(a) * * *

(5) An applicant that has been determined to be unqualified to offer a Specialized MA Plan for Special Needs Individuals.

(b) * * *

(5) During a hearing to review a determination as described at § 422.641(d) of this subpart, the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 422.2; § 422.4(a)(1)(iv); § 422.101(f); § 422.107, if applicable; and § 422.152(g) of this part.

* * * * *

Subpart V—Medicare Advantage Marketing Requirements

21. Section 422.2274 is amended as follows:

A. Revising paragraph (a)(1)(i).

B. Removing and reserving paragraph (a)(1)(ii).

C. Revising paragraph (a)(1)(iii).

D. Adding a new paragraph (f).

The revisions and addition read as follows:

§ 422.2274 Broker and agent requirements.

* * * * *

(a) * * *

(1) * * *

(i) The compensation amount paid by plan sponsors to an independent broker or agent:

(A) For an initial enrollment of a Medicare beneficiary into an MA plan, must be at or below the fair market value (FMV) cut-off amounts published annually by CMS.

(B) For renewals, must be an amount equal to 50 percent of the initial compensation in paragraph (a)(1)(i)(A) of this section.

(ii) [Reserved].

(iii) The independent broker or agent is paid a renewal compensation for each of the next 5 years that the enrollee remains in the plan in an amount equal to 50 percent of the initial year compensation amount (creating a 6-year compensation cycle).

* * * * *

(f) A plan sponsor must report annually, as directed by CMS—

(1) Whether it intends to use independent agents or brokers or both in the upcoming plan year; and

(2) If applicable, the specific amount or range of amounts independent agents or brokers or both will be paid.

PART 423—MEDICARE PROGRAM; MEDICARE PRESCRIPTION DRUG PROGRAM

22. The authority citation for part 423 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh).

Subpart B—Eligibility and Enrollment

23. Section 423.56 is amended by revising paragraphs (a) and (f)(3) to read as follows:

§ 423.56 Procedures to determine and document creditable status of prescription drug coverage.

(a) *Definition. Creditable prescription drug coverage* means any of the following types of coverage listed in paragraph (b) of this section only if the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage under Part D in effect at the start of such plan year, not taking into account the value of any discount or coverage provided during the coverage gap, and demonstrated through the use of generally accepted actuarial principles and in accordance with CMS guidelines.

* * * * *

(f) * * *

(3) Prior to the commencement of the Annual Coordinated Election Period as defined in § 423.38(b); and

* * * * *

Subpart C—Benefits and Beneficiary Protections

24. Section 423.100 is amended as follows:

A. Adding the definition of ''Daily cost-sharing rate.''

B. Revising paragraph (2)(iii) of the definition of ''Incurred costs.''

C. In paragraph (2)(ii) of the definition of ''Part D drug,'' the phrase ''smoking cessation agents'' is removed and adding in its place the phrase ''smoking cessation agents, benzodiazepines, and barbiturates when used to treat epilepsy, cancer, or chronic mental health disorder.''

D. Revising the definition of ''Supplemental benefits''.

E. Adding the definition of ''Valid prescription''

The additions and revision read as follows:

§ 423.100 Definitions.

* * * * *

Daily cost-sharing rate means, as applicable, the established monthly—

(1) Copayment under the enrollee's Part D plan divided by 30 or 31 and rounded to the nearest lower dollar amount or to another amount but in no event to an amount which would require the enrollee to pay more for a month's supply of the prescription than the enrollee would have paid if a month's supply had been dispensed; or

(2) Coinsurance rate under the enrollee's Part D plan applied to the ingredient cost of the prescription for a month's supply divided by 30 or 31.

* * * * *

Incurred costs

* * * * *

(2) * * *

(ii) Under State Pharmaceutical Assistance Program (as defined in § 423.464); by the Indian Health Service, an Indian tribe or tribal organization, or urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act) or under an AIDS Drug Assistance Program (as defined in part B of title XXVI of the Public Health Service); or by a manufacturer as payment for an applicable discount (as defined in § 423.2305) or under the Medicare Coverage Gap Discount Program (as defined in § 423.2305); or

* * * * *

Supplemental benefits means benefits offered by Part D plans, other than employer group health or waiver plans, that meet the requirements of § 423.104(f)(1)(ii).

* * * * *

Valid prescription means a prescription that complies with all applicable State law requirements constituting a valid prescription.

* * * * *

25. Section 423.104 is amended by adding new paragraphs (h) and (i) to read as follows:

§ 423.104 Requirements related to qualified prescription drug coverage.

* * * * *

(h) *Valid prescription.* A Part D sponsor may only provide benefits for Part D drugs that require a prescription if those drugs are dispensed upon a valid prescription.

(i) *Daily cost-sharing rate.* A Part D sponsor is required provide its enrollees access to a daily cost-sharing rate in accordance with § 423.153(b)(4).

26. Section 423.120 is amended by adding a new paragraph (c)(5) to read as follows:

§ 423.120 Use of standardized technology.

* * * * *

(c) * * *

(5)(i) Part D sponsor must submit to CMS only a prescription drug event (PDE) record that contains an active and valid individual prescriber NPI.

(ii) Notwithstanding paragraph (c)(5)(i) of this section, a Part D sponsor may not reject a claim from a network pharmacy solely on the basis that it does not contain an active and/or valid NPI unless the issue can be resolved at point-of-sale, there is an indication of fraud, the prescription was written by a provider excluded from the Medicare program or the claim involves a prescription written by a foreign prescriber (where permitted by State law).

(iii) With respect to non-standard requests for reimbursement submitted by Medicare beneficiaries, a Part D sponsor may not make payment to a beneficiary dependent upon the sponsor's acquisition of the prescriber NPI. If the sponsor is unable to retrospectively acquire an active and valid individual prescriber NPI, the sponsor may not seek recovery of the payment from the beneficiary solely on the basis that the non-standard request did not include a valid individual prescriber NPI.

* * * * *

Subpart D—Cost Control and Quality Improvement Requirements

27. Section 423.153 is amended as follows:

A. In the introductory text for paragraph (b), the phrase ''that -'' is removed and the phrase ''that address all of the following:'' is added in its place.

B. In paragraph (b)(1) removing '';'' and adding in its place ''.''.

C. In paragraph (b)(2) removing ''; and'' and adding in its place ''.''.

D. Adding a new paragraph (b)(4).

E. Revising paragraphs (d)(1)(vii)(B), and (d)(2).

The addition and revision read as follows:

§ 423.153 Drug utilization management, quality assurance, and medication therapy management programs (MTMPs).

* * * * *

(b) * * *

(4)(i) Establishes and applies a daily cost-sharing rate to a prescription dispensed by a network pharmacy for a covered Part D generic or brand drug that is dispensed for a supply less than 30 days, multiplied by the days supply actually dispensed, plus any dispensing fee in the case of coinsurance—

(A) If the drug is in the form of a solid oral dose, subject to paragraph (b)(4)(ii) of this section; and

(B) The prescription is—

(*1*) For an initial fill of a new medication;

(*2*) Intended to allow the enrollee to synchronize refill dates of multiple drugs; or

(*3*) Dispensed in accordance with § 423.154.

(ii) The requirements of paragraph (b)(4)(i) of this section do not apply to either of the following:

(A) Solid oral doses of antibiotics.

(B) Solid oral doses that are dispensed in their original container as indicated in the Food and Drug Administration Prescribing Information or are customarily dispensed in their original packaging to assist patients with compliance.

* * * * *

(d) * * *

(1) * * *

(vii) * * *

(B) *Annual comprehensive medication review with written summaries.* (*1*) The beneficiary's comprehensive medication review—

(*i*) Must include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider; and

(*ii*) May result in a recommended medication action plan.

(2) If a beneficiary residing in an LTC setting is offered the annual comprehensive medication review and cannot accept the offer to participate, the pharmacist or other qualified provider must perform the medication review without the beneficiary's participation.

* * * * *

Subpart J—Coordination of Part D Plans with Other Prescriptions Drug Coverage

28. Section 423.458 is amended by adding a new paragraph (c)(3) to read as follows:

§ 423.458 Application of Part D rules to certain Part D plans on or after January 1, 2006.

* * * * *

(c) * * *

(3) Employer-sponsored group prescription drug plans must comply with all applicable requirements under this part that are not specifically waived or modified in accordance with in paragraph (c)(2) of this section.

* * * * *

Subpart K—Application Procedures and Contracts with Part D Plan Sponsors

29. Section 423.501 is amended by adding the definition of ''Bona fide service fees'' to read as follows:

§ 423.501 Definitions.

* * * * *

Bona fide service fees means fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drugs. Bona fide service fees include, but are not limited to distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs).

* * * * *

30. Section 423.503 is amended as follows:

A. In paragraph (b)(1), removing the phrase ''If a Part D'' and adding in its place '' Except as provided in paragraphs (b)(2), (b)(3), and (b)(4) of this section, if a Part D''.

B. Adding new paragraphs (b)(3) and (b)(4).

The additions read as follows:

§ 423.503 Evaluation and determination procedures for applications to be determined qualified to act as a sponsor.

* * * * *

(b) * * *

(3) If CMS has terminated, under § 423.509, or non-renewed, under § 423.507(b), a Part D plan sponsor's contract, effective within the 38 months preceding the deadline established by CMS for the submission of contract qualification applications, CMS may deny an application based on the applicant's substantial failure to comply with the requirements of the Part D program even if the applicant currently meets all of the requirements of this part.

(4) During the same 38-month period as specified in (b)(3) of this section, CMS may deny an application where the applicant's covered persons also served as covered persons for the terminated or non-renewed contract. A ''covered person'' as used in this paragraph means one of the following:

(i) All owners of terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(iii) A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

* * * * *

31. Section 423.505 is amended to read as follows:

A. Adding new paragraphs (b)(24) through (b)(26).

B. Revising paragraphs (i)(3) introductory text, (i)(3)(iii), (i)(3)(v), and (i)(4)(i) through (iv).

§ 423.505 Contract provisions.

* * * * *

(b) * * *

(24) Provide applicable beneficiaries with applicable discounts on applicable drugs in accordance with the requirements in subpart W of Part 423.

(25) Maintains administrative and management capabilities sufficient for the organization to organize, implement, and control the financial, marketing, benefit administration, and quality assurance activities related to the delivery of Part D services.

(26) Maintains a Part D summary plan rating score of at least 3 stars. A Part D summary plan rating is calculated by taking an average of a contract's Part C performance measure scores.

* * * * *

(i) * * *

(3) Each and every contract governing Part D sponsors and first tier, downstream, and related entities, must contain the following:

* * * * *

(iii) A provision requiring that any services or other activity performed by a first tier, downstream, and related entity in accordance with a contract are consistent and comply with the Part D sponsor's contractual obligations.

* * * * *

(v) Each and every contract must specify that first tier, downstream, and related entities must comply with all applicable Federal laws, regulations, and CMS instructions.

* * * * *

(4) * * *

(i) Each and every contract must specify delegated activities and reporting responsibilities.

(ii) Each and every contract must either provide for revocation of the delegation activities and reporting responsibilities described in paragraph (i)(4)(i) of this section or specify other remedies in instances when CMS or the Part D plan sponsor determine that the parties have not performed satisfactorily.

(iii) Each and every contract must specify that the Part D plan sponsor on an ongoing basis monitors the performance of the parties.

(iv) Each and every contract must specify that the related entity, contractor, or subcontractor must comply with all applicable Federal laws, regulations, and CMS instructions.

* * * * *

32. Section 423.509 is amended by adding a new paragraph (a)(13) to read as follows:

§ 423.509 Termination of Contract by CMS.

* * * * *

(a) * * *

(13) Achieves a Part D summary plan rating of less than 3 stars for 3

consecutive contract years. Plan ratings issued by CMS before September 1, 2012 are not included in the calculation of the 3-year period.

* * * * *

33. Section 423.514 is amended as follows:

A. Redesignating paragraphs (d) through (g) as paragraphs (g) through (j), respectively.

B. Adding new paragraphs (d), (e), and (f).

The additions read as follows:

§ 423.514 Validation of Part D reporting requirements.

* * * * *

(d) *Reporting requirements for pharmacy benefits manager data.* Each entity that provides pharmacy benefits management services must provide to the Part D sponsor, and each Part D sponsor must provide to CMS, in a manner specified by CMS, the following:

(1) The total number of prescriptions that were dispensed.

(2) The percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies.

(3) The percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate), by pharmacy type (which includes an independent pharmacy, chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medication to the general public), that is paid by the Part D sponsor or PBM under the contract.

(4) The aggregate amount and type of rebates, discounts, or price concessions (excluding bona fide service fees as defined in § 423.501) that the PBM negotiates that are attributable to patient utilization under the plan.

(5) The aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed.

(6) The aggregate amount of the difference between the amount the Part D sponsor pays the PBM and the amount that the PBM pays retail pharmacies, and mail order pharmacies.

(e) *Confidentiality of pharmacy benefits manager data.* Information disclosed by a Part D sponsor or PBM as specified in paragraph (d) of this section is confidential must not be disclosed by the Secretary or by a plan receiving the information, except that the Secretary may disclose the information in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs, for the following purposes:

(1) As the Secretary determines necessary to carry out section 1150A of the Act or Part D of Title XVIII.

(2) To permit the Comptroller General to review the information provided.

(3) To permit the Director of the Congressional Budget Office to review the information provided.

(f) *Penalties for failure to provide pharmacy benefits manager data.* The provisions of section 1927(b)(3)(C) of the Act are applicable to a Part D sponsor or PBM that fails to provide the required information on a timely basis or knowingly provides false information in the same manner as such provisions apply to a manufacturer with an agreement under section 1927 of the Act.

* * * * *

Subpart M—Grievances, Coverage Determinations, Redeterminations, and Reconsiderations

34. Section 423.600 is amended by revising paragraphs (a) through (c) to read as follows:

§ 423.600 Reconsideration by an independent review entity (IRE).

(a) An enrollee who is dissatisfied with the redetermination of a Part D plan sponsor has a right to a reconsideration by an independent review entity that contracts with CMS. The prescribing physician or other prescriber (acting on behalf of an enrollee), upon providing notice to the enrollee, may request an IRE reconsideration. The enrollee, or the enrollee's prescribing physician or other prescriber (acting on behalf of the enrollee) must file a written request for reconsideration with the IRE within 60 calendar days of the date of the redetermination by the Part D plan sponsor.

(b) When an enrollee, or an enrollee's prescribing physician or other prescriber (acting on behalf of the enrollee) files an appeal, the IRE is required to solicit the views of the prescribing physician or other prescriber. The IRE may solicit the views of the prescribing physician or other prescriber orally or in writing. A written account of the prescribing physician's or other prescriber's views (prepared by either the prescribing physician, other prescriber, or IRE, as appropriate) must be contained in the IRE record.

(c) In order for an enrollee or a prescribing physician or other prescriber (acting on behalf of an enrollee) to request an IRE reconsideration of a determination by a Part D plan sponsor not to provide for a Part D drug that is not on the formulary, the prescribing physician or other prescriber must determine that all covered Part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the non-formulary drug, would have adverse effects for the individual, or both.

* * * * *

35. Section 423.602 is amended by revising paragraph (a) to read as follows:

§ 423.602 Notice of reconsideration determination by the independent review entity.

(*a) Responsibility for the notice.* When the IRE makes its reconsideration determination, it is responsible for mailing a notice of its determination to the enrollee and the Part D plan sponsor, and for sending a copy to CMS. When the prescribing physician or other prescriber requests the reconsideration on behalf of the enrollee, the IRE is also responsible for notifying the prescribing physician or other prescriber of its decision.

* * * * *

Subpart T—Appeal Procedures for Civil Money Penalties

36. Section 423.1000 is amended by adding paragraph (a)(3) to read as follows:

§ 423.1000 Basis and scope.

* * * * *

(a) * * *

(3) Section 1860D–14A(e)(2) of the Act specifies that the Secretary must impose a civil money penalty on a manufacturer that fails to provide applicable beneficiaries discounts for applicable drugs of the manufacturer in accordance with its Discount Program Agreement. Section 1860D–14A(e)(2)(B) of the Act makes certain provisions of section 1128A of the Act applicable to such civil money penalties imposed on manufacturers.

37. Section 423.1002 is amended by revising the definition of ''Affected party'' to read as follows:

§ 423.1002 Definitions.

Affected party means any Part D sponsor or manufacturer (as defined in § 423.2305) impacted by an initial determination or if applicable, by a subsequent determination or decision issued under this part, and ''party'' means the affected party or CMS, as appropriate.

Subpart V—Part D Marketing Requirements

38. Section § 423.2274 is amended to read as follows:

A. Revising paragraph (a)(1)(i).

B. Removing and reserving paragraph (a)(1)(ii).

C. Revising paragraph (a)(1)(iii).

D. Adding a new paragraph (f).

The revisions and addition read as follows:

§ 423.2274 Broker and agent requirements.

* * * * *

(a) * * *

(1) * * *

(i) The compensation amount paid by plan sponsors to an independent broker or agent—

(A) For an initial enrollment of a Medicare beneficiary into a PDP must be at or below the fair market value (FMV) cut-off amounts published annually by CMS; or

(B) For renewals, must be an amount equal to 50 percent of the initial compensation in paragraph (a)(1)(i)(A) of this section.

(ii) [Reserved].

(iii) The independent broker or agent is paid a renewal compensation for each of the next 5 years that the enrollee remains in the plan in an amount equal to 50 percent of the initial year compensation paid (creating a 6-year compensation cycle).

* * * * *

(f) Plan sponsor must report annually, as directed by CMS the following:

(1) Whether it intends to use independent agents or brokers or both in the upcoming plan year.

(2) If applicable, the specific amount or range of amounts independent agents or brokers or both will be paid.

* * * * *

39. Part 423 is amended by adding a new subpart W to read as follows:

Subpart W—Medicare Coverage Gap Discount Program

Sec.

423.2300 Scope.
423.2305 Definitions.
423.2310 Condition for coverage of drugs under Part D.
423.2315 Medicare Coverage Gap Discount Program Agreement.
423.2320 Payment processes for Part D sponsors.
423.2325 Provision of applicable discounts on applicable drugs for applicable beneficiaries.
423.2330 Manufacturer discount payment audit and dispute resolution.
423.2335 Beneficiary dispute resolution.
423.2340 Compliance monitoring and civil money penalties.
423.2345 Termination of Discount Program Agreement.

Subpart W—Medicare Coverage Gap Discount Program

§ 423.2300 Scope.

This subpart implements provisions included in sections 1860D–14A and 1860D–43 of the Act. This subpart sets forth requirements regarding the following:

(a) Condition for coverage of applicable drugs under Part D.

(b) The Medicare Coverage Gap Discount Program Agreement.

(c) Coverage gap discount payment processes for Part D sponsors.

(d) Provision of applicable discounts on applicable drugs for applicable beneficiaries.

(e) Manufacturer audit and dispute resolution processes.

(f) Resolution of beneficiary disputes involving coverage gap discounts.

(g) Compliance monitoring and civil money penalties.

(h) The termination of the Discount Program Agreement.

§ 423.2305 Definitions.

As used in this subpart, unless otherwise specified—

Applicable discount means 50 percent of the portion of the negotiated price (as defined in § 423.2305) of the applicable drug of a manufacturer that falls within the coverage gap and that remains after such negotiated price is reduced by any supplemental benefits that are available.

Applicable number of calendar days means, with respect to claims for reimbursement submitted electronically, 14 days, and otherwise, 30 days.

Date of dispensing means the date of service.

Labeler code means the first segment of the Food and Drug Administration national drug code (NDC) that identifies a particular manufacturer.

Manufacturer means any entity which is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drug products, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. For purposes of the Discount Program, such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law, but includes entities otherwise engaged in repackaging or changing the container, wrapper, or labeling of any applicable drug product in furtherance of the distribution of the applicable drug from the original place of manufacture to the person who makes the final delivery or sale to the ultimate consumer or use.

Medicare Coverage Gap Discount Program (or Discount Program) means the Medicare coverage gap discount program established under section1860D–14A of the Act.

Medicare Coverage Gap Discount Program Agreement (or Discount Program Agreement) means the agreement described in section 1860D–14A(b) of the Act.

Medicare Part D discount information means the information sent from CMS or the TPA to the manufacturer along with each quarterly invoice that is derived from applicable data elements available on prescription drug events as determined by CMS.

National Drug Code (NDC) means the unique identifying prescription drug product number that is listed with the Food and Drug Administration (FDA) identifying the product and package size.

Negotiated price for purposes of the Discount Program, means the price for a covered Part D drug that—

(1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug;

(2) Is reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point-of-sale; and

(3) Excludes any dispensing fee or vaccine administration fee for the applicable drug. In connection with applicable drugs dispensed by an out-of-network provider in accordance with the applicable beneficiary's Part D plan out-of-network policies, the negotiated price means the plan allowance as set forth in § 423.124, less any dispensing fee or vaccine administration fee.

Other health or prescription drug coverage means any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of applicable beneficiaries, including, in the case of employer group health or waiver plans, other than basic prescription drug coverage as defined in § 423.100.

Third Party Administrator (TPA) means the CMS contractor responsible for administering the requirements established by the CMS to carry out section 1860D–14A of the Act.

§ 423.2310 Condition for coverage of drugs under Part D.

(a) *Covered Part D drug coverage requirement.* Except as specified in paragraph (b) of this section, in order for coverage to be available under Medicare Part D for applicable drugs of a manufacturer, the manufacturer must do all of the following:

(1) Participate in the Discount Program.

(2) Have entered into and have in effect an agreement described in § 423.2315(b).

(3) Have entered into and have in effect, under terms and conditions specified by CMS, a contract with the TPA.

(b) *Exception to covered drug coverage requirement.* Paragraph (a) of this section does not apply to an applicable drug if CMS has made a determination that the availability of the applicable drug is essential to the health of beneficiaries enrolled in Medicare Part D.

§ 423.2315 Medicare Coverage Gap Discount Program Agreement.

(a) *General rule.* The Medicare Coverage Gap Discount Program Agreement (or Discount Program Agreement) between the manufacturer and CMS must contain, the provisions specified in paragraph (b) of this section, and may contain such other provisions as are established in a model agreement consistent with section 1860D–14A (a)(1) of the Act.

(b) *Agreement requirements.* The manufacturer agrees to the following:

(1) All the applicable requirements and conditions set forth in this part and general instructions.

(2) Reimburse all applicable discounts provided by Part D sponsors on behalf of the manufacturer for all applicable drugs having NDCs with the manufacturer's FDA-assigned labeler code(s) invoiced to the manufacturer within a maximum of 3 years of the date of dispensing based upon information reported to CMS by Part D sponsors.

(3) Pay each Part D sponsor in the manner specified by CMS within 38 calendar days of receipt of the invoice and Medicare Part D Discount Information for the applicable discounts included on the invoice, except as specified in § 423.2330(c)(3).

(4) Provide CMS with all labeler codes for all the manufacturer's applicable drugs and to promptly update such list with any additional labeler codes for applicable drugs no later than 3 business days after having received written notification of the codes from the FDA.

(5) Collect, have available, and maintain appropriate data, including data related to manufacturer's labeler codes, NDC expiration dates, utilization and pricing information relied on by the manufacturer to dispute quarterly invoices and any other data CMS determines are necessary to carry out the Discount Program for a period of not less than 10 years from the date of payment of the invoice.

(6) Comply with the audit and dispute resolution requirements in § 423.2330.

(7) Electronically list and maintain up-to-date electronic FDA listings of all NDCs of the manufacturer, including the timely removal of discontinued NDCs in the FDA NDC Directory.

(8) Maintain up-to-date NDC listings with the electronic database vendors for which the manufacturer provides NDCs for pharmacy claims processing.

(9) Enter into and have in effect, under terms and conditions specified by CMS, an agreement with the TPA that has a contract with CMS under section 1860D–14(A)(d)(3) of the Act.

(10) Pay quarterly invoices directly to accounts established by Part D sponsors via electronic funds transfer, or other manner if specified by CMS, within the time period specified in paragraph (b)(3) and within 5 business days of the transfer to provide the TPA with electronic documentation of such payment in a manner specified by CMS.

(11) Use information disclosed to the manufacturer on the invoice, as part of the Medicare Part D Discount Information, or upon audit or dispute only for purposes of paying the discount under the Discount Program.

(c) *Timing and length of agreement.* (1) For 2011, a manufacturer must enter into a Discount Program Agreement not later than 30 days after the date of establishment of the model Discount Program Agreement.

(2) For 2012 and subsequent years, for a Discount Program Agreement to be effective for a year, a manufacturer must enter into a Discount Program Agreement not later than January 30th of the preceding year.

(3) Unless terminated in accordance with § 423.2345, the initial period of a Discount Program Agreement is 24 months and the agreement is automatically renewed for a one year period on January first each year for a period of 1 year thereafter.

(d) *Compliance with requirements for administration of the Program.* Each manufacturer with an agreement in effect under this subpart must comply with the requirements imposed by CMS or the third party administrator (as defined in § 423.2305) for purposes of administering the program.

§ 423.2320 Payment processes for Part D sponsors.

(a) *Interim payments.* CMS provides monthly interim coverage gap discount program payments as necessary for Part D sponsors to advance coverage gap discounts to beneficiaries.

(b) *Coverage Gap Discount Reconciliation.* CMS reconciles interim payments with invoiced manufacturer discount amounts made available to each Part D plan's enrollee under the Discount Program.

§ 423.2325 Provision of applicable discounts on applicable drugs for applicable beneficiaries.

(a) *General rule.* On behalf of the manufacturers, Part D sponsors must provide applicable beneficiaries with applicable discounts on applicable drugs at the point-of-sale.

(b) *Discount determination.* (1) Part D sponsors must determine the following:

(i) Whether an enrollee is an applicable beneficiary (as defined in § 423.100).

(ii) Whether a Part D drug is an applicable drug (as defined in § 423.100).

(iii) The amount of the applicable discount (as defined in § 423.2305) to be provided at the point-of-sale.

(2) Part D sponsors must make retroactive adjustments to the applicable discount as necessary to reflect changes to the claim or beneficiary eligibility determined after the date of dispensing.

(3) In determining whether an enrollee is entitled to an applicable discount and the amount of the applicable discount, the Part D sponsor must apply any dispensing fee or vaccine administration fee for a claim that straddles the coverage gap and either the initial coverage limit or annual out-of-pocket threshold (or both) such that the dispensing fee or vaccine administration fee is within the initial coverage limit or the catastrophic phase of coverage to the maximum extent possible, and then determines the amount of the applicable discount based on the negotiated price (as defined in § 423.2305).

(4) Part D sponsors must determine whether any affected beneficiaries need to be notified by the Part D sponsor that an applicable drug is eligible for Part D coverage whenever CMS specifies a retroactive effective date for a labeler code and notify such beneficiaries.

(c) *Exception to point-of-sale requirement.* Part D sponsors must provide an applicable discount for applicable drugs submitted by applicable beneficiaries via paper claims, including out-of-network and in-network paper claims, if such claims are payable under Part D.

(d) *Collection of data.* Part D sponsors must provide CMS with appropriate data on the applicable discounts provided by the Part D sponsors in a manner specified by CMS.

(e) *Supplemental benefits.* (1) An applicable discount must be applied to beneficiary cost-sharing after supplemental benefits (as defined in § 423.100) have been applied to the claim for an applicable drug.

(2) No applicable discount is available if supplemental benefits (as defined in § 423.100) eliminate the coverage gap so that a beneficiary has zero cost-sharing.

(3) In determining whether an enrollee is entitled to an applicable discount and the amount of the applicable discount, the Part D sponsor applies any dispensing fee or vaccine administration fee for a claim such that the dispensing fee or vaccine administration fee is within the supplemental benefits to the maximum extent possible, and then determines the amount of the applicable discount based on the negotiated price (as defined in § 423.2305).

(f) *Other health or prescription drug coverage.* An applicable discount must be applied to beneficiary cost-sharing when Part D is the primary payer before any other health or prescription drug coverage is applied.

(g) *Pharmacy prompt payment.* Part D sponsors must reimburse a network pharmacy (as defined in § 423.100) the amount of the applicable discount no later than the applicable number of calendar days after the date of dispensing of an applicable drug.

§ 423.2330 Manufacturer discount payment audit and dispute resolution.

(a) *Third-party Administration (TPA) audits.* (1) Manufacturers participating in the Discount Program may conduct periodic audits, no more often than annually, directly or through third parties as specified in this section.

(2) The manufacturer must provide the TPA with 60 days notice of the reasonable basis for the audit and a description of the information required for the audit.

(3) The manufacturer must have the right to audit a statistically significant sample of data and information held by the TPA that were used to determine applicable discounts for applicable drugs having NDCs with the manufacturer's FDA-assigned labeler code(s). Such data and information will be made available on-site, and with the exception of work papers, such information cannot be removed from the audit site.

(4) The auditor for the manufacturer may release only an opinion of the audit results and is prohibited from releasing other information obtained from the audit, including work papers, to its client, employer, or any other party.

(b) *Manufacturer audits.* (1) A manufacturer is subject to periodic audit by CMS no more often than annually, directly or through third parties, as specified in this section.

(2) CMS provides the manufacturer with 60 days notice of the audit and a description of the information required for the audit.

(3) CMS has the right to audit appropriate data, including data related to a manufacturer's FDA-assigned labeler codes, expiration date of NDCs, utilization, and pricing information relied on by the manufacturer to dispute quarterly invoices, and any other data CMS determines are necessary to carry out the Discount Program.

(c) *Dispute resolution.* (1) Manufacturers may dispute applicable discounts invoiced to the manufacturer on quarterly invoices by providing notice of the dispute to the TPA in a manner specified by CMS within 60 days of receipt of the information that is the subject of the dispute.

(2) Such notice must be accompanied by supporting evidence that is material, specific, and related to the dispute in a manner specified by CMS.

(3) The manufacturer must not withhold any invoiced discount payments pending dispute resolution with the sole exception of invoiced amounts for applicable drugs that do not have labeler codes provided by the manufacturer to CMS in accordance with § 423.2306(b)(4) of this subpart. If payment is withheld in accordance with this paragraph, the manufacturer must notify the TPA and applicable Part D sponsors within 38 days of receipt of the applicable invoice that payment is being withheld for this reason.

(4) If the manufacturer receives an unfavorable determination from the TPA, or the dispute is not resolved within 60 calendar days of the TPA's receipt of the notice of dispute, the manufacturer may request review by the independent review entity contracted by CMS within—

(i) Thirty calendar days of the unfavorable determination; or

(ii) Ninety calendar days after the TPA's receipt of the notice of dispute if dispute is not resolved within 60 days, whichever is earlier.

(5) The independent review entity must make a determination within 90 calendar days of receipt of the manufacturer's request for review.

(6)(i) CMS or a manufacturer that receives an unfavorable determination from the independent review entity may request review by the CMS Administrator within 30 calendar days of receipt of the notification of such determination.

(ii) The decision of the CMS Administrator is final and binding.

(7) CMS adjusts future invoices (or implements an alternative reimbursement process if determined necessary by CMS) if the dispute is resolved in favor of the manufacturer.

§ 423.2335 Beneficiary dispute resolution.

The Part D coverage determination and appeals process as described in § 423.558 through § 423.638 applies to beneficiary disputes involving the availability and amount of applicable discounts under the Discount Program.

§ 423.2340 Compliance monitoring and civil money penalties.

(a) *General rule.* CMS monitors compliance by a manufacturer with the terms of the Discount Program Agreement.

(b) *Basis for imposing civil money penalties.* CMS imposes a civil money penalty (CMP) on a manufacturer that fails to provide applicable beneficiaries applicable discounts for applicable drugs of the manufacturer in accordance with the Discount Program Agreement.

(c) *Determination of the civil money penalty amounts.* CMS imposes a CMP for each failure by a manufacturer to provide an applicable discount in accordance with the Discount Program Agreement equal to the sum of the following:

(1) The amount of applicable discount the manufacturer would have paid under the Discount Program Agreement, which will then be used to pay the applicable discount that the manufacturer had failed to provide.

(2) Twenty-five percent of such amount.

(d) *Procedures for imposing civil money penalties.* (1) If CMS makes a determination to impose a CMP described in paragraph (c) of this section, CMS sends a written notice of its decision to impose a CMP to include the following:

(i) A description of the basis for the determination.

(ii) The basis for the penalty.

(iii) The amount of the penalty.

(iv) The date the penalty is due.

(v) The manufacturer's right to a hearing (as specified in § 423.1006).

(vi) Information about where to file the request for hearing.

(e) *Collection of civil money penalties imposed by CMS.* (1) When a manufacturer does not request a hearing, CMS initiates the collection of the CMP following the expiration of the

timeframe for requesting an ALJ hearing as specified in § 423.1020.

(2) If a manufacturer requests a hearing and the Administrator upholds CMS' decision to impose a CMP, CMS may initiate collection of the CMP once the Administrator's decision is final.

(f) *Other applicable provisions.* The provisions of section 1128A of the Act (except subsections (a) and (b)) apply to CMPs under this subpart to the same extent that they apply to a CMP or procedure under section 1128A(a) of the Act.

§ 423.2345 Termination of Discount Program Agreement.

(a)(1) CMS may terminate the Discount Program Agreement for a knowing and willful violation of the requirements of the agreement or other good cause shown in relation to the manufacturer's participation in the Discount Program.

(2) The termination must not be effective earlier than 30 days after the date of notice to the manufacturer of such termination and must not be effective prior to resolution of timely appeal requests received in accordance with paragraphs (a)(4) and (a)(5) of this section.

(3)(i) CMS provides the manufacturer with an opportunity to cure any ground for termination for cause or to show the manufacturer is in compliance with the Discount Program Agreement within 30 calendar days of receipt of the written termination notice.

(ii) If the manufacturer cures the violation, or establishes that it was in compliance within the cure period, CMS repeals the termination notice by written notice.

(4) CMS provides upon request a manufacturer with a hearing with the hearing officer concerning such termination if requested in writing within 15 calendar days of receiving notice of the termination. The hearing takes place prior to the effective date of the termination with sufficient time for such effective date to be repealed if CMS determines appropriate.

(5)(i) CMS or a manufacturer that has received an unfavorable determination from the hearing officer may request review by the CMS Administrator within 30 calendar days of receipt of the notification of such determination.

(ii) The decision of the CMS Administrator is final and binding.

(b)(1) The manufacturer may terminate the Discount Program Agreement for any reason.

(2) Such termination is effective as of the day after the end of the calendar year if the termination occurs before January 30 of a calendar year, or as of the day after the end of the succeeding calendar year if the termination occurs on or after January 30 of a calendar year.

(c) Any termination does not affect the manufacturer's responsibility to reimburse Part D sponsors for applicable discounts incurred before the effective date of the termination.

(d) Upon the effective date of termination of the Discount Program Agreement, CMS ceases releasing data to the manufacturer except as necessary to ensure that the manufacturer reimburses applicable discounts for previous time periods in which the Discount Program Agreement was in effect, and notifies the manufacturer to destroy data files provided by CMS under the Discount Program Agreement.

(e) Manufacturer reinstatement is available only upon payment of any and all outstanding applicable discounts incurred during any previous period under the Discount Program Agreement. The timing of any such reinstatement is consistent with the requirements for entering into a Discount Program Agreement under § 423.2315(c) of this subpart.

Authority: (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 25, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: September 16, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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Part VI

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; 12-Month Finding for a Petition To List the California Golden Trout as Endangered; Proposed Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R8–ES–2011–0089 MO 92210–0–008]

Endangered and Threatened Wildlife and Plants; 12-Month Finding for a Petition To List the California Golden Trout as Endangered

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of 12-month petition finding.

SUMMARY: We, the U.S. Fish and Wildlife Service, announce a 12-month finding on a petition to list the California golden trout (*Oncorhynchus mykiss aguabonita*) as endangered under the Endangered Species Act of 1973, as amended (Act). After review of all available scientific and commercial information, we find that listing the California golden trout is not warranted at this time. However, we ask the public to submit to us any new information that becomes available concerning the threats to the California golden trout or its habitat at any time.

DATES: The finding announced in this document was made on October 11, 2011.

ADDRESSES: This finding is available on the Internet at *http://www.regulations.gov* at Docket Number FWS–R8–ES–2011–0089. Supporting documentation we used in preparing this finding is available for public inspection, by appointment, during normal business hours at the U.S. Fish and Wildlife Service, Sacramento Field Office, 2800 Cottage Way, Sacramento, CA 95825. Please submit any new information, materials, comments, or questions concerning this finding to the above address.

FOR FURTHER INFORMATION CONTACT: Karen Leyse, Field Office Listing/Critical Habitat Coordinator, Sacramento Field Office (see **ADDRESSES**); by telephone at 916–414–6600; or by facsimile at 916–414–6712. If you use a telecommunications device for the deaf (TDD), please call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Background

Section 4(b)(3)(B) of the Act (16 U.S.C. 1531 *et seq.*) requires that, for any petition to revise the Federal Lists of Endangered and Threatened Wildlife and Plants, to the maximum extent practicable, within 90 days after receiving the petition, we make a finding as to whether the petition presents substantial scientific or commercial information indicating that the petitioned action may be warranted. In addition, within 12 months of the date of the receipt of the petition, we must make a finding on whether the petitioned action is: (a) Not warranted, (b) warranted, or (c) warranted but precluded by other pending proposals. Section 4(b)(3)(C) of the Act requires that we treat a petition for which the requested action is found to be warranted but precluded as though resubmitted on the date of such finding, that is, requiring a subsequent finding to be made within 12 months. Such 12-month findings are to be published promptly in the **Federal Register**. This notice constitutes our 12-month finding on the October 23, 2000, petition to list the California golden trout as endangered.

Previous Federal Actions

On October 23, 2000, we received a petition dated October 13, 2000, from Trout Unlimited, requesting that the California golden trout be listed on an emergency basis as endangered under the Act, and that critical habitat be designated. Included in the petition was supporting information on the subspecies' taxonomy, distribution, and ecology, as well as information regarding factors considered by the petitioners to threaten the subspecies. We acknowledged receipt of the petition in a letter to Trout Unlimited, dated November 7, 2000. In that letter, we also stated that we would be unable to address the petition until fiscal year 2002 or later due to court orders and judicially approved settlement agreements for listing and critical habitat determinations under the Act, which required nearly all of our listing and critical habitat funding for fiscal year 2001. The petitioner filed a complaint in Federal District Court on November 29, 2001, resulting in a ruling on June 21, 2002, ordering us to complete the 90-day finding by September 19, 2002. We completed the finding by the requisite date, and published it in the **Federal Register** on September 20, 2002 (67 FR 59241). In the finding we determined that the petition presented substantial scientific or commercial information to indicate that listing the California golden trout may be warranted. We also determined that an emergency rule to list was not warranted at the time of the 90-day finding. We concurrently initiated a status review on which to base our eventual 12-month finding regarding whether listing of the California golden trout is warranted. On September 22, 2003, Trout Unlimited sent a Notice of Intent to sue the Service for violating the Act by failing to make a 12-month finding within the statutory timeframe. This 12-month finding resolves that issue.

Subspecies Information

Taxonomy and Subspecies Description

The California golden trout (*Oncorhynchus mykiss aguabonita*) (formerly known as Volcano Creek golden trout) is one of three subspecies of rainbow trout (*O. mykiss*) native to the Kern River basin in Tulare and Kern Counties, California (Behnke 1992, p. 191; Behnke 2002, p. 105; Moyle 2002, p. 283). The two other subspecies native to this basin are the Little Kern golden trout (*O. mykiss whitei*), which is found in the Little Kern River and its tributaries, and the Kern River rainbow trout (*O. mykiss gilberti*), which is found in the Kern River. All three subspecies most likely originated from successive invasions of primitive redband trout (ancestral rainbow trout) of the Kern River approximately 10,000 to 20,000 years ago (Behnke 1992, p. 189; Behnke 2002, p. 107; Moyle 2002, p. 283). These fish gained access to the Kern River drainage during glacial cycles and short-term interglacial wet cycles that allowed Lake Tulare to overflow and connect the Kern River drainage to the San Joaquin River and Pacific Ocean (Behnke 2002, p. 109). These primitive forms of rainbow trout that became isolated in the Kern River watershed gave rise to the California golden trout, Little Kern River golden trout, and the Kern River rainbow trout due to local selective factors in their environment (Behnke 2002, p. 111; Moyle 2002, p. 283).

The taxonomy of golden trout in the Kern River basin has been revised several times. Originally, four species of trout were described: *Salmo aguabonita* from the South Fork Kern River, *S. roosevelti* from Golden Trout Creek, *S. whitei* (Little Kern golden trout) from the Little Kern River, and *S. gairdeneri gilberti* (Kern River rainbow trout) from the lower Kern River (Moyle 2002, p. 284). Trout from the South Fork Kern River and Golden Trout Creek were later recognized as color variants of *S. aguabonita* (Schreck and Behnke 1971, p. 994). More recently, rainbow trout were reclassified as *Oncorhynchus mykiss* to reflect their relationship to Pacific salmon, and California golden trout in both the South Fork Kern River and Golden Trout Creek became recognized as the same subspecies of rainbow trout, *Oncorhynchus mykiss*

aguabonita (Behnke 1992, pp. 163, 172). Similarly, Little Kern golden trout became *O. mykiss whitei,* and Kern River rainbow trout became *O. mykiss gilberti.*

California golden trout are well known for their bright coloration, red to red-orange belly and cheeks, bright gold lower sides, a central lateral band that is red-orange, and a deep olive-green back (Moyle 2002, p. 283). Typically, 10 parr marks (oval colorations) are present along the lateral line on both young fish and adults, but may be lost in older fish under some conditions (Behnke 2002, p. 106). The pectoral, pelvic, and anal fins are orange with a white to yellow tip preceded by a black band; dorsal fins may also have a white to yellow tip (Moyle 2002, p. 283). Body spotting is highly variable, but spots are usually scattered across the dorsal surface with a few below the lateral line (Moyle 2002, p. 283). California golden trout from Golden Trout Creek have few spots on the body, primarily concentrated on and near the caudal peduncle (the muscle before the tail fin), whereas California golden trout in the South Fork Kern River typically have small dark spots present over most of the length of the body above the lateral line, although a few spots can be found below the lateral line (Fisk 1983, p.1; Stephens 2001a, p. 4). Golden trout are rainbow trout, so the basic rainbow trout characteristics apply to the subspecies (Moyle 2002, p. 283); however, golden trout have the lowest number of vertebrae (59 to 60) and pyloric caeca (finger-like projections of the intestine (30 to 32)), and the highest number of scales along the lateral line (170 to 200) of any rainbow trout (Behnke 2002, p. 106). California golden trout in streams can obtain lengths of 19 to 20 centimeters (cm) (7.5 to 7.9 inches (in)) (Knapp and Dudley 1990, p. 168). California golden trout remain geographically isolated from Little Kern golden trout and Kern River rainbow trout, but historical planting of nonnative hatchery trout (*O. mykiss irideus*) has resulted in hybridization in most of the range (see the Hybridization section under Factor E below).

California golden trout also present behavioral and life-history characters that help distinguish them from other subspecies of rainbow trout (see also discussion under the Habitat and Life History section below). These include smaller home ranges (Matthews 1996a, p. 84; Matthews 1996b, p. 587), remaining active during both day and night (Matthews 1996a, pp. 82, 84–85), a relatively long lifespan (Knapp and Dudley 1990, p. 169), and the construction of redds (depressions in the substrate for eggs) using relatively small-grained substrate (Knapp and Vredenburg 1996, pp. 528, 529).

For purposes of this finding, we have considered California golden trout to be those trout within the native range of the subspecies (see Distribution section below) that present the morphological and behavioral characters listed above. We do not rely on genetic tests indicating levels of genetic introgression (infiltration of genes from one species into the gene pool of another species through repeated backcrossing of a hybrid with one of its parent species) with nonnative trout (see Factor E—Hybridization section below) to determine what constitutes a member of the subspecies because the most recent genetic analysis of introgression in California golden trout populations specifically cautioned against the use of strict cutoffs of introgression levels in determining management categories based on any single genetic test (Stephens 2007, p. 55). According to this study, the algorithm used by one genetic test may result in an estimation of low levels of introgression where none actually exist, essentially not allowing for an unambiguous determination between low levels of introgression and genetically ''pure'' populations (Stephens 2007, p. 56). This caution against using single methods for determining cutoffs was due in part to considerable differences in introgression estimates for certain populations of California golden trout, which were generated by the different methodologies and assumptions of the various genetic tests that have been used to test those populations (Stephens 2007, p. 72), as well as to the general need for an adequate understanding of the variance surrounding introgression estimates (Stephens 2007, p. 57). However, while we do not rely on genetic tests of introgression levels to distinguish California golden trout populations from nonnative trout, we do consider such genetic information useful for evaluating the effectiveness of measures taken to prevent further introgression.

Hybridization between California golden trout and nonnative rainbow trout is sometimes displayed by an increased number and location of body spots, especially below the lateral line, and a more rainbow trout-like body coloration; however, not all hybrid trout display rainbow trout characteristics (CDFG *et al.* 2004a, p. 24). We have anecdotal information that suggests there are trout that exhibit changed coloration and spotting patterns from those ascribed to the California golden trout (Trout Unlimited 2000, pp. 18, 19) and that these intergrades may predominate in the lower reaches of the South Fork Kern River (Sims 2011a). Such reports have not been substantiated with systematic measures of, or comparison with, introgression levels or with other morphological or behavioral attributes described above, and there are no studies that have measured the morphological or behavioral changes in introgressed California golden trout as compared to ''pure'' golden trout. Furthermore, there is no documentation that we are aware of that indicates that additional meristic measures used to describe California golden trout (such as number of vertebrae, scale counts, and pyloric caeca) have changed with introgression levels.

Distribution

The historical range of the California golden trout included only the South Fork Kern River and Golden Trout Creek in the upper Kern River basin. Golden Trout Creek and upper portions of the South Fork Kern River were once part of the same stream, which became separated by volcanic activity in the region approximately 10,000 years ago (Cordes *et al.* 2003, p. 20). This led to Golden Trout Creek and the South Fork Kern River as known today (Evermann 1906, pp. 11–14) in two adjacent watersheds draining the Kern Plateau of the southern Sierra Nevada.

The Golden Trout Creek watershed is 155 square kilometers (km^2) (60 square miles (mi^2)). Golden Trout Creek drainage begins around 3,292 meters (m) (10,800 feet (ft)) elevation near Cirque Peak and extends to 2,135 m (7,000 ft) elevation at the confluence of Golden Trout Creek and the Kern River. The headwaters are in the northern section of the Kern Plateau, and several lakes (Chicken Spring, Johnson, and Rocky Basins lakes) drain into the watershed. With the exception of headwater lakes, and the probable exception of upper reaches of some tributary streams, Golden Trout Creek was historically occupied by the California golden trout from the headwaters to a series of waterfalls near the confluence of the creek with the Kern River (Evermann 1906, pp. 12–14; 28, 30). The waterfalls are impassable and thus isolate California golden trout in Golden Trout Creek from fish found in the Kern River. Within Golden Trout Creek, California golden trout currently maintain the same distribution as they did historically.

The South Fork Kern River watershed covers 1,380 km^2 (533 mi^2). The South Fork Kern River begins southeast of Cirque Peak at approximately 3,170 m

(10,400 ft) in elevation and continues until it reaches Isabella Reservoir at 794 m (2,605 ft) in elevation. The headwaters are in the eastern section of the Kern Plateau, starting at South Fork and Mulkey Meadows. California golden trout were historically known in the South Fork Kern River from the headwaters to the southern boundary of the Domeland Wilderness (CDFG *et al.* 2004a, p. 8). The subspecies currently maintains the same distribution as it did historically within the South Fork Kern River; however, the degree of genetic introgression from nonnative rainbow trout increases as one proceeds downstream from Templeton Barrier (Stephens 2007, pp. 42, 72). There is no evidence to suggest that the degree of introgression has been sufficient to remove morphologically and behaviorally distinct California golden trout from the southern portion of its historical range. Therefore, we are considering the subspecies to be present in its entire historical range for purposes of this finding. The range is completely within the Inyo and Sequoia National Forests, which are administered by the U.S. Forest Service.

Range Expansion

California golden trout have been widely transplanted outside of their historical range, but the history of these transplants is poorly documented. Most of these transplanted fish came from hybridized Cottonwood Lakes stock that was derived from Golden Trout Creek (Stephens 2007, pp. 54, 55). Fish were transplanted into fishless lakes and streams within the Golden Trout Creek watershed, the South Fork Kern River watershed, and other areas throughout the Sierra Nevada (such as adjacent to the Kern Plateau, including Ninemile Creek, Cold Creek, Salmon Creek, many of the lakes and streams to the north in Sequoia National Park, and all tributaries to the Kern River). In California, planting records and historical documents indicate that California golden trout have been stocked in Alpine, El Dorado, Nevada, Placer, Sierra, Fresno, Inyo, Madera, Mono, Siskiyou, Trinity, Tulare, and Tuolumne Counties (Fisk 1983, p. 11). Outside of California, golden trout were sent to England, Colorado, Utah, Montana, New York, and Wyoming between 1928 and 1937 (McCloud 1943, p. 194).

For the purposes of this finding, we are analyzing a petitioned entity that includes populations of California golden trout considered native to the South Fork Kern River and Golden Trout Creek in the upper Kern River basin. We do not consider introduced populations present elsewhere as part of the listable entity because we do not consider them to be native populations. Neither the Act nor our implementing regulations expressly address whether introduced populations should be considered part of an entity being evaluated for listing, and no Service policy addresses the issue. Consequently, in our evaluation of whether or not to include introduced populations in the potential listable entity we considered the following:

(1) Our interpretation of the intent of the Act with respect to the disposition of native populations;

(2) A policy used by the National Marine Fisheries Service (NMFS) to evaluate whether hatchery-origin populations warrant inclusion in the listable entity; and

(3) A set of guidelines from another organization (International Union for Conservation of Nature (IUCN)) with specific criteria for evaluating the conservation contribution of introduced populations.

Our interpretation is that the Act is intended to preserve native populations in their ecosystems. While hatchery or introduced populations of fishes may have some conservation value, this does not appear to be the case with introduced populations of California golden trout in California and elsewhere in the United States. These introduced populations were apparently established to support recreational fisheries without any formal genetic consideration to selecting and mating broodstock (group of mature fish kept for breeding purposes), and are not part of any conservation program to benefit the native populations. Consequently, we do not consider the introduced populations of California golden trout in California, England, Colorado, Utah, Montana, New York, and Wyoming to be part of the listable entity.

Habitat and Life History

California golden trout reach sexual maturity when they are 3 to 4 years old and begin spawning during the spring or early summer when maximum water temperatures consistently exceed 15 to 18 degrees Celsius (°C) (59 to 64 degrees Fahrenheit (°F)) and average stream water temperatures exceed 7 to 10 °C (45 to 50 °F) (Stefferud 1993, pp. 139–140; Knapp and Vredenburg 1996, p. 528). Spawning begins with female California golden trout moving fine gravel substrate to construct a shallow depression, known as a redd, to lay their eggs. Although California golden trout can construct redds using gravel of smaller average diameter than other trout species or subspecies, they still select the largest substrates available (Knapp and Vredenburg 1996, pp. 528, 529).

Growth of California golden trout shows a negative correlation with fish density and a positive correlation with several factors, including the stability of the stream bed and banks, and the presence of aquatic and streamside vegetation (Knapp and Dudley 1990, pp. 165, 170, 171). Aquatic vegetation provides habitat for small invertebrates preyed on by the trout, while overhanging streamside vegetation provides habitat for terrestrial invertebrates that can serve as a food source when they fall in the water (Knapp and Dudley 1990, p. 170; Moyle 2002, p. 285). Streamside vegetation also tends to stabilize banks and to provide cover for young trout from potential predators such as birds (Moyle 2002, p. 277). Overhanging vegetation, steep or undercut banks, and deeper streambeds are all needed by trout (Moyle 2002, p. 286), in part because they provide shade and cooler water during the day. Average daily water temperatures can fluctuate from 2 to 22 °C (Knapp and Dudley 1990, p. 163), while optimal temperatures for trout range from 15 to 18 °C (59 to 64 °F) (Moyle 2002, p. 276). Deeper streambeds and steeper banks are associated with greater stream stablity, thus helping to explain the positive correlation between stream stability and trout growth found by Knapp and Dudley (1990, pp. 165, 171). Stream stability is also likely important because erosion of unstable streams produces higher sediment loads that can cover redds and interfere with feeding by clouding the water (Moyle 2002, p. 278).

California golden trout have been known to live as long as 9 years, and commonly reach 6 to 7 years old (Knapp and Dudley 1990, p. 169). This long lifespan is likely due to a short growing season, high fish densities, and a low food abundance, all of which promote slow growth rates and old ages of trout (Knapp and Dudley 1990, p. 169).

California golden trout adapted to the South Fork Kern River and Golden Trout Creek in the absence of competitors, although they probably did coexist with Sacramento suckers (*Catostomus occidentalis*) in the South Fork Kern River (Moyle 2002, p. 284). Long isolation of California golden trout from other species has likely resulted in a lack of competitive ability, making them vulnerable to replacement by other trout species (Behnke 1992, p. 191). Likewise, the subspecies is thought to have evolved without substantial interspecific predation risk; the birds and mammals that might have been

likely predators of the California golden trout occur infrequently in high alpine areas where California golden trout are found (Moyle 2002, p. 285). One possible indication that California golden trout adapted without predators is the trout's active behavior during both day and night (Matthews 1996a, pp. 82, 84–85).

California golden trout home ranges were calculated as the linear distance that encompasses 90 percent of trout locations, based on movements recorded using radio-telemetry during the months of July and September (Matthews 1996a, p. 84; Matthews 1996b, p. 587). California golden trout were found to have small home ranges that average 5 m (16 ft) (Matthews 1996a, p. 84; Matthews 1996b, p. 587). Movements of 26 to 100 m (86 to 328 ft) were observed, but these constituted less than 1 percent of all observations (Matthews 1996b, p. 587).

The Conservation Strategy

Since publication of the 90-day finding in 2002 (67 FR 59241; September 20, 2002), the California Department of Fish and Game (CDFG), the Forest Service, and the Service (hereafter referred to collectively as the Agencies) completed a revised *Conservation Assessment and Strategy for the California Golden Trout* (Conservation Strategy) dated September 17, 2004 (CDFG et al. 2004a). The Conservation Strategy replaced a previous guidance document known as the *Conservation Strategy for the Volcano Creek (California) Golden Trout* (1999 Conservation Strategy), which had been in effect since April 22, 1999. The Agencies also signed a Memorandum of Agreement (MOA) on September 17, 2004, to implement the Conservation Strategy (CDFG et al. 2004b); both the Conservation Strategy and MOA are currently in effect. The purposes of the Conservation Strategy are to:

(1) Protect and restore California golden trout genetic integrity and distribution within its native range;

(2) Improve riparian and instream habitat for the restoration of California golden trout populations; and

(3) Expand educational efforts regarding California golden trout restoration and protection.

The Agencies' intent has been to encourage ongoing nongovernmental stakeholder coordination and consultation throughout the implementation phase of the Conservation Strategy. The Conservation Strategy is based on adaptive management, with tasks being removed, added, or adjusted annually as new information becomes available. The Agencies, through the MOA, agreed to formally implement and collaborate on the Conservation Strategy and make any necessary adaptive management changes as the primary mechanism for the conservation of the California golden trout. Implementation of many tasks described in the Conservation Strategy began while it was under development, and have continued since its finalization. Those tasks and other conservation efforts implemented in prior years are summarized below throughout the five-factor analysis.

Summary of Information Pertaining to the Five Factors

Section 4 of the Act (16 U.S.C. 1533) and implementing regulations (50 CFR 424) set forth procedures for adding species to, removing species from, or reclassifying species on the Federal Lists of Endangered and Threatened Wildlife and Plants. The Act treats subspecies such as the California golden trout as species for these purposes (16 U.S.C. 1532(16)). Under section 4(a)(1) of the Act, a species may be determined to be endangered or threatened based on any of the following five factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

In considering what factors might constitute threats, we must look beyond the mere exposure of the species to the factor to determine whether the species responds to the factor in a way that causes actual impacts to the species. If there is exposure to a factor, but no response, or only a positive response, that factor is not a threat. If there is exposure and the species responds negatively, the factor may be a threat and we then attempt to determine how significant a threat it is. If the threat is significant, it may drive or contribute to the risk of extinction of the species such that the species warrants listing as threatened or endangered as those terms are defined by the Act. This does not necessarily require empirical proof of a threat. The combination of exposure and some corroborating evidence of how the species is likely impacted could suffice. The mere identification of factors that could impact a species negatively is not sufficient to compel a finding that listing is appropriate; we require evidence that these factors are operative threats that act on the species to the point that the species meets the definition of threatened or endangered under the Act.

In making this finding, information pertaining to the California golden trout in relation to the five factors in section 4(a)(1) of the Act is discussed below. In making our 12-month finding on the petition, we considered and evaluated the best available scientific and commercial information. We reviewed the petition, information available in our files, and other available published and unpublished information.

Factor A. The Present or Threatened Destruction, Modification, or Curtailment of the Species' Habitat or Range

The petition and our subsequent investigations have identified several habitat-related activities relevant to the conservation status of California golden trout, including: Livestock grazing management, pack stock use, recreation, artificial fish barriers, and beavers. We address each activity below.

Livestock Grazing Management

The combined effect of current livestock grazing activities in the Golden Trout Wilderness and legacy conditions from historically excessive grazing use have the potential to impact habitat and the range of the California golden trout. The following subsections discuss the effects of excessive historical grazing, current grazing management practices, and habitat restoration and monitoring efforts within the basins in which the native stream habitat of the California golden trout occurs.

Historical Effects of Excessive Grazing

Grazing of livestock in Sierra Nevada meadows and riparian areas began in the mid-1700s with the European settlement of California (Menke *et al.* 1996, p. 909). Following the gold rush of the mid-1800s, grazing rose to a level that exceeded the carrying capacity of the available range and caused significant impacts to the grazed ecosystems (Meehan and Platts 1978, p. 275; Menke *et al.* 1996, p. 909). Approximately 95 percent of the California golden trout's native stream habitat has been subjected to varying intensities of grazing for more than 130 years (CDFG *et al.* 2004a, p. 31). Livestock grazing within the national forests in the southern and high Sierras has continued with gradual reductions since the 1920s, except for an increase during World War II (Menke *et al.* 1996, pp. 909–910, 916–919).

Livestock can contribute to the destabilization of stream banks by

accelerating erosion and increasing bank disturbance (Kauffman *et al.* 1983, pp. 684–685; Marlow and Pogacnik 1985, p. 279). Livestock grazing in meadows and on stream banks can compact soils, which reduces water infiltration rates and the soil's ability to hold water, thereby increasing surface runoff rates into adjacent streams, downcutting streambeds, and lowering the watertable (Meehan and Platts 1978, pp. 275–276; Kauffman *et al.* 1983, pp. 684–685; Kauffman and Krueger 1984, pp. 433–434; Bohn and Buckhouse 1985, p. 378; Armour *et al.* 1994, pp. 7–10). In some cases, excessive livestock grazing has resulted in the conversion of wet meadows into dry flats and in diminished perennial stream flows (Armour *et al.* 1994, p. 7). Erosion from trampling causes stream bank collapse and an accelerated rate of soil movement from land into streams (Meehan and Platts 1978, pp. 275–276). Accelerated rates of erosion lead to elevated instream sediment loads and depositions, and changes in channel morphology, which alter the structure of the aquatic environment used by fish for spawning (Meehan and Platts 1978, pp. 275–276; Kauffman and Krueger 1984, pp. 433–434; Bohn and Buckhouse 1985, p. 378). These effects to the aquatic ecosystem increase with increases in the intensity of grazing (Meehan and Platts 1978, pp. 275–276).

Livestock grazing can cause a nutrient loading problem due to urination and defecation in or near the water, and elevate bacteria levels in areas where cattle are concentrated near water (Meehan and Platts 1978, p. 276; Stephenson and Street 1978, p. 152; Kauffman and Krueger 1984, p. 432). The nutrient status of streams can create a cause and effect relationship between nutrient levels, bacterial growth, and insect mortality (Lemly 1998, p. 234). Growth of filamentous bacteria on the bodies and gills of aquatic insects was demonstrated to be an effect of nutrient loading in livestock-use pastures, significantly lowering the density of insect occurrences at downstream sites (Lemly 1998, pp. 234–235). Aquatic insects suffered extensive mortality because of this bacterial growth in laboratory and field studies, indicating that elevated bacteria levels can negatively influence stream insect populations (Lemly 1998, pp. 234–235, 237), which can result in detrimental effects to prey species important to fish.

Several studies have documented the environmentally detrimental impacts of historical grazing practices in areas within the range of the California golden trout. Albert (1982, pp. 29–47) studied factors influencing the riparian condition of streams in the Golden Trout Wilderness and adjoining watersheds in Sequoia National Park. Her results showed that stream zones in the South Fork Kern River and Golden Trout Creek were less stable, had more livestock damage, and were generally in poorer condition than those in Sequoia National Park, which had not been grazed for the preceding 50 years. Stream reaches with light cattle use had channel bottoms that were more stable (less subject to erosional and depositional changes) than heavily used reaches (Albert 1982, pp. 48–51).

Odion *et al.* (1988, pp. 277–289) examined the effects of cattle grazing and recovery potential in Templeton and Ramshaw Meadows along the South Fork Kern River. Vegetation change was monitored inside and outside of exclosures that were established along riparian areas within the range of California golden trout. Odion *et al.* (1988, pp. 277–289) concluded that livestock trampling and defoliation caused a breakdown of the protective sod layer in the meadows, allowing streams to incise (where the streambed channel downcuts in elevation, reducing habitat quality and quantity), produce gullies, and lower the water table. Subsequently, plants adapted for a dry habitat, such as sagebrush, invaded the altered meadows. Results of density monitoring indicated that cattle trampling impaired colonization of plant species important in stabilizing substrate on stream banks, thus reducing the natural revegetation potential of bare stream bank habitat (Odion *et al.* 1988, p. 283).

Matthews (1996b, pp. 579–589) used radio transmitters to determine habitat selection and movement patterns of California golden trout in two stream reaches with different levels of habitat recovery on Mulkey Creek. The study areas were differentiated by high and low coverage of *Carex rostrata* (beaked sedge) along the stream banks. Low coverage areas were typically associated with signs of cattle degradation, such as widened stream channels, collapsed banks, and a reduction in areas with undercut banks. In both low and high sedge reaches, California golden trout more often selected undercut banks, aquatic vegetation, and sedge while avoiding bare and collapsed banks caused by livestock grazing. They were most commonly found in pools and runs (slow moving areas in a stream), where they used habitat features such as undercut banks, aquatic vegetation, and sedges, all of which typically can be damaged by excessive cattle grazing along stream banks.

Knapp and Matthews (1996, pp. 816–817) examined the effects of excessive livestock grazing on California golden trout and their habitat inside and outside of grazing exclosures in the South Fork Kern River watershed. In the 2-year study, most physical parameters of the stream channels showed large differences between grazed and ungrazed sites, with ungrazed sites displaying greater canopy shading, stream depth, bank-full height, and narrower stream width. Densities and biomass of California golden trout per unit area were significantly higher in ungrazed versus grazed areas in three out of four comparisons, but differences were less consistent when density and biomass were calculated using stream length. Other findings of this study indicate a significant decrease in stream width in the upper Ramshaw Meadows exclosure between 1984 and 1993, and a greater number of willow plants inside exclosures than outside.

Not all studies found differences in grazed and ungrazed areas. Sarr (1995, pp. 97, 104) did not find significant differences in stream morphology in his study between grazed and ungrazed reaches on the South Fork Kern River. In a movement and habitat use study, California golden trout were monitored with radio transmitters inside and outside of grazing exclosures on the South Fork Kern River (Matthews 1996a, pp. 78–85). No differences in distance moved or home range were found between California golden trout inside and outside exclosures, and most fish were found within 5 m (16.4 ft) of their previously recorded location.

Current Levels of Grazing Use

Many grazing impacts to the Kern Plateau were originally caused by unmanaged grazing practices dating back to the late 1800s, during which tens of thousands of cattle were grazed over long periods of time (CDFG *et al.* 2004a, p. 31). Grazing use has been greatly reduced since then in order to restore natural habitat conditions (CDFG *et al.* 2004a, p. 34). Additionally, during the past decade the Inyo National Forest has completely restricted grazing on two of its four grazing allotments. In February of 2001, a Decision Notice was signed that implemented a 10-year period of rest on the Templeton and Whitney grazing allotments to facilitate recovery of watershed and channel conditions. The notice indicated that grazing on the two allotments would be reconsidered at the end of the 10-year period (USFS 2001a, p. 5). The USFS expects to reach a decision on this issue in June of 2012 (USFS 2011, p. 10).

Within the Sequoia National Forest from 2001 to 2004, two of the three available grazing allotments had little or no grazing, while the third utilized up to 65 percent of the total livestock permitted (CDFG *et al.* 2004a, p. 19). Grazing use levels in the Sequoia National Forest are lower than permitted largely because of remoteness and inaccessibility (Anderson 2006), whereas in the Inyo National Forest, a 1995 amendment (typically referred to as Amendment 6, discussed below) to the Forest-wide grazing utilization standards of the Forest's Land and Resource Management Plan (LRMP) has apparently resulted in reduced cattle use (CDFG *et al.* 2004a, p. 34).

Current Grazing Management Practices

In 1995, Amendment 6 to the Inyo National Forest LRMP was developed to establish forest-wide grazing utilization standards, which are requirements in addition to existing utilization standards contained in grazing permits (USFS 1995, pp. 13, 14). The forest-wide standards were designed, in part, to improve the existing condition of streams supporting California golden trout in grazed watersheds (USFS 1995, pp. 27, 28). The Amendment allows Forest Service personnel to tailor grazing utilization standards to maintain or improve hydrologic and meadow conditions. Grazing utilization standards establish an upper limit of forage that grazing cattle may consume before being moved to a new area (Sims 2011b, p. 1). Inyo National Forest personnel conduct annual monitoring of representative meadows to determine whether utilization standards have been exceeded. If they do find that standards have been exceeded they adjust the standards downwards in following years to allow recovery. The utilization standards themselves are reassessed every 5 to 10 years to ensure that they avoid habitat degradation (including the degradation of stream habitat) (Sims 2011b, p. 1).

The Inyo National Forest LRMP also restricts trampling of streambanks to 10 percent of the streambank length along State trout waters (which include most of the streams supporting California golden trout), and to 20 percent along other waters (USFS 1988a, pp. 78–79). As with utilization standards, annual monitoring of representative streambanks helps assure these standards are not exceeded, and allows grazing prescriptions to be adjusted to promote recovery of the streambanks if the standards are exceeded (Sims 2011b, p. 1). Additionally, salt provided for cattle must be located at least 0.25 mi (0.4 km) away from riparian areas, and additional requirements may apply to specific management areas with unique characteristics. For example, range management direction for the Golden Trout Management Area (#19) amends grazing allotment plans to include necessary mitigation measures and corrective actions if grazing is significantly impacting fish habitat (USFS 1988a, p. 236).

On the Sequoia National Forest, LRMP grazing standards and guidelines applicable to all streams within the habitat of the California golden trout were amended in 2004 (subsequent to the October 13, 2000, petition to list the California golden trout) by the adoption of the Sierra Nevada Forest Plan Amendment (SNFPA) (CDFG *et al.* 2004a, p. 23). The new standards and guidelines, established for the protection of rare aquatic populations such as the California golden trout, require habitat managers to implement the following conservation measures:

(1) Prevent disturbance to meadow-associated streambanks and natural lake and pond shorelines caused by resource activities from exceeding 20 percent of stream reach or 20 percent of natural lake and pond shorelines.

(2) Limit livestock utilization of grass and grass-like plants to a maximum consumption of 30 percent of each plant by volume (or minimum 6 in (15 cm) stubble height) for meadows in early seral status; limit livestock utilization of grass and grass-like plants to a maximum consumption of 40 percent of each plant by volume (or minimum of 4 in (10 cm) stubble height for meadows in late seral status).

(3) Determine ecological status on all key areas monitored for grazing utilization prior to establishing utilization levels.

(4) Limit browsing to no more than 20 percent of the annual leader growth of mature riparian shrubs and no more than 20 percent of individual seedlings (CDFG *et al.* 2004a, pp. 23, 84, 87).

Habitat Restoration and Monitoring Efforts

The Inyo National Forest has installed several exclosures in riparian areas within the range of the California golden trout to protect and restore portions of the South Fork Kern River, Mulkey Creek, Ninemile Creek, and Golden Trout Creek from grazing impacts (see also Historical Effects of Excessive Grazing section above). Livestock exclosures totaling several miles exist on numerous stream reaches in all four grazing allotments within Inyo National Forest. Exclosures in the Monache and Mulkey allotments, where grazing is currently allowed, are currently excluding cattle from areas where they would otherwise be grazing. Exclosures in the Whitney and Templeton allotments, which are currently being rested from grazing, will only begin to actively exclude cattle if and when grazing is resumed on those allotments.

Research by Knapp and Matthews (1996, pp. 816–817) in Mulkey and Ramshaw Meadows showed that areas within exclosures display greater canopy shading, stream depth, bankful height, and narrower stream width. Studies by Odion *et al.* (1988, p. 277) in Ramshaw and Templeton Meadows indicated that exclosures allowed significantly more pioneer species to colonize areas that were bare from disturbance. Photo-points recorded between 1989 and 2005 within a number of these exclosures indicate recovery in many areas that were once degraded by grazing (Sims 2006a). For these reasons, livestock exclosures have contributed to restoring habitat, reducing the effects of grazing, and preventing future damage to these habitats for the subspecies. Because exclosures require maintenance, activities conducted pursuant to annual work plans within the Conservation Strategy have included annual maintenance of cattle exclosure fencing (McGuire and Sims 2006, p. 17; Sims and McGuire 2006, p. 12).

In addition to monitoring and cattle exclusion efforts, Inyo National Forest has completed numerous projects to stabilize soil and prevent erosion (USFS 2005 *in* McGuire and Sims 2006, p. 35). In addition to preventing further degradation, such treatments can direct stream flows to reestablish stream characteristics beneficial to California golden trout, such as overhanging banks and vegetation. These restoration and stabilization projects generally involve placing materials such as rocks or logs at key points of eroding streams in a given area to catch sediments and prevent further erosion. Since 1996, such projects have been completed at 19 sites (USFS 2005 *in* McGuire and Sims 2006, pp. 35, 37). Between 1933 and the mid-1980s, approximately 800 erosion control structures were installed in the Golden Trout Wilderness (USFS 1988a, p. 236; CDFG *et al.* 2004a, p. 34).

Conservation activities that have been conducted for the benefit of the California golden trout are described in the report titled, ''Watershed Restoration and Monitoring Accomplishments on the Kern Plateau'' (Kern Plateau Report) (USFS 2005 *in* McGuire and Sims 2006, pp. 32–42), which summarizes watershed improvement and monitoring projects within the grazing allotments on the

Kern Plateau since the 1930s. For example, from 2002 to 2003, the Forest Service implemented intensive monitoring and data collection over a wide area of the South Fork Kern River and Golden Trout Creek watersheds to assist in determining watershed condition trends (USFS 2005 *in* McGuire and Sims 2006, p. 32). A wide-scale headcut monitoring effort was initiated in 2003 at various parts of the Kern Plateau on both active and rested grazing allotments. Photo-points have been established at various locations on the Kern Plateau to monitor trends in stream bank stability, headcut migration, and vegetation patterns, with data collected indicating recovery in many areas that were affected by grazing (Sims 2006a, p. 1). The Kern Plateau Report also identifies opportunities for monitoring and evaluating the effectiveness of management practices. Recent results from these monitoring efforts showed significant improvement in meadow condition and streambank stability for the two allotments rested from grazing (Templeton and Whitney), and a positive trend in meadow and streambank conditions for the Mulkey allotment (Weixelman 2011, p. 12). No sites were shown to decline in condition (Ettema and Sims 2010, p. 63). Overall, 64 percent of sites in grazed allotments and 74 percent in ungrazed allotments are now meeting desired conditions (good to excellent) (Weixelman 2011, pp. 3, 12).

The Conservation Strategy also includes monitoring of the effectiveness of best management practices (BMPs) to determine their effectiveness in protecting California golden trout habitat, with an annual report completed for inclusion in the annual accomplishment reports (CDFG *et al.* 2004a, p. 54). BMPs are a practice or combination of practices that are the most effective and practical means of preventing or reducing water pollution from non-point sources. We also note that the MOA commits the signatories of the Conservation Strategy to meet annually to evaluate the effectiveness of the strategy, determine whether the goals and objectives are being adequately achieved, and discuss whether the strategy requires any adaptive changes to better conserve the California golden trout (CDFG *et al.* 2004b, p. 3). This means that changes in management can occur if conditions or results of monitoring indicate there is a negative change to the California golden trout's habitat or range. The MOA also contains a provision that if any element of the Conservation Strategy is determined infeasible, or if any new threat is identified, then the Agencies will be notified within 30 days and a meeting will be held to determine the course of action (CDFG *et al.* 2004b, p. 4). Thus, in the event of a change in future conditions that result in an unacceptable level of impacts due to excessive grazing, appropriate changes in management can occur.

Summary of Livestock Grazing Management

In summary, historical excessive grazing practices have affected the stream habitat in nearly the entire native range of the California golden trout. Habitat degradation has been addressed in recent decades with numerous conservation efforts, such as reducing the season of use and number of cattle allowed to graze on an allotment, implementing grazing standards and guidelines in the LRMPs, resting of grazing allotments, implementing watershed monitoring, and completing restoration projects. Monitoring of Golden Trout Creek and upper South Fork Kern watersheds has found that implementing these conservation efforts has improved meadow and streambank conditions for three of four grazing allotments, and has stabilized conditions in the fourth grazing allotment (Ettema and Sims 2010, p. 63; Weixelman 2011, p. 12). Based on our evaluation of current practices and of recent and ongoing restoration activities, we do not consider livestock grazing to present a significant threat to the California golden trout now or into the future.

Pack Stock Use

Similar to cattle, horses and mules may significantly overgraze, trample, or pollute streamside habitat if too many are concentrated in riparian areas too often or for too long. Commercial pack stock trips are permitted in national forests within the Sierra Nevada, providing transport services into wilderness areas with the use of horses or mules. Use of pack stock in the Sierra Nevada increased after World War II as road access, leisure time, and disposable income increased (Menke *et al.* 1996, p. 919). The Inyo National Forest has permitted commercial pack operators since the 1920s (USFS 2006a, p. 1). Current commercial pack stock use is approximately 27 percent of the level of use in the 1980s reflecting a decline in the public's need and demand for pack stock trips. From 2001 to 2005, commercial pack stock outfitters within the Golden Trout and South Sierra Wilderness Areas averaged 28 percent of their current authorized use (USFS 2006b, p. 3–18).

Currently, pack stock use within Golden Trout and South Sierra Wilderness Areas overlaps with historical and current livestock grazing locations, thus making it difficult to identify impacts to vegetation that are due specifically to pack stock use (USFS 2006b, p. 3–13). Monitoring of pack stock grazing impacts on meadows within the California golden trout's range shows a general trend of decreasing impacts to stream bank stability. This trend is believed to be due to restoration efforts and the cancellation of cattle grazing permits (USFS 2006b, p. 3–12).

Allowable pack stock uses are limited in the Inyo National Forest by the same restrictions discussed above for cattle, such as the Amendment 6 forest-wide grazing utilization standards and the 10 percent limit to bank trampling along State trout waters (USFS 200b, p. 3–353). Pack stock grazing is also prohibited in specific meadows, including Volcano Meadow, South Fork Meadow (at the headwaters of the South Fork of the Kern River), and parts of Ramshaw Meadow. As discussed above, these restrictions have resulted in improved conditions for the majority of monitored habitat for which we have monitoring results, and stabilized conditions for the remainder of that habitat (Ettema and Sims 2010, p. 63; Weixelman 2011, p. 12). Accordingly, we consider current habitat management practices sufficient to prevent pack stock use from posing a significant threat to the California golden trout.

Recreation

Recreational activities that include hiking, camping, and off-road vehicle (ORV) use take place throughout the Sierra Nevada and can have impacts on fish and wildlife and their habitats (impacts from fishing are discussed below under Factor B—*Overutilization for Commercial, Recreational, Scientific, or Educational Purposes* section). Impacts to wilderness areas can vary in their extent, longevity, and intensity (Cole and Landres 1996, pp. 169–170). In easily accessible areas, heavy foot traffic in riparian areas can trample vegetation, compact soils, and physically damage stream banks (Kondolf *et al.* 1996, pp. 1014, 1019). Human foot, horse, bicycle, or ORV trails can replace riparian habitat with compacted soil (Kondolph *et al.* 1996, pp. 1014, 1017, 1019), lower the water table, and cause increased erosion.

Recreation is the fastest growing use of national forests (USFS 2001b, p. 453). Because of an increasing demand for wilderness recreational experiences,

wilderness land management now includes standards for wilderness conditions, implementing permit systems, and other visitor management techniques to reduce impacts to habitat, including riparian habitat (Cole 2001, pp. 4–5). These wilderness land management techniques are currently being used on the Inyo and Sequoia National Forests where they are expected to benefit California golden trout by reducing impacts on its habitat.

All of the current range of the California golden trout, with the exception of the Monache Meadow and Kennedy Meadow areas, is encompassed within the federally designated Golden Trout, South Sierra, and Domeland Wilderness areas, where access is difficult and impacts from recreation are lower than in easily accessible areas. Recreational use currently is low and well-dispersed in these areas. The Forest Service monitors wilderness use levels and limits wilderness use if recreation levels are determined to be high (Sims 2006a, p. 1). Recreational impacts are ameliorated by the implementation of various management actions, such as camping restrictions, wilderness ranger presence, and permit requirements. Camping within the Golden Trout Wilderness is not allowed within 100 ft (30 m) of lakes or streams, and a permit is required by the Sequoia National Forest for overnight use. These measures minimize impacts to the fish's habitat. Additionally, Federal designation of an area as Wilderness prohibits the use of motorized or mechanized equipment by the public, with limited exceptions, and therefore provides protection from ORV impacts within these areas.

On National Forest lands outside of federally designated wilderness areas, California golden trout stream habitat occurs in high-use areas, such as Monache and Kennedy Meadows. In these areas, recreational impacts are occurring and are expected to continue. Recreational use occurs primarily on the South Fork Kern River through Monache Meadows on the Inyo National Forest and Kennedy Meadows on the Sequoia National Forest. Motorized access in Monache Meadows is restricted to use of a single 4-wheel-drive road that enters to the south of the meadow. Camping, fishing, and hunting are the primary uses, as well as access for pack stock (CDFG *et al.* 2004a, p. 21). Kennedy Meadows is easily accessed by road and receives heavy use during the trout season for fishing and camping activities. Easily accessible and popular fishing areas, such as Monache and Kennedy Meadows, are being impacted by anglers, whose use of the stream banks can lead to collapsed undercut banks, compacted soils, and disturbed riparian vegetation (Stephens 2001a, p. 64).

Although recreational impacts are expected to continue, they are localized to a few areas within the native range of the California golden trout. In addition, the Forest Service and CDFG have implemented measures identified in the Conservation Strategy to offset recreational impacts to the subspecies. Restoration and stabilization projects were implemented adjacent to and within the Monache Allotment in 2004 to address ORV impacts to the meadow habitat in the South Fork Kern River drainage. A brochure for recreational users was produced in 2005 and 2006 that informed the public about fishing and requested help with restoration projects aimed at protecting the California golden trout; it is available for recreational users at area ranger stations, visitor centers, and local flyfishing shops. Information regarding volunteer field activities, opportunities for public involvement, subspecies information, and agency contacts is also posted on the California Trout and Trout Unlimited web pages. Through these volunteer field activities, Trout Unlimited, California Trout, and the Federation of Flyfishers have assisted CDFG and the Forest Service to protect and restore California golden trout and their habitat.

In summary, recreational activities have the potential to negatively impact the habitat and range of the California golden trout through trampling and vegetation loss due to use by pack stock, humans, and ORVs. We believe that some adverse effects to the California golden trout from recreation at high-use areas outside of federally designated Wilderness Areas will continue; however, these effects are expected to remain localized and not rise to a level that would significantly affect the subspecies as a whole. We conclude that current wilderness land management standards afford considerable protection from a variety of potential recreational impacts to habitat of the California golden trout in wilderness. Implementation of management activities by the Forest Service and CDFG have offset recreational impacts to California golden trout habitat in several high-use recreational areas outside of designated wilderness. Activities such as public outreach and stakeholder involvement have been, and continue to be, conducted to help limit potential recreational impacts over the native range of the California golden trout. Consequently, we conclude that habitat loss due to recreational activity does not currently present a significant threat to the California golden trout, and we do not expect it to become a significant threat in the future.

Artificial Fish Barriers

Three barriers have been constructed on the South Fork Kern River to prevent upstream migration of nonnative trout species, and thereby to reduce their introgression and competition with California golden trout. Between 1970 and 1973, the Ramshaw Barrier was constructed in a gorge at the upper end of Ramshaw Meadows; it is located farthest upstream from the other barriers on the South Fork Kern River. In 1973, the Templeton Barrier was constructed of rock, chain-link fencing, and filter fabric at the head of Templeton Gorge, located approximately 11.3 km (7 mi) downstream of the Ramshaw Barrier at the eastern end of Templeton Meadows. In 1980, Templeton Barrier was replaced with a rock-filled gabion structure across the river that resembled a small dam. In 1981, the Schaeffer Barrier was constructed 11.3 km (7 mi) downstream from the Templeton Barrier at the upper end of Monache Meadows.

Although the Ramshaw Barrier has been impassable to fish since 1973, both the Templeton and Schaeffer barriers were determined in 1994 to be on the verge of collapse (Stephens 2001a, p. 33; CDFG *et al.* 2004a, p. 36). In 1996, the gabion dam at Templeton was replaced with a rock and concrete dam immediately downstream and in contact with the existing structure (CDFG *et al.* 2004a, p. 37). In 2003, Schaeffer Barrier was replaced with a reinforced concrete dam that is 2 ft (0.6 m) higher than the old barrier and includes a concrete apron below the spillway to prevent the formation of a jump pool below the barrier (CDFG *et al.* 2004a, p. 37). As a result of these modifications, all three barriers now effectively prevent upstream fish passage (CDFG *et al.* 2004a, p. 37; Lentz 2011, p. 1).

The construction of these fish barriers and subsequent modifications likely have had some negative effect on California golden trout by altering their stream habitat. Dams, water diversions, and their associated structures can alter the natural flow regime both upstream and downstream of dams. However, because the barriers have been constructed to prevent passage of nonnative fish and to protect the California golden trout rather than to impound water, we expect that their effect on stream conditions and hydrology are limited to localized areas where the barriers are placed. The barriers have the potential to fragment

the California golden trout's stream habitat because they generally prevent the upstream movement of fish, including California golden trout. However, California golden trout may be somewhat insulated from these effects because they generally do not move far from where they were hatched, except under unusually high flood flows (Stephens 2003, p. 5). The barriers also facilitate the restoration of natural prey and competitor conditions in the California golden trout's stream habitat by preventing population of the streams by nonnative brown trout (*Salmo trutta*). The effects of artificial fish barriers on movement of brown trout are discussed below under Factor C—*Disease or Predation.* Effects on movement of hybridized trout are discussed under Factor E—*Other Natural or Human Factors.*

In summary, the three artificial fish barriers that have been placed on the South Fork Kern River are expected to have localized effects to the stream habitat of the California golden trout, and are also expected to benefit the subspecies in the future by allowing restoration of natural predator and prey relationships within the habitat. We conclude that the barriers do not constitute a significant threat to California golden trout at this time or in the future.

Beavers

Beavers (*Castor canadensis*) currently exist within the native range of the California golden trout. Although beavers were native to California's Central Valley in the early 19th century, they were not generally known from the Sierra Nevada except where introduced by humans (Tappe 1942, pp. 7, 8, 13, 14, 20). Native beaver populations experienced great declines during the early exploration of California by traders and trappers (Tappe 1942, p. 6). Subsequent reestablishment and introductions have extended their original range (CDFG 2006, p. 1). In the Sierra Nevada and Cascade Mountain ranges, beavers inhabit streams, ponds, and lake margins from Modoc County south to Inyo County (CDFG 2006, pp. 1, 2). Beavers commonly inhabit riparian areas of mixed coniferous-deciduous forests and deciduous forests containing abundant beaver forage and lodge-building material, including *Salix* spp. (willows), *Alnus* spp. (alders), and *Populus* spp. (cottonwoods) (Allen 1983, p. 1; CDFG 2006).

There is debate over whether beavers are native to the Kern River basin (Townsend 1979, pp.16–20; CDFG *et al.* 2004a, p. 33). Beavers were introduced by CDFG in the 1940s and 1950s as a tool to restore meadow habitat degraded by livestock grazing. Beavers can have positive and negative effects on trout habitat. Beaver ponds can provide pool habitat for fish, reduce severe ice conditions, and increase populations of bottom-dwelling invertebrates suitable for trout to eat (Gard 1961, p. 240). However, siltation resulting from beaver dams can also degrade spawning habitat for California golden trout, which require gravel for spawning (Knapp and Vredenburg 1996, pp. 528, 529). In a study conducted on Sagehen Creek on the eastern slope of the Sierra Nevada, Gard (1961, pp. 240–241) concluded that beavers were a benefit to trout in this high-elevation creek because they improved fish habitat, forage, spawning activities, and population numbers.

Currently, large beaver populations occur in upper and lower Ramshaw Meadows. Additional populations of unknown size also exist at other locations within the Kern River Plateau (CDFG *et al.* 2004a, p. 33). As of 2004, negative effects of beaver activity within the native range of the California golden trout have not been documented (CDFG *et al.* 2004a, p. 33). Additionally, we are currently unaware of any additional information that document negative effects of beaver within the range of the California golden trout. The Conservation Strategy discusses the beaver as a potential issue for the California golden trout; therefore, CDFG and the Inyo National Forest monitor and evaluate the effect of beaver activity within the native range of the California golden trout. For example, beaver populations were monitored in 2004, 2005, and 2008 at areas on Golden Trout Creek and Ramshaw Meadow that are considered to have the highest potential impacts from beaver on golden trout habitat (CDFG and USFS 2006a, pp. 16–17; CDFG and USFS 2006b, p. 11; McGuire *et al.* 2009, p. 11). At Ramshaw, two active dams were observed in 2008 and the beaver population appeared stable since the previous monitoring in 2005. At Golden Trout Creek, a single beaver dam had been maintained since 2003. No negative impacts from the beaver populations were documented. Therefore, we conclude that beaver activity does not currently constitute a threat to the California golden trout, nor do we expect it to in the future.

Summary of Factor A

California golden trout stream habitat has historically been adversely affected by livestock grazing and, to a lesser degree, pack stock use, recreational activities, and artificial fish barriers. Conservation efforts related to reducing the effects of livestock grazing (including reduced seasonal use, reduced numbers of cattle grazed, resting of grazing allotments, and installation of livestock exclosures) have improved habitat conditions for the California golden trout, resulting in improvements to the majority of monitored habitat for which we have results and stabilization of the remainder of that habitat (Ettema and Sims 2010, p. 63; Weixelman 2011, p. 12). Pack stock use has a minimal effect on the habitat of the California golden trout, and those effects are subject to the same protections governing livestock use. Current wilderness land management standards, restoration activities, and public outreach and stakeholder involvement have reduced potential threats of recreational activities. Although artificial fish barriers have locally altered the stream habitat of the California golden trout, these structures perform a crucial role in the prevention of upstream migration of nonnative brown trout and introgression with nonnative rainbow trout. Finally, available information does not indicate that beaver activity is a concern to the California golden trout. Based on the best available scientific and commercial information, we have determined that the California golden trout is not currently threatened by the present or threatened destruction, modification, or curtailment of its habitat or range such that it warrants listing under the Act, nor do we anticipate it posing a threat in the future.

Factor B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

There is no commercial fishing for California golden trout; however, recreational fishing is permitted by CDFG. In the Golden Trout Wilderness, the fishing season begins on the last Saturday in April and ends November 15. CDFG regulations allow anglers to possess five California golden trout, which is a bag limit guided by State policy to maintain wild trout stocks (CDFG 1979, p. 1). Regulations allow anglers to use only artificial lures with barbless hooks. Angler harvest is light in most areas within the native range of California golden trout except at Monache Meadows, Kennedy Meadows, and a few other easily accessible areas (Stephens 2001a, p. 64). Angler harvest does appear to have depressed the population numbers at these heavily used locations (Stephens 2001a, pp. 64, 65); however, impacts appear to be localized, well-regulated, and small enough to allow sustainable

populations. Angling regulations are posted in fishing areas and enforced (McGuire *et al.* 2009, p. 15). Knapp and Matthews (1996, p. 805) reported that California golden trout densities were generally among the highest ever recorded for a stream-dwelling trout in the western United States. Surveys conducted at Templeton Meadow on the South Fork Kern River indicate that California golden trout population numbers increased from 2,000 trout per mile in 1985 to about 7,000 trout per mile in 1999 (Stephens 2001b, p. 2). This indicates that California golden trout population numbers were at a high density in 1999 and not at risk from overutilization from recreational fishing. We are currently unaware of any information that demonstrates a decrease in fish densities or impacts from overutilization from recreational fishing as compared to 1999. Accordingly, the relatively limited harvest of California golden trout does not appear to pose a significant threat to the survival of the subspecies now or in the future.

California golden trout are utilized in a nonlethal way for scientific purposes. Specifically, CDFG, together with conservation partners and volunteers, has been collecting trout fin tissue samples since 2003 to conduct genetic evaluations necessary to restore native golden trout populations. The genetic studies require a small clipping from a fin, and this process rarely results in the death of an individual fish. Because scientific collection is being conducted for the betterment of the subspecies and because it rarely results in death of fish, we conclude that overutilization for scientific purposes is not a threat to California golden trout across its range, nor do we anticipate overutilization for commercial, recreational, scientific or education purposes posing a threat in the future.

Factor C. Disease or Predation

Predation and Competition With Brown Trout

Brown trout are not native to California. They have been introduced to the South Fork Kern River and have established populations there, but they have not established populations in Golden Trout Creek. Brown trout have been noted to thrive in sections of many major west slope streams in the Sierra Nevada mountain range, although their distribution, even in small streams, is noted to be often quite discontinuous, with pools and quieter waters thought to be more to their liking (Dill and Cordone 1997, p. 100). Brown trout distribution within specific habitat types has not been quantified for the South Fork Kern River. The presence of brown trout in the South Fork Kern River is likely due to stocking of the species at Kennedy Meadows carried out by CDFG in 1940, 1941, and 1996 (McGuire 2011, pp. 2, 3). The stocking program predates the construction of the Ramshaw, Templeton, and Schaeffer fish barriers by at least 30 years (see Factor A—Artificial Fish Barriers section above).

CDFG and Inyo National Forest have attempted to eradicate brown trout from the upper reaches of the California golden trout range a number of times by using piscicides (pesticides specific for fish) and then restocking the areas with California golden trout. In 1969, brown trout were present throughout the drainage and even in the headwaters of the South Fork Kern River where brown trout outnumbered golden trout by approximately 50 to 1 (CDFG *et al.* 2004a, pp. 28, 37). Installation of the Ramshaw Barrier, in combination with chemical treatments, resulted in removal of brown trout from the headwaters. Chemical treatments were conducted from the Ramshaw to Templeton barriers in 1981, and the last treatments from the Templeton to Schaeffer barriers in 1987. Subsequent monitoring of the treated reach of South Fork Kern River indicated that the treatment was ineffective due to barrier deterioration, which is now repaired (CDFG *et al.* 2004a, p. 38). Movie Stringer Creek, a western tributary to the South Fork Kern River upstream of Templeton Barrier, was chemically treated in 2000; no other chemical treatments have occurred since then.

The Strawberry Connection was a constructed diversion on Strawberry Creek that facilitated a possible hydrologic route for brown trout to enter the South Fork Kern River above the Templeton Barrier. This diversion was removed in 1999, and efforts have been made to restore Strawberry Creek to its historic channel. The Conservation Strategy indicates some concern that brown trout may still be able to access waters upstream of the Templeton Barrier during high flows (CDFG *et al.* 2004a, p. 25); however, no brown trout have been located above the barrier to date. Subsequent to completion of the Conservation Strategy, the Inyo National Forest conducted an evaluation of the Strawberry Connection during runoff events to map hydrologic flow (Sims and McGuire 2006, p. 7). The evaluation noted that, due in part to the absence of cattle for the previous 5 years, the Strawberry Connection may be converting back to its natural state (Sims and McGuire 2006, p. 7). The area showed less compacted soils and was in the process of reverting to a more boggy meadow, with channel flows focusing more towards Strawberry Creek rather than towards the ''connection'' area. This indicates the likely elimination of a possible passage for brown trout around the Templeton Barrier during high water flows (Sims and McGuire 2006, p. 7).

Annual monitoring of the South Fork Kern River indicates that brown trout are still not present above the Templeton Barrier (Sims and McGuire 2006, p. 6; Lentz 2011, p. 2). Brown trout are currently found in the South Fork Kern River below Templeton Barrier, however, which includes over 483 km (300 mi) of the stream distance that comprises the historical range of the California golden trout (Stephens 2001a, p. 43). The remaining stream length in the historical range above the Templeton Barrier is approximately 161 km (100 mi). The competitive success of brown trout, where present, over California golden trout is likely due to the fact that brown trout prey on all life stages of California golden trout, and are a superior competitor for limited food and habitat resources (Stephens 2001a, p. 43). The South Fork Kern River below Schaeffer barrier has never been treated to remove brown trout. Consequently, brown trout have been present in the lower South Fork Kern River more than 70 years. Successful sampling of California golden trout populations for genetic status has been conducted along the South Fork Kern River (and its tributaries) below Schaeffer Barrier, demonstrating that the species remains in sufficient numbers to maintain reproducing populations in these lower reaches, despite the presence of brown trout.

There is a potential threat of illegal fish transportation due to the ease of vehicular access to Monache Meadows, the recreational popularity of this area, and the presence of nonnative salmonids in downstream portions of the South Fork Kern River. However, enforcement of State fish and game laws are ongoing, and conservation efforts are occurring to inform and educate the public about the conservation needs of the California golden trout. CDFG wildlife protection personnel and National Forest law enforcement personnel continue to inform visitors of regulations, including the illegality of possession and transportation of live trout within the California golden trout's range. CDFG also produced brochures in 2005 and 2006 to inform the public about the restoration program. The brochures were distributed to Forest Service offices and

visitor centers, and also to local flyfishing shops, thereby informing the public that transplanting fish is illegal and subject to a fine.

Summary of Predation and Competition With Brown Trout

The risk of predation and interspecific competition from nonnative trout have been addressed through establishment and repair of the three fish barriers, elimination of CDFG-sanctioned brown trout stocking within the native range of the California golden trout, and various treatments (described above) to eliminate brown trout above the established barriers. The Forest Service and CDFG have been monitoring barriers, conducting surveys, and eradicating brown trout. Electrofishing surveys above and below Templeton and Schaeffer Barriers are being conducted annually to assess the effectiveness of the barriers, determine the current status and distribution of brown trout, and reduce brown trout numbers at the upstream extent of their distribution (Lentz 2011, p. 2). Although the goals of completely controlling brown trout in the South Fork Kern River are yet to be achieved, we nonetheless consider active programs by the Forest Service and CDFG to discourage illegal transport, and to monitor for and remove brown trout from California golden trout waters, to be reasonable and effective approaches for addressing the threat of brown trout.

No brown trout have been found above the Templeton Barrier since they were eradicated in the early 1980s (McGuire and Sims 2006, p. 10; Sims and McGuire 2006, p. 6). Mark-recapture tests of golden trout hybrids captured below the Schaeffer Barrier subsequent to its improvement in 2003 failed to find any fish that had successfully navigated past the barrier, indicating that brown trout are also incapable of passing the barrier (Sims and McGuire 2006, p. 6). Subsequent elimination of brown trout between the Schaeffer and Templeton barriers (a goal of the Conservation Strategy (CDFG et al. 2004a, p. 28)) is, therefore, possible. Additionally, current information available to us does not indicate a population-level effect of brown trout predation or competition that would warrant listing. Therefore, we conclude that, due to the management efforts being implemented, risk of predation and competition from brown trout does not pose a significant threat to the California golden trout throughout its range, nor do we anticipate predation posing and competition from brown trout posing a threat in the future.

Whirling Disease

Whirling disease is caused by *Myxobolus cerebralis,* a metazoan parasite that penetrates the head and spinal cartilage of fingerling trout, where it multiplies very rapidly and puts pressure on the organ of equilibrium. This causes the fish to swim erratically (whirl) and have difficulty feeding and avoiding predators. In severe infections, the disease can cause high rates of mortality in young-of-the-year fish. Those that survive until the cartilage hardens to bone can live a normal lifespan, but are marred by skeletal deformities. Fish can reproduce without passing on the parasite to their offspring. Rearing ponds used in many trout hatcheries provide conditions where the second host of the parasite (the oligochaete worm *Tubifex tubifex*) can thrive.

Myxobolus cerebralis has never been found in any golden trout sampled in California streams (Cox 2006, p. 1; Lentz 2011, p. 1). The only fish currently stocked within the native range (sterile trout stocked in Kennedy Meadows) are raised in a hatchery that is certified free of disease (Stephens 2006, p. 1). Because hatchery-raised California golden trout are no longer stocked within the native range of this subspecies, it is extremely unlikely that whirling disease could be spread to wild California golden trout populations. The disease has not been found in California golden trout to date, and there has been no documented loss or decline in California golden trout populations due to the disease. Although it could represent a future threat to the California golden trout, at this time the best scientific and commercial information does not indicate that it is a threat now nor likely to be a threat in the future.

Summary of Factor C

Although predation by, and competition with, brown trout have posed a threat to the California golden trout in the past, continuing conservation measures implemented by the State, cooperating agencies, and other interested groups have reduced this threat to manageable levels. Continued improvements of barriers have eliminated brown trout from the upper reaches of the South Fork Kern River where they were previously identified as a threat to the California golden trout. In the lower reaches of the South Fork Kern River, our best information indicates that populations descended from California golden trout have not sustained population-level declines due to brown trout. Finally, whirling disease has not been found in California golden trout to date. Therefore, we conclude that predation (and competition) with brown trout and whirling disease do not currently pose a threat to the California golden trout throughout its range, nor do we anticipate these to become threats in the future, such that listing under the Act is warranted.

Factor D. The Inadequacy of Existing Regulatory Mechanisms

Federal Regulations

Management of habitat for the California golden trout falls under the direction of the Sequoia and Inyo National Forests. Existing Federal regulatory mechanisms that are relevant to providing protection for the California golden trout in the Sierra Nevada include the following: National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*), Wilderness Act of 1964 (16 U.S.C. 1131–1136), Wild and Scenic Rivers Act (16 U.S.C. 1271–1287), Multiple-Use Sustained-Yield Act of 1960 (MUSY) (16 U.S.C. 528–531), Federal Land Policy and Management Act of 1976 (FLPMA) (43 U.S.C. 1701 *et seq.*), National Forest Management Act of 1976 (NFMA) (16 U.S.C. 1601 *et seq.*), Land and Resource Management Plans for the Inyo and Sequoia National Forests (USFS 1988a; CDFG *et al.* 2004a, pp. 79–82), as amended by the SNFPA, and the Clean Water Act (CWA) (33 U.S.C. 1344).

National Environmental Policy Act (NEPA) (42 U.S.C. 4321 et seq.)

NEPA requires all Federal agencies to formally document, consider, and publicly disclose the environmental impacts of major Federal actions and management decisions significantly affecting the human environment. NEPA documentation is provided in an environmental impact statement, an environmental assessment, or a categorical exclusion, and may be subject to administrative or judicial appeal. The California golden trout has been identified as a sensitive species by the Region 5 (Pacific Southwest Region) Regional Forester. As part of Forest Service policy, an analysis will be conducted to evaluate potential management decisions under NEPA, including preparation of a biological evaluation to determine the potential effect of potential Forest Service actions on this sensitive subspecies. However, the Forest Service is not required to select an alternative having the least significant environmental impacts and may select an action that will adversely affect sensitive species provided that

these effects were known and identified in a NEPA document. The NEPA process in itself is not likely to be considered a regulatory mechanism that is certain to provide significant protection for the California golden trout.

Wilderness Act of 1964 (16 U.S.C. 1131–1136)

The Wilderness Act of 1964 established a National Wilderness Preservation System made up of Federal lands designated by Congress as ''wilderness areas'' for the purpose of preserving and protecting designated areas in their natural condition, ''where the earth and its community of life are untrammeled by man, where man himself is a visitor who does not remain.'' The native range of the California golden trout within the South Fork Kern River lies within three wilderness areas: Golden Trout, South Sierra, and Domeland. The Domeland Wilderness was designated in 1964 and is just south of the South Sierra Wilderness (the road to Kennedy Meadows separates these two wildernesses). The Golden Trout Wilderness was designated in 1978 specifically to provide protection for California golden trout; Golden Trout Creek is wholly within this wilderness area. The South Sierra Wilderness was designated in 1984 and is adjacent to and south of the Golden Trout Wilderness.

Grazing of livestock is permitted within wilderness areas if it was established prior to the passage of this Act. The Wilderness Act does not specifically mention fish stocking, though it does state that the Wilderness Act shall not affect the jurisdiction or responsibilities of States with wildlife and fish responsibilities in the national forests. Fish stocking in wilderness areas is a controversial issue (Bahls 1992, pp. 2568–2578, p. 2568; Landres *et al.* 2001, pp. 287–294); however, wilderness designation generally has not limited fish stocking in the Sierra Nevada (Knapp 1996, pp. 3–12). The Wilderness Act has direction for managing designated wilderness to protect natural ecological processes and is a regulatory mechanism that protects California golden trout habitat from development or other types of habitat conversions, such as commercial enterprise, road construction, use of motorized vehicles or other equipment, and structural developments.

Wild and Scenic Rivers Act (16 U.S.C. 1271–1287)

Congress established the National Wild and Scenic Rivers System in 1968 to protect certain outstanding rivers from the harmful effects of new Federal projects, such as dams, hydroelectric facilities, bank armoring, and bridges. Rivers are classified as wild, scenic, or recreational, and fishing is permitted in components of the system under applicable Federal and State laws. The South Fork Kern River is designated as Wild and Scenic throughout 66 river km (41 mi) as the river passes through the South Sierra, Golden Trout, and Domeland Wildernesses. This regulatory mechanism, along with the Wilderness Act, thus protects approximately 10 percent of the California golden trout's range from new Federal projects such as those listed above.

Multiple-Use Sustained-Yield Act of 1960 (MUSY) (16 U.S.C. 528–531)

The Multiple-Use Sustained-Yield Act of 1960 (MUSY) provides direction that the national forests be managed using principles of multiple-use and that the forests produce a sustained yield of products and services. Specifically, MUSY provides policy that the national forests are established and shall be administered for outdoor recreation, range, timber, watershed, and wildlife and fish purposes. MUSY directs resource management not to impair the productivity of the land while giving consideration to the relative values of the various resources, though not necessarily in terms of the greatest financial return or unit output. MUSY provides direction to the Forest Service that fish and wildlife is a value that must be managed for, though discretion is given to each forest when considering the value of fish and wildlife relative to the other uses for which it is managing. Because the entire range of the California golden trout falls within lands administered by the Forest Service, this regulatory mechanism aids in the conservation of the subspecies in that fish are an important benefit for which management must occur.

Federal Land Policy and Management Act of 1976 (FLPMA) (43 U.S.C. 1701 et seq.)

The Federal Land Policy and Management Act was enacted in 1976, and as amended by the Public Rangelands Improvement Act of 1978 (43 U.S.C. 1901–1908), provides the primary legal foundation for how the Forest Service manages livestock grazing under its jurisdiction. This Act requires that a percentage of all monies received through grazing fees collected on Federal lands (including the Forest Service-administered lands within the range of the California golden trout) be spent for the purpose of on-the-ground range rehabilitation, protection, and improvement, including all forms of rangeland betterment, including fence construction, water development, and fish and wildlife enhancement. Half of the appropriated amount must be spent within the national forest where such monies were derived. FLPMA, as amended, is a regulatory mechanism that provides for some rangeland improvements intended for the long-term betterment of forage conditions and resulting benefits to wildlife, watershed protection, and livestock production, which if implemented can result in various habitat improvements and protections for the California golden trout.

National Forest Management Act of 1976 (NFMA) (16 U.S.C. 1601 et seq.)

National Forest Management Act of 1976 (NFMA) provides the primary legal foundation for Forest Service management of the public lands under its jurisdiction. NFMA includes a provision that planning regulations will include guidelines for land management plans that provide for diversity of plant and animal communities based on the suitability and capability of the specific land area in order to meet overall multiple-use objectives. Current planning regulations direct that forests manage fish and wildlife habitat to maintain viable populations of existing native and nonnative vertebrate species. Within each planning area, the provided habitat must support at least a minimum number of reproductive individuals (36 CFR 219.20). The Forest Service published new proposed planning regulations on February 14, 2011, which are intended ''to guide the collaborative and science-based development, amendment, and revision of land management plans that promote healthy, resilient, diverse, and productive national forests and grasslands'' (76 FR 8480, pp. 8480, 8481). The proposed regulations specify that plans must maintain viable populations of species of conservation concern within the plan area to the extent that it is within the authority of the Forest Service or the inherent capability of the plan area to do so (76 FR 8480, p. 8518). Revisions to the Inyo and Sequoia National Forest LRMPs would follow the regulations established by this proposed rule, if made final.

Land and Resource Management Plans (LRMPs) for the Inyo and Sequoia National Forests

The 1988 Inyo National Forest LRMP, as amended (USFS 1995), and the 1988 Sequoia National Forest LRMP, were

both amended by the SNFPA (USFS 2004) and provide management direction for the California golden trout. The Inyo National Forest is expecting to revise its LRMP in 2014 (Sims 2011c, p. 1), while the date for revision of the Sequoia National Forest LRMP is uncertain (Galloway 2011, p. 1) Specific direction under the current LRMPs is described in the following paragraphs.

The Sequoia National Forest LRMP provides direction for managing general aquatic and riparian species to increase the diversity of the animal communities. Riparian areas are managed to maintain or restore habitats for riparian species and those species associated with late successional stages of vegetation.

The Inyo National Forest LRMP has direction specific for managing a variety of resources. Specific standards and guidelines concerning grazing are presented in Factor A above, but in brief, they include trampling standards, direction for developing range Allotment Management Plans, conducting annual utilization checks, and locating salt outside of riparian areas. Direction specific for managing riparian resources includes forest-wide standards and guidelines aimed at maintaining or enhancing riparian-dependent resources and includes (but is not limited to): Giving priority to the rehabilitation of riparian areas when planning range, wildlife habitat, and watershed improvements; using Allotment Management Plans as a vehicle for ensuring protection of riparian areas from unacceptable impacts from grazing; and rehabilitating or fencing riparian areas that consistently show resource damage.

On January 12, 2001, a record of decision (ROD) was signed by the Forest Service for the SNFPA Final Environmental Impact Statement (USFS 2001b). The SNFPA addresses five problem areas: Old-forest ecosystems and associated species; aquatic, riparian, and meadow ecosystems and associated species; fire and fuels; noxious weeds; and lower west-side hardwood ecosystems. Subsequent to the establishment of management direction by the SNFPA ROD, the Regional Forester assembled a review team to evaluate specific plan elements. The review was completed in March 2003, and as a result the Final Supplemental Environmental Impact Statement was issued in January 2004 (USFS 2004). Forest Plans were amended to be consistent with the new (2004) ROD, and all subsequent project decisions fall under the 2004 direction. Within the native range of the California golden trout, management of the Inyo and Sequoia National Forests is affected by the SNFPA (USFS 2004).

Relevant to the California golden trout, the SNFPA aims to protect and restore aquatic, riparian, and meadow ecosystems and to provide for the viability of its associated native species through an Aquatic Management Strategy (AMS). The AMS is a general framework with broad goals for watershed processes and functions, habitats, attributes, and populations. There are nine goals associated with the AMS:

(1) Maintenance and restoration of water quality to comply with the Clean Water Act and the Safe Drinking Water Act.

(2) Maintenance and restoration of habitat to support viable populations of native and desired nonnative riparian-dependent species and to reduce negative impacts of nonnative species on native populations.

(3) Maintenance and restoration of species diversity in riparian areas, wetlands, and meadows to provide desired habitats and ecological functions.

(4) Maintenance and restoration of the distribution and function of biotic communities and biological diversity in special aquatic habitats (such as springs, seeps, vernal pools, fens, bogs, and marshes).

(5) Maintenance and restoration of spatial and temporal connectivity for aquatic and riparian species within and between watersheds to provide physically, chemically, and biologically unobstructed movement for their survival, migration, and reproduction.

(6) Maintenance and restoration of hydrologic connectivity between floodplains, channels, and water tables to distribute flood flows and to sustain diverse habitats.

(7) Maintenance and restoration of watershed conditions as measured by favorable infiltration characteristics of soils and diverse vegetation cover to absorb and filter precipitation and to sustain favorable conditions of stream flows.

(8) Maintenance and restoration of in-stream flows sufficient to sustain desired conditions of riparian, aquatic, wetland, and meadow habitats and to keep sediment regimes within the natural range of variability.

(9) Maintenance and restoration of the physical structure and condition of stream banks and shorelines to minimize erosion and sustain desired habitat diversity.

Riparian conservation objectives were developed to implement the Aquatic Management Strategy. These objectives contain standards and guidelines to maintain and restore riparian habitat and species.

The SNFPA ROD also includes two designations for aquatic and riparian areas: Critical Aquatic Refuges (CARs) and Riparian Conservation Areas (RCAs) (CDFG 2004a, p. 23). CARs are sub-watersheds that contain either known locations of threatened, endangered, or sensitive species, highly vulnerable populations of native plant or animal species, or localized populations of rare aquatic or riparian-dependent plant or animal species. RCAs are the lands around aquatic features where special standards and guidelines exist to conserve those features. RCA standards and guidelines apply in CARs except where an overlapping land allocation has a greater restriction on management activities. The width of an RCA is 91 m (300 ft) on each side of the stream for perennial streams, and 46 m (150 ft) on each side of intermittent and ephemeral streams, both being measured from the bankfull edge of the stream (the edge of the channel slope descending from the floodplain). An RCA width of 91 m (300 ft) is applicable to the California golden trout because it exists in perennial streams. Several CARs occur within the native range of the California golden trout. Two CARs occur on the Sequoia National Forest, and one CAR occurs on the Inyo National Forest.

Clean Water Act (CWA) (33 U.S.C. 1344)

The Clean Water Act (CWA) is the primary mechanism in the United States for surface water quality protection. It establishes the basic structure for regulating discharges of pollutants into waters of the United States. It employs a variety of regulatory and nonregulatory tools to reduce direct water quality impacts, finance water treatment facilities, and manage polluted run-off. The Forest Service is the designated water quality management agency under the CWA Section 208 Management Agency Agreement. Under this Agreement, the Forest Service is required to implement State-approved BMPs and other measures to achieve full compliance with all applicable State water quality standards. Project-level analysis conducted under NEPA is required to demonstrate compliance with CWA and State water quality standards (USFS 2004). Waterbodies that do not meet water quality standards with implementation of existing management measures are listed as impaired under section 303(d) of the CWA. Waters within California golden trout habitat are not listed as impaired by the State (Strand 2006), indicating that, in implementing this regulatory

mechanism, the Forest Service designs land management activities so that existing levels of water quality and beneficial uses are maintained and protected.

State Regulations

State regulatory mechanisms that could provide some protection for the California golden trout and its habitat include the California Endangered Species Act (CESA), California Environmental Quality Act (CEQA) (Pub. Resources Code § 21000 *et seq.*), and the California Fish and Game Code (14 C.C.R. § 1 *et seq.*). Applicable sections are discussed below. In addition, the California Fish and Game Commission (Commission) has regulatory powers to decide policy such as season, bag limits, and methods of take for sport fish.

California Endangered Species Act (CESA)

The California golden trout was designated as the State freshwater fish of California in 1947 and was listed as a fish species of special concern by CDFG in 1995. The status of ''species of special concern'' applies to animals that are not listed under the Act or the California Endangered Species Act (CESA) but meet the following criteria: Populations are low, scattered, or highly localized and require active management to prevent them from becoming threatened or endangered species (Moyle *et al.* 1995, p. 3).

California Environmental Quality Act (CEQA) (Pub. Resources Code § 21000 et seq.)

CEQA is the principal statute mandating environmental assessment of projects in California. The purpose of CEQA is to evaluate whether a proposed project may have an adverse effect on the environment (including native fish and wildlife species), to disclose that information to the public, and to determine whether significant adverse effects can be reduced or eliminated by pursuing an alternative course of action or through mitigation. CEQA applies to projects proposed to be undertaken or requiring approval by State and local public agencies. CEQA requires full disclosure of the potential environmental impacts of public or private projects carried out by or authorized by non-Federal agencies within the State of California. As such, CEQA provides some protection for the California golden trout, should projects that would be subject to CEQA be proposed within the native range of the species. Fish stocking is not subject to full disclosure of its potential environmental impacts, as it is exempt from CEQA under Article 19 section 15301(j). However, as discussed elsewhere stocking of nonnative trout has been discontinued within the species' range.

California Fish and Game Code (14 C.C.R. § 1 et seq.)

The California Fish and Game Commission, a separate entity from CDFG, is a five-member group appointed by the Governor and confirmed by the Senate. The Commission has set up several policies regarding the California golden trout. Pursuant to section 703 of the Fish and Game Code, the Commission has designated certain State waters to be managed exclusively for wild trout. Those waters include the entire Golden Trout Creek watershed and the majority of the South Fork Kern watershed from the headwaters to the southern end of the South Sierra Wilderness.

In 1952, the Commission developed the Golden Trout Policy that covers the three subspecies of golden trout in the Sierra Nevada. In summary, the policy states the following:

(1) Certain waters within the high mountainous areas of Madera, Fresno, Inyo, Mono, and Tulare Counties may be designated by CDFG as ''Golden Trout Waters of California'' and shall be maintained in as genetically pure state as possible, and rainbow trout and other species of trout shall not be planted in these designated golden trout waters.

(2) A brood stock shall be maintained in lakes set aside for the sole purpose of egg production to provide fingerlings for planting waters.

(3) Hatchery-reared or wild fingerlings may be used for initial stocking in streams and lakes designated by CDFG, and whenever practicable, the range of golden trout will be extended through wild fish or fingerling plantings in native waters, or in other waters possessing adequate spawning grounds.

(4) The Golden Trout Policy prevails over the general Trout Policy if the two are in conflict.

Contrary to the Golden Trout Policy that ''rainbow trout and other species of trout shall not be planted in designated golden trout waters,'' rainbow trout have been stocked in the South Fork Kern River at Kennedy Meadows since about 1947. To prevent additional hybridization, CDFG began planting triploid rainbow trout in 2004, of which 99 to 100 percent are sterile (CDFG *et al.* 2004a, p. 52; McGuire 2011, p. 3). Although the trout planting has been popular with some members of the angling public, CDFG discontinued the stocking program entirely in 2009 (McGuire 2009, p. 9; McGuire 2011, p. 3).

Section 200 of the Fish and Game Code delegates to the Commission the power to regulate the taking or possession of fish. California Sport Fishing Regulations include the California golden trout and require a sport fishing license and the use of barbless hooks to take a maximum of five California golden trout in the Golden Trout Wilderness (CDFG 2011a, p. 13). Outside the Golden Trout Wilderness, a fisherman may possess up to 10 California golden trout, but may only take 5 per day (CDFG 2011b, p. 2). These limits, coupled with the remote backcountry condition of much of the subspecies' range, appear sufficient to prevent angling pressure from posing a threat (see Factor B—*Overutilization for Commercial, Recreational, Scientific, or Educational Purposes* section above).

Section 1603(a) of the California Fish and Game Code necessitates a permit from CDFG for any activity that may alter the bed, channel, or bank of any river, stream, or lake. The permit may incorporate measures to minimize adverse impacts to fish and wildlife; therefore, this regulation may offer protection to California golden trout habitat. The extent to which this regulation has provided the California golden trout with protection is unknown, as much of the range of this subspecies is protected under management of federally protected areas where few habitat modifications subject to this permit have been proposed. Section 6400 of the California Fish and Game Code declares it unlawful to place, plant, or cause to be placed or planted in any waters of California any live fish without permission from CDFG. Violation could result in a fine of up to $50,000 and 1 year imprisonment, with revocation of fishing privileges. In addition, violators would be held liable for damages. Rewards of up to $50,000 may be offered for information leading to the conviction of persons violating Section 6400, pursuant to Section 2586.

Thus, State regulations provide protections primarily through State Fish and Game Codes, and enforcement of these regulations by both CDFG wildlife protection personnel and by Forest Service law enforcement personnel (CDFG *et al.* 2004a, pp. 57–58; McGuire and Sims 2006, p. 18; Sims and McGuire 2006b, p. 13).

Summary of Factor D

Some Federal and State regulations afford protections for the California golden trout and their habitat. Implementation of LRMPs, as amended

by the SNFPA, provides protections through management direction for the subspecies and the aquatic, riparian, and meadow ecosystems that it relies on. State regulations provide some protections through the Golden Trout Policy and the Fish and Game Code. Therefore, based on the best scientific and commercial information available, we find that the California golden trout is not currently threatened by the inadequate regulatory mechanisms throughout its range, nor do we anticipate inadequate regulatory mechanisms posing a threat in the future.

Factor E. Other Natural or Manmade Factors Affecting the Continued Existence of the Species

Potential Factor E threats include hybridization, fire suppression activities, invasion of California golden trout waters by the New Zealand mudsnail (*Potamopyrgus antipodarum*), and climate change. With regard to hybridization, this potential threat involves introduced nonnative rainbow trout breeding with the California golden trout. For purposes of this review, ''hybridization'' refers to the creation of hybrid individuals due to matings between California golden trout and nonnative rainbow trout (in this case introduced hatchery trout, *Oncorhynchus mykiss spp.*) or due to matings between California golden trout and hybrid trout. Genetic introgression refers to the movement of genes originally indicative of nonnative trout into the gene pool of California golden trout populations. Because native California golden trout, introduced rainbow trout, and hybrid offspring interbreed, hybridization leads to genetic introgression, and the threats (discussed below) of both hybridization and introgression are treated the same.

Hybridization

The petition states that hybridization, due to the substantial stocking of rainbow trout and hybridized golden trout during the past 100 years, is the most immediate and destructive threat that California golden trout faces (Trout Unlimited 2000, pp. 17–18). Hybridization and consequent introgression is thought to dilute the fundamental genetic characteristics of California golden trout populations (CDFG *et al.* 2004a, p. 24). If the hybridization and introgression continue at large enough rates, those fundamental genetic characteristics could be lost entirely, leading to ''genetic extinction'' (Rhymer and Simberloff 1996, p. 100). In the Golden Trout Creek watershed, Trout Unlimited (2000, pp. 20–24) cites the past stocking of hybridized California golden trout in the fishless headwater lakes, Johnson Lake, Rocky Basin Lakes 1, 2, 3, and 4, and Chicken Spring Lake, as potential sources of hybridization. In the South Fork Kern River watershed, the petition (Trout Unlimited 2000, p. 18) states that hybridization has resulted from the extensive official and unofficial stocking of rainbow trout that has occurred at various places throughout the watershed.

Hybridization in Relation to Implementing the Endangered Species Act

The Act does not directly address questions related to species that have some degree of hybridization. The purpose of the Act is to conserve threatened and endangered species and the ecosystems on which those species depend. The definition of species under the Act includes any taxonomic species or subspecies, and distinct population segments of vertebrate species. Key issues for this status review are the scientific criteria used by professional zoologists and field biologists to taxonomically classify individuals, and populations of interbreeding individuals, as members of the California golden trout subspecies (*Oncorhynchus mykiss aguabonita*).

Previous Service positions regarding hybridization, based upon interpretations in a series of opinions by the U.S. Department of the Interior, Office of the Solicitor, generally precluded conservation efforts under the authorities of the Act for progeny, or their descendants, produced by matings between taxonomic species or subspecies (O'Brien and Mayr 1991, pp. 1–3). However, advances in biological understanding of natural hybridization (such as Arnold 1997, pp. 182–183) prompted withdrawal of those opinions. The reasons for that action were summarized in two sentences in the withdrawal memorandum (Memorandum from Assistant Solicitor for Fish and Wildlife, U.S. Department of the Interior, to Director, U.S. Fish and Wildlife Service, dated December 14, 1990): ''New scientific information concerning genetic introgression has convinced us that the rigid standards set out in those previous opinions should be revisited. In our view, the issue of ''hybrids'' is more properly a biological issue than a legal one.''

Our increasing understanding of the wide range of possible outcomes resulting from exchanges of genetic material between taxonomically distinct species and between entities within taxonomic species that also can be listed under the Act (i.e., subspecies, DPSs) requires the Service to address these situations on a case-by-case basis. In some cases, introgressive hybridization (infiltration of genes from one species into the gene pool of another species through repeated backcrossing of a hybrid with one of its parents) may be considered a natural evolutionary process reflecting active speciation or simple gene exchange between naturally sympatric species (or those species that occupy the same or overlapping geographic areas without interbreeding). Introgressed populations may contain unique or appreciable portions of the genetic resources of an imperiled or listed species. For example, populations with genes from another taxon at very low frequencies may still express important behavioral, life-history, or ecological adaptations of the indigenous population or species within a particular geographic area. In other cases, human-caused or facilitated hybridization may threaten the existence of a taxon, either because native genes are lost due to sheer numbers of introgressing genes, or because hybridized individuals have lowered fitness (Rhymer and Simberloff 1996, pp. 85–86, 92). Consequently, the Service carefully evaluates the long-term conservation implications for each taxon separately on a case-by-case basis where introgressive hybridization may have occurred. The Service performs these evaluations objectively based on the best scientific and commercial information available consistent with the intent and purpose of the Act.

A potential dichotomy thus exists under the Act between: (a) The need to protect the genetic resources of a species in which introgression has occurred, and (b) the need to minimize or eliminate the threat of hybridization posed by another taxon. Implementing actions under the Act that distinguish between these two alternatives is difficult when imperiled species are involved because a large number of populations may have experienced varying amounts of genetic introgression from another taxon. With regard to the California golden trout, an acceptable level of hybridization has not yet been defined.

Hybridization as a Potential Threat to California Golden Trout

In Golden Trout Creek, which contains approximately 82 km (51 mi) of native range, movement and reproduction of introgressed California golden trout from headwater lakes into downstream reaches has resulted in introgression at low levels, estimated at 0 to 8 percent on average (Cordes *et al.*

2006, pp. 110, 117; Stephens 2006, p. 2). Higher introgression rates (10 to 12 percent on average) were found in the headwater lakes (Cordes *et al.* 2006, p. 117), which had been stocked with hybridized California golden trout. Since 1995, managers have concentrated efforts to remove the hybridized trout from these lakes (Johnson Lake, Rocky Basin Lakes, and Chicken Spring Lake) (Cordes *et al.* 2001, p. 15). Survey results indicate that the six lakes are now fishless (Sims and McGuire 2006, p. 4; McGuire *et al.* 2009, p. 3). Thus, the source for future introgression has been removed. The removal of these source populations of introgressed fish will allow rainbow trout alleles to become less common in the watershed (Cordes *et al.* 2001, p. 15). Eventually, many of the rainbow trout alleles may drop out of the population altogether due to genetic drift (Cordes *et al.* 2001, p. 15). Within the Golden Trout Creek watershed, the Volcano Creek population, representing the only known pure population to date, contains approximately 8 km (5 mi) of stream habitat. This population is isolated from introgressed trout by a natural bedrock barrier near its mouth. Cordes *et al.* (2001, p. 15) found that this population had reduced genetic variability and are genetically distinct from other populations in Golden Trout Creek; however, these samples only came from one reach of stream, necessitating the need for additional analysis.

In the South Fork Kern River, which comprises approximately 644 km (400 mi) of native range, genetic tests indicate that all California golden trout have detectable levels of introgression with rainbow trout, with the downstream populations exhibiting the highest known levels, congruent with the known historical management of these populations (Cordes *et al.* 2003, pp. 16, 40; Stephens 2007, p. 72). Prior to construction and improvement of the manmade barriers, there were no upstream impediments to fish movement in the mainstem South Fork Kern. Currently, there are relatively low levels of introgression in the headwater reaches, and percentages of rainbow trout alleles are fairly uniform in samples collected above Templeton Barrier, likely reflecting the homogenizing effect of previous chemical treatments and restocking efforts (Cordes *et al.* 2003, p. 12). With no pure populations known to exist within this watershed, Cordes *et al.* (2003, p. 22) recommend that management focus should be to isolate the California golden trout with high levels of hybridization in the lower reaches from those less hybridized in the upper reaches, and to maintain and expand remaining pure populations if these are identified. If no pure populations are found, then Cordes *et al.* (2003, p. 22) recommend preservation of the existing South Fork Kern River populations with the lowest levels of introgression. Currently, introgression levels measured at barrier sites (41 percent at Schaeffer Barrier, 17 percent at Templeton Barrier, which is upstream) indicate that separation of lower levels of introgression above Schaeffer Barrier has been successful.

As both the petition and the Conservation Strategy note, illegal transport of nonnative or introgressed trout into areas that currently have low introgression levels, is a serious concern (Trout Unlimited 2000, pp. 26, 27; CDFG *et al.* 2004a, pp. 57, 58). However, as discussed above under under Factor C—Predation and Competition with Brown Trout,'' we consider the management actions that have been and are being undertaken to address this threat to be effective. Additionally, although the petition indicated that the Schaeffer barrier (the farthest downstream of the three) has historically been ineffective at preventing upstream movement (Trout Unlimited 2000, p. 6), the barrier was repaired in 2003, and is now considered impassable (CDFG *et al.* 2004a, p. 37; Lentz 2011, p. 1). See Factor A—Artificial Fish Barriers above. In addition, all fish stocking has been discontinued within the native range of the California golden trout; at Kennedy Meadows Reservoir, stocking of fertile rainbow trout ended in 2003 and stocking of sterile rainbow trout ended in 2008 (McGuire 2011, p. 3).

Once more genetic information becomes available, the Conservation Strategy describes management actions that can be undertaken, starting with the development and implementation of a peer-reviewed genetics management plan (CDFG *et al.* 2004a, p. 47). The genetics management plan is currently in development, with an expected completion date of December 31, 2011.

In summary, the best available scientific and commercial data, as described above, indicates that California golden trout in Volcano Creek and Golden Trout Creek are not threatened by hybridization to the point where listing is warranted. Stocking of nonsterile fish has ceased; all fish have been removed from the headwater lakes of Golden Trout Creek; barriers in the South Fork Kern River to prevent migration of hybridized fish have been repaired and tested; and measures are in place to address risks of illegal fish stocking (Sims and McGuire 2006, pp. 6, 7). We expect that due to the management actions taken to isolate California golden trout from nonnative trout within their native range, that, for the species as a whole, the level of introgression should not increase and may decrease over time. Therefore, we determine that existing levels of introgression within the subspecies do not constitute a significant threat, and that management actions have lowered the extent and likelihood of further hybridization, such that introgression is unlikely to become a significant threat in the future.

Fire Suppression Activities

Potential adverse effects to the California golden trout resulting from fire suppression activities include changed forest structure; direct mortality due to water drafting (taking of water) from occupied drainages; hybridization and competition with nonnative trout that may arise from dropping water from a helicopter within the Golden Trout Creek and South Fork Kern River watersheds using water that may contain trout not native to the watersheds; and contamination due to use of fire retardants for fire suppression.

In some areas within the range of the California golden trout, long-term fire suppression has changed forest structure and conditions, resulting in the potential for increased fire severity and intensity (McKelvey *et al.* 1996, p. 1038). Fire can cause direct mortality of fish and aquatic invertebrates within aquatic ecosystems. However, even in the case of high-severity fires, local extirpations of fish have been patchy, allowing for relatively rapid recolonization (Gresswell 1999, p. 193). Lasting adverse effects of fire on fish populations have consequently been limited to areas where native populations had declined for reasons other than fire, and were already small and isolated prior to the fire (Gresswell 1999, pp. 193, 212). In contrast, California golden trout typically show relatively high population densities where they occur (Knapp and Dudley 1990, p. 169), and known populations are not typically isolated from each other (Stephens 2007, p. 72). In 2000, the Manter Fire burned on the Sequoia National Forest, and surveys found dead California golden trout on Fish Creek and the South Fork Kern River. Since live fish were seen in these areas after the fire, it is likely that the fire did not result in total mortality of the local population (Strand 2006).

The Federal Wildland Fire Policy and Program Review, which is a comprehensive Federal fire policy for the Departments of the Interior and Agriculture, was created in 1995 and recognizes the essential role of fire in maintaining natural systems. Wildland fire use is a management option on Federal lands and is available to Federal agencies with an approved land use plan and a fire management plan (USDA and USDOI 2005, p. 2; USDA and USDOI 2009, pp. 8, 9). The Sequoia National Forest has begun using wildland fire on a case-by-case basis as a tool to reduce fuel loading in wilderness areas, most recently in 2010 on the Big Sheep Fire (Lang 2011, p. 1). In 2004, the Forest Service completed the Fisheries and Aquatic Input for Wildland Fire Suppression Planning Specific to Golden Trout Management (McGuire and Sims 2006, pp. 22–25). Criteria include avoiding moderate to extreme fire intensities within the Golden Trout watershed, avoiding water transfers in key areas, and using small intake screens when drafting from water sources.

Fire retardants and suppressant chemicals are used extensively in the United States for suppression and control of range and forest fires, and are often applied in environmentally sensitive areas (Hamilton *et al.* 1996, introduction). Laboratory tests of these chemicals have shown that they cause mortality in fishes and aquatic invertebrates by releasing surfactants and ammonia when added to water (Hamilton *et al.* 1996, pp. 1–5). Fire retardant chemicals dropped in or near California golden trout habitat could have negative effects on individuals or isolated populations. On April 20, 2000, direction was given to all national forests in regard to fire retardant use during wildland fire suppression activities. Guidance includes avoiding aerial application of retardant or foam within 91 m (300 ft) of waterways. Further details concerning delivery from different types of aircraft, interactions with threatened and endangered species, and exceptions are given in the document. These guidelines are updated annually and published in the Interagency Standards for Fire and Fire Aviation Operations (National Interagency Fire Center 2006, Chapter 12, pp. 1–6) for the Bureau of Land Management, Forest Service, National Park Service, and the Service.

The Forest Service, through the direction of the Conservation Strategy, created written plans for integration of California golden trout populations and habitat protection in Forest Service fire suppression planning. Both the Inyo and the Sequoia National Forests' fishery biologists have been coordinating with fire personnel to ensure that measures contained in the plans are implemented (McGuire and Sims 2006, p. 8; Sims and McGuire 2006, p. 5). One such avoidance measure identifies the need to prevent water transfers from nonnative water bodies into California golden trout waters during fire suppression activities, or any other management activity that would use large quantities of water.

While fire suppression activities have the potential to affect the California golden trout, evidence indicates that lasting adverse effects on fish populations are rare. Although inadvertent application of fire suppression chemicals could negatively affect some isolated populations, the potential for this is lessened by implementation of the national direction on aerial applications of these fire retardants. Furthermore, the Forest Service has incorporated measures into fire suppression planning documents, and implementation of these measures reduces the effects that fire management activities would otherwise have on California golden trout. Therefore, we conclude that fire suppression activities are not a threat to the California golden trout.

New Zealand Mudsnail (*Potamopyrgus antipodarum*)

The New Zealand mudsnail (NZMS) is an invasive nonnative mollusk that can impact the food chain of native trout by competing with native invertebrates (including native mollusks) for food and space, and through altering the physical characteristics of the streams (Aquatic Nuisance Species Task Force 2006, p. 1). NZMS are able to withstand a variety of temperature regimes and can stay alive out of water under moist conditions for 5 or more days, and are small enough that anglers can inadvertently transfer this species between different waterbodies (Aquatic Nuisance Species Task Force 2006, pp. 1, 2; Sims 2006b, p. 1). Since they reproduce clonally, one introduced NZMS can begin a new population. NZMS has the ability to reproduce quickly and mass in high densities (Aquatic Nuisance Species Task Force 2006, p. 1).

The closest location of NZMS to the California golden trout is in the Owens River drainage, which is approximately a 2-hour drive to Horseshoe Meadow trailhead and an hour hike into California golden trout habitat, or about a 4-hour drive to Monache Meadows (Sims 2006b, p. 1; Lentz 2011, p. 2). These NZMS were located in 2000 at the lower Owens River near Bishop; since 2000, NZMS has moved throughout the Owens drainage including Hot Creek, Rush Creek, and Lone Pine Creek. Because NZMS can survive on waders for several days, human transport of the organism to the California golden trout's habitat would be likely if precautions are not taken by anglers. The Inyo National Forest requires all permitted fishing guides to follow appropriate disinfection methods for their gear (Sims 2006b, p. 1).

Several conservation measures reduce the likelihood that this invasive species will enter the native waters, including the cooperative effort between the Inyo and Sequoia National Forests and CDFG to ensure that the transfer of water from nonnative waterbodies does not occur during fire suppression activities. Also, a brochure has been distributed that informs the public about how to prevent the spread of nuisance species, with an Internet link provided to a NZMS Web site.

In summary, NZMSs have not been found within the native range of the California golden trout. While it is possible that this invasive species will continue to spread, ongoing efforts are occurring to address the risk of spread of NZMS to habitat of the California golden trout. Consequently, we conclude NZMS is not a threat to the subspecies.

Climate Change

''Climate'' refers to an area's long-term average weather statistics (typically for at least 20- or 30-year periods), including the mean and variation of surface variables such as temperature, precipitation, and wind, whereas ''climate change'' refers to a change in the mean and/or variability of climate properties that persists for an extended period (typically decades or longer), whether due to natural processes or human activity (Intergovernmental Panel on Climate Change (IPCC) 2007a, p. 78). Although changes in climate occur continuously over geological time, changes are now occurring at an accelerated rate. For example, at continental, regional, and ocean-basin scales, recent observed changes in long-term trends include: A substantial increase in precipitation in eastern parts of North America and South America, northern Europe, and northern and central Asia, and an increase in intense tropical cyclone activity in the North Atlantic since about 1970 (IPCC 2007a, p. 30); and an increase in annual average temperature of more than 2 °F (1.1 °C) across the United States since

1960 (Global Climate Change Impacts in the United States (GCCIUS) 2009, p. 27). Examples of observed changes in the physical environment include: An increase in global average sea level, and declines in mountain glaciers and average snow cover in both the northern and southern hemispheres (IPCC 2007a, p. 30), substantial and accelerating reductions in Arctic sea-ice (such as Comiso *et al.* 2008, p. 1), and a variety of changes in ecosystem processes, the distribution of species, and the timing of seasonal events (such as GCCIUS 2009, pp. 79–88).

The IPCC used Atmosphere-Ocean General Circulation Models and various greenhouse gas emissions scenarios to make projections of climate change globally and for broad regions through the 21st century (Meehl *et al.* 2007, p. 753; Randall *et al.* 2007, pp. 596–599), and reported these projections using a framework for characterizing certainty (Solomon *et al.* 2007, pp. 22–23). Examples include: (1) It is virtually certain there will be warmer and more frequent hot days and nights over most of the earth's land areas; (2) it is very likely there will be increased frequency of warm spells and heat waves over most land areas, and the frequency of heavy precipitation events will increase over most areas; and (3) it is likely that increases will occur in the incidence of extreme high sea level (excludes tsunamis), intense tropical cyclone activity, and the area affected by droughts (IPCC 2007b, p. 8, Table SPM.2). More recent analyses using a different global model and comparing other emissions scenarios resulted in similar projections of global temperature change across the different approaches (Prinn *et al.* 2011, pp. 527, 529).

All models (not just those involving climate change) have some uncertainty associated with projections due to assumptions used, data available, and features of the models; with regard to climate change this includes factors such as assumptions related to emissions scenarios, internal climate variability, and differences among models. Despite this, however, under all global models and emissions scenarios, the overall projected trajectory of surface air temperature is one of increased warming compared to current conditions (Meehl *et al.* 2007, p. 762; Prinn *et al.* 2011, p. 527). Climate models, emissions scenarios, and associated assumptions, data, and analytical techniques will continue to be refined, as will interpretations of projections, as more information becomes available. For instance, some changes in conditions are occurring more rapidly than initially projected, such as melting of Arctic sea ice (Comiso *et al.* 2008, p. 1; Polyak *et al.* 2010, p. 1797), and since 2000 the observed emissions of greenhouse gases, which are a key influence on climate change, have been occurring at the mid- to higher levels of the various emissions scenarios developed in the late 1990's and used by the IPPC for making projections (such as Raupach *et al.* 2007, Figure 1, p. 10289; Manning *et al.* 2010, Figure 1, p. 377; Pielke *et al.* 2008, entire). Also, the best scientific and commercial data available indicate that average global surface air temperature is increasing and several climate-related changes are occurring and will continue for many decades even if emissions are stabilized soon (such as Meehl *et al.* 2007, pp. 822–829; Church *et al.* 2010, pp. 411–412; Gillett *et al.* 2011, entire).

Changes in climate can have a variety of direct and indirect impacts on species, and can exacerbate the effects of other threats. Rather than assessing ''climate change'' as a single threat in and of itself, we examine the potential consequences to species and their habitats that arise from changes in environmental conditions associated with various aspects of climate change. For example, climate-related changes to habitats, predator-prey relationships, disease and disease vectors, or conditions that exceed the physiological tolerances of a species, occurring individually or in combination, may affect the status of a species. Vulnerability to climate change impacts is a function of sensitivity to those changes, exposure to those changes, and adaptive capacity (IPCC 2007, p. 89; Glick *et al.* 2011, pp. 19–22). As described above, in evaluating the status of a species, the Service uses the best scientific and commercial data available, and this includes consideration of direct and indirect effects of climate change. As is the case with all potential threats, if a species is currently affected or is expected to be affected by one or more climate-related impacts, this does not necessarily mean the species is a threatened or endangered species as defined under the Act. If a species is listed as threatened or endangered, this knowledge regarding its vulnerability to, and impacts from, climate-associated changes in environmental conditions can be used to help devise appropriate strategies for its recovery.

While projections from global climate model simulations are informative and in some cases are the only or the best scientific information available, various downscaling methods are being used to provide higher resolution projections that are more relevant to the spatial scales used to assess impacts to a given species (see Glick *et al.,* 2011, pp. 58–61). With regard to the area of analysis for the California golden trout, downscaled projections are not available.

Climate change may potentially impact California golden trout populations by affecting water temperature, water availability, or the timing of flows. California golden trout prefer temperatures below 60 °F (15 °C), but can endure daytime temperatures ranging into the 70's °F (21 °C) so long as temperatures cool again at night (CDFG 2004a, pp. 11–12). Stretches of the South Fork Kern can currently reach up to 77 °F (25.2 °C) (CDFG 2004a, p. 55). Stream temperatures are being monitored, as required by the Conservation Strategy, but a detailed report has not yet been produced (McGuire *et al.* 2009, p. 11).

Both the Golden Trout Creek and South Fork Kern watersheds are high-elevation watersheds strongly influenced by snowmelt. The extent of water contained in the spring snowpack (typically measured as the snow water equivalent on April 1st) is thus an important predictor of summer streamflow and temperatures (Mote *et al.* 2005, p. 40). Most areas in the western United States have shown decreases since 1950 in the amount of water contained in their spring snowpacks (Mote *et al.* 2005, p. 41). However, the water content of spring snowpacks in the southern Sierras (including the areas surrounding the Golden Trout Creek and South Fork Kern watersheds) have actually increased over that same time (Mote *et al.* 2005, pp. 41, 42; Ray *et al.* 2010, p. 16). Mote *et al.* (2005, pp. 46, 47) attributed this effect to an increase in precipitation, combined with relatively mild temperature increases at the high elevations involved. Mote *et al.* (2005, p. 40) compared the water content of spring snowpacks across the American West, both as measured from 1950 to 1997 and as predicted by a hydrologic model called the Variable Infiltration Capacity (VIC). The VIC accounts for vegetation, soil layers, and the interaction of water and heat energy at the land surface. They found general agreement between the model and observations, except that the model, while correctly predicting an increase in snowpack water content for the southern Sierras (Mote *et al.* 2005, pp. 41, 42), still under-predicted the amount of snowpack water content due to a lack of meteorological information for the highest elevations (Mote *et al.* 2005, pp. 41, 43).

Changes in timing of flows may be possible despite predicted trends in springtime snowpack. For instance the snowpack may be maintained by increased snowfall, despite earlier melting of some portion of that snowpack (Stewart *et al.* 2005, p. 1144). This may advance the timing of relatively warm water entering the Golden Trout Creek and South Fork Kern watersheds. California golden trout spawn when water temperatures consistently exceed 59 °F (15 °C) (Knapp and Vredenburg 1996, p. 1). They also tend to spawn more actively during times of day when the water is warmest. Earlier meltwater runoff from the snowpack might reasonably cause the minimum spawning temperatures to be reached earlier in the year. As the Conservation Strategy notes, California golden trout tend to grow slowly, in part because of cold water temperatures and a short growing season (CDFG 2004a, p. 12). Earlier meltwater runoff may, therefore, have a positive effect on California golden trout populations.

In summary, modeled and observed data indicate that the water content of snowpacks in the southern Sierras is likely to increase or at least remain the same in the future. Streams supporting California golden trout are, therefore, likely to remain supplied year round with water in the temperature ranges required by the subspecies. We conclude that global climate change does not pose a threat to the subspecies, either now or in the future.

Summary of Factor E

Although California golden trout have historically been adversely affected by several manmade or human exacerbated factors, those potential threats have been well-addressed by conservation efforts. Threats of increased hybridization resulting from natural fish movement and interbreeding in areas that are currently less-hybridized have been ameliorated by conservation efforts that include repair and maintainance of the three fish barriers on the South Fork Kern River, removal of all fish from the headwater lakes of Golden Trout Creek, and various genetic monitoring efforts. While these efforts do not eliminate introgression that has already occurred, they prevent areas of low introgression, such as the upper reaches of the South Fork Kern River, from being further introgressed by hybridized fish coming upstream from lower reaches. This stabilization of the threat has allowed management efforts, including elimination of introgressed populations, to proceed in a well-considered manner.

Fire suppression planning and guidance documents, including the Conservation Strategy (CDFG *et al.* 2004a, p. 87), Interagency Standards for Fire and Fire Aviation Operations (National Interagency Fire Center 2006, chapter 12, pp. 1–6), and the Wildland Fire Use Implementation Procedures Reference Guide (USDA and USDOI 2005, entire) adequately address both the direct potential impacts of fire suppression activities and the indirect habitat impacts that may result from fuels buildup in the lack of fire. The threat that the New Zealand mudsnail may be introduced into California golden trout waters is relatively low due to distance to source areas, and is addressed by public education efforts. Available data also indicate that water temperature and availability issues related to climate change will not threaten the subspecies. Based on the above, we conclude that the California golden trout is not currently threatened by other natural or manmade factors affecting its continued existence throughout its range, nor do we anticipate other natural or manmade factors posing a threat in the future.

Finding

As required by the Act, we considered the five factors in assessing whether the California golden trout is threatened or endangered throughout all or a significant portion of its range. We examined the best scientific and commercial information available regarding the past, present, and future threats faced by the California golden trout. We reviewed the petition, information available in our files, other available published and unpublished information, and we consulted with recognized California golden trout experts and other Federal and State agencies.

The primary potential threats to the subspecies include livestock grazing at levels that are environmentally harmful, competition and predation from introduced brown trout, and hybridization with nonnative trout. These potential threats are all addressed by a Conservation Strategy and Memorandum of Agreement that we, the USFS, and CDFG are currently implementing (CDFG *et al.* 2004a, entire; CDFG *et al.* 2004b, entire). Impacts from environmentally detrimental grazing practices have been greatly reduced through the resting of grazing allotments and establishment of cattle exclosures, by the implementation of standards for maintaining desired vegetative and habitat conditions, and by significant reductions in the number of cattle using the area.

Predation and competition with brown trout have been addressed by the discontinuation of brown trout stocking, construction and improvement of fish barriers, chemical treatments, and annual surveys to keep brown trout out of cleared areas. Hybridization concerns have been addressed under the Conservation Strategy through the discontinuation of fish stocking in the California golden trout's home range, the removal of hybridized fish from Golden Trout Creek headwater lakes, and the restoration of fish barriers on the South Fork Kern River. In the South Fork Kern River, introgression levels appear to be generally uniform in stream sections that are separated by barriers, indicating that in general, particular populations are insulated from increased introgression. In Golden Trout Creek, the source of introgression has been removed. California golden trout densities have generally been among the highest ever recorded for a stream-dwelling trout in the western United States (Knapp and Matthews 1996, p. 805). Population surveys conducted at Templeton Meadow on the South Fork Kern River have indicated that population numbers increased between 1985 and 1999 (Stephens 2001b, p. 2), indicating that in general golden trout population numbers are at a high density and do not appear to be at risk.

Based on our review of the best available scientific and commercial information pertaining to the five factors, we find that the threats are not of sufficient imminence, intensity, or magnitude to indicate that the California golden trout is in danger of extinction (endangered), or likely to become endangered within the foreseeable future (threatened), throughout its range at this time.

Distinct Vertebrate Population Segment

Under the Service's Policy Regarding the Recognition of Distinct Vertebrate Population Segments Under the Endangered Species Act (61 FR 4722; February 7, 1996), three elements are considered in the decision concerning the establishment and classification of a possible DPS. These are applied similarly for additions to or removal from the Federal List of Endangered and Threatened Wildlife. These elements include:

(1) The discreteness of a population in relation to the remainder of the species to which it belongs;

(2) The significance of the population segment to the species to which it belongs; and

(3) The population segment's conservation status in relation to the Act's standards for listing, delisting, or reclassification (i.e., is the population segment endangered or threatened).

Discreteness

Under the DPS policy, a population segment of a vertebrate taxon may be considered discrete if it satisfies either one of the following conditions:

(1) It is markedly separated from other populations of the same taxon as a consequence of physical, physiological, ecological, or behavioral factors. Quantitative measures of genetic or morphological discontinuity may provide evidence of this separation.

(2) It is delimited by international governmental boundaries within which differences in control of exploitation, management of habitat, conservation status, or regulatory mechanisms exist that are significant in light of section 4(a)(1)(D) of the Act.

If the population meets the first two criteria under the DPS policy, we then proceed to the third element in the process, which is to evaluate the population segment's conservation status in relation to the Act's standards for listing as an endangered or threatened species. The DPS evaluation in this finding concerns the California golden trout that we were petitioned to list as endangered.

In the threats assessment performed above, we concluded that in relation to the entire range of the California golden trout, none of the activities identified as potential threats, either singly or in combination, constitute a level of risk serious enough to bring a local population to the point where it would be in danger of extinction, either now or in the foreseeable future.

Under the DPS Policy, California golden trout in both Golden Trout Creek and the South Fork Kern River each could meet the criterion for discreteness as a markedly separate population because while the two drainages were connected in the geologic past, they became separated by volcanic activity in the region approximately 10,000 years ago (Cordes *et al.* 2003, p. 20). This led to Golden Trout Creek and the South Fork Kern River as known today (Evermann 1906, pp. 11–14) in two adjacent watersheds draining the Kern Plateau of the southern Sierra Nevada.

Significance

If a population segment is considered discrete under one or more of the conditions described in the Service's DPS policy, its biological and ecological significance will be considered in light of Congressional guidance that the authority to list DPSs be used ''sparingly'' while encouraging the conservation of genetic diversity. In making this determination, we consider available scientific evidence of the discrete population segment's importance to the taxon to which it belongs. Since precise circumstances are likely to vary considerably from case to case, the DPS policy does not describe all the classes of information that might be used in determining the biological and ecological importance of a discrete population. However, the DPS policy describes four possible classes of information that provide evidence of a population segment's biological and ecological importance to the taxon to which it belongs. As specified in the DPS policy (61 FR 4722), this consideration of the population segment's significance may include, but is not limited to, the following:

(1) Persistence of the discrete population segment in an ecological setting unusual or unique to the taxon;

(2) Evidence that loss of the discrete population segment would result in a significant gap in the range of a taxon;

(3) Evidence that the discrete population segment represents the only surviving natural occurrence of a taxon that may be more abundant elsewhere as an introduced population outside its historic range; or

(4) Evidence that the discrete population segment differs markedly from other populations of the species in its genetic characteristics.

A population segment needs to satisfy only one of these conditions to be considered significant. Furthermore, other information may be used as appropriate to provide evidence for significance.

California golden trout in Golden Trout Creek and the South Fork Kern River could each be considered to meet the significance criterion of the DPS policy because the evidence indicates that the loss of either population segment could result in a significant gap in the range of the subspecies.

However, since it is our conclusion that, based on the best information available, recent management actions and restoration activities have ameliorated the risks presented by these potential threats to the extent that they do not present a concentrated level of risk to California golden trout anywhere in its range, including in Golden Trout Creek and the South Fork Kern watershed, we conclude that there is no geographic concentration of threats and thus no need to proceed further with an evaluation of potential DPSs within the range of the subspecies. Even if populations of California golden trout were found to meet the distinctness and significance criteria of the DPS Policy, we have already found that the conservation status of these entities would not meet the Act's standards for listing as endangered or threatened. As a result, no further analysis under the DPS policy is necessary.

Significant Portion of the Range and Distinct Vertebrate Population Segments

After assessing whether the California golden trout is threatened or endangered throughout its range, we next consider whether either a significant portion of the California golden trout's range or a distinct population segment (DPS) of the species meets the definition of endangered or is likely to become endangered in the foreseeable future (threatened).

Significant Portion of the Range

The Act defines ''endangered species'' as any species which is ''in danger of extinction throughout all or a significant portion of its range,'' and ''threatened species'' as any species which is ''likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' The definition of ''species'' is also relevant to this discussion. The Act defines the term ''species'' as follows: ''The term 'species' includes any subspecies of fish or wildlife or plants, and any distinct population segment [DPS] of any species of vertebrate fish or wildlife which interbreeds when mature.'' The phrase ''significant portion of its range'' (SPR) is not defined by the statute, and we have never addressed in our regulations: (1) The consequences of a determination that a species is either endangered or likely to become so throughout a significant portion of its range, but not throughout all of its range; or (2) what qualifies a portion of a range as ''significant.''

Two recent district court decisions have addressed whether the SPR language allows the Service to list or protect less than all members of a defined ''species:'' *Defenders of Wildlife* v. *Salazar,* 729 F. Supp. 2d 1207 (D. Mont. 2010), concerning the Service's delisting of the Northern Rocky Mountain gray wolf (74 FR 15123, April 2, 2009); and *WildEarth Guardians* v. *Salazar,* 2010 U.S. Dist. LEXIS 105253 (D. Ariz. Sept. 30, 2010), concerning the Service's 2008 finding on a petition to list the Gunnison's prairie dog (73 FR 6660, Feb. 5, 2008). The Service had asserted in both of these determinations that it had authority, in effect, to protect only some members of a ''species,'' as defined by the Act (i.e., species, subspecies, or DPS), under the Act. Both courts ruled that the determinations were arbitrary and capricious on the grounds that this approach violated the plain and unambiguous language of the

Act. The courts concluded that reading the SPR language to allow protecting only a portion of a species' range is inconsistent with the Act's definition of ''species.'' The courts concluded that once a determination is made that a species (i.e., species, subspecies, or DPS) meets the definition of ''endangered species'' or ''threatened species,'' it must be placed on the list in its entirety and the Act's protections applied consistently to all members of that species (subject to modification of protections through special rules under sections 4(d) and 10(j) of the Act).

Consistent with that interpretation, and for the purposes of this finding, we interpret the phrase ''significant portion of its range'' in the Act's definitions of ''endangered species'' and ''threatened species'' to provide an independent basis for listing; thus there are two situations (or factual bases) under which a species would qualify for listing: a species may be endangered or threatened throughout all of its range; or a species may be endangered or threatened in only a significant portion of its range. If a species is in danger of extinction throughout an SPR, it, the species, is an ''endangered species.'' The same analysis applies to ''threatened species.'' Therefore, the consequence of finding that a species is endangered or threatened in only a significant portion of its range is that the entire species shall be listed as endangered or threatened, respectively, and the Act's protections shall be applied across the species' entire range.

We conclude, for the purposes of this finding, that interpreting the SPR phrase as providing an independent basis for listing is the best interpretation of the Act because it is consistent with the purposes and the plain meaning of the key definitions of the Act; it does not conflict with established past agency practice (i.e., prior to the 2007 Solicitor's Opinion), as no consistent, long-term agency practice has been established; and it is consistent with the judicial opinions that have most closely examined this issue. Having concluded that the phrase ''significant portion of its range'' provides an independent basis for listing and protecting the entire species, we next turn to the meaning of ''significant'' to determine the threshold for when such an independent basis for listing exists.

Although there are potentially many ways to determine whether a portion of a species' range is ''significant,'' we conclude, for the purposes of this finding, that the significance of the portion of the range should be determined based on its biological contribution to the conservation of the species. For this reason, we describe the threshold for ''significant'' in terms of an increase in the risk of extinction for the species. We conclude that a biologically based definition of ''significant'' best conforms to the purposes of the Act, is consistent with judicial interpretations, and best ensures species' conservation. Thus, for the purposes of this finding, a portion of the range of a species is ''significant'' if its contribution to the viability of the species is so important that, without that portion, the species would be in danger of extinction.

We evaluate biological significance based on the principles of conservation biology using the concepts of redundancy, resiliency, and representation. *Resiliency* describes the characteristics of a species that allow it to recover from periodic disturbance. *Redundancy* (having multiple populations distributed across the landscape) may be needed to provide a margin of safety for the species to withstand catastrophic events. *Representation* (the range of variation found in a species) ensures that the species' adaptive capabilities are conserved. Redundancy, resiliency, and representation are not independent of each other, and some characteristic of a species or area may contribute to all three. For example, distribution across a wide variety of habitats is an indicator of representation, but it may also indicate a broad geographic distribution contributing to redundancy (decreasing the chance that any one event affects the entire species), and the likelihood that some habitat types are less susceptible to certain threats, contributing to resiliency (the ability of the species to recover from disturbance). None of these concepts is intended to be mutually exclusive, and a portion of a species' range may be determined to be ''significant'' due to its contributions under any one of these concepts.

For the purposes of this finding, we determine if a portion's biological contribution is so important that the portion qualifies as ''significant'' by asking whether, *without that portion,* the representation, redundancy, or resiliency of the species would be so impaired that the species would have an increased vulnerability to threats to the point that the overall species would be in danger of extinction (i.e., would be ''endangered''). Conversely, we would not consider the portion of the range at issue to be ''significant'' if there is sufficient resiliency, redundancy, and representation elsewhere in the species' range that the species would not be in danger of extinction throughout its range if the population in that portion of the range in question became extirpated (extinct locally).

We recognize that this definition of ''significant'' establishes a threshold that is relatively high. On the one hand, given that the consequences of finding a species to be endangered or threatened in an SPR would be listing the species throughout its entire range, it is important to use a threshold for ''significant'' that is robust. It would not be meaningful or appropriate to establish a very low threshold whereby a portion of the range can be considered ''significant'' even if only a negligible increase in extinction risk would result from its loss. Because nearly any portion of a species' range can be said to contribute some increment to a species' viability, use of such a low threshold would require us to impose restrictions and expend conservation resources disproportionately to conservation benefit: listing would be rangewide, even if only a portion of the range of minor conservation importance to the species is imperiled. On the other hand, it would be inappropriate to establish a threshold for ''significant'' that is too high. This would be the case if the standard were, for example, that a portion of the range can be considered ''significant'' only if threats in that portion result in the entire species' being currently endangered or threatened. Such a high bar would not give the SPR phrase independent meaning, as the Ninth Circuit held in *Defenders of Wildlife* v. *Norton,* 258 F.3d 1136 (9th Cir. 2001).

The definition of ''significant'' used in this finding carefully balances these concerns. By setting a relatively high threshold, we minimize the degree to which restrictions will be imposed or resources expended that do not contribute substantially to species conservation. But we have not set the threshold so high that the phrase ''in a significant portion of its range'' loses independent meaning. Specifically, we have not set the threshold as high as it was under the interpretation presented by the Service in the *Defenders* litigation. Under that interpretation, the portion of the range would have to be so important that current imperilment there would mean that the species would be *currently* imperiled everywhere. Under the definition of ''significant'' used in this finding, the portion of the range need not rise to such an exceptionally high level of biological significance. (We recognize that if the species is imperiled in a portion that rises to that level of biological significance, then we should conclude that the species is in fact imperiled throughout all of its range,

and that we would not need to rely on the SPR language for such a listing.) Rather, under this interpretation we ask whether the species would be in danger of extinction everywhere without that portion, *i.e.,* if that portion were completely extirpated.

The range of a species can theoretically be divided into portions in an infinite number of ways. However, there is no purpose to analyzing portions of the range that have no reasonable potential to be significant *and* threatened or endangered. To identify only those portions that warrant further consideration, we determine whether there is substantial information indicating that: (1) The portions may be ''significant,'' and (2) the species may be in danger of extinction there or likely to become so within the foreseeable future. Depending on the biology of the species, its range, and the threats it faces, it might be more efficient for us to address the significance question first or the status question first. Thus, if we determine that a portion of the range is not ''significant,'' we do not need to determine whether the species is endangered or threatened there; if we determine that the species is not endangered or threatened in a portion of its range, we do not need to determine if that portion is ''significant.'' In practice, a key part of the portion status analysis is whether the threats are geographically concentrated in some way. If the threats to the species are essentially uniform throughout its range, no portion is likely to warrant further consideration. Moreover, if any concentration of threats applies only to portions of the species' range that clearly would not meet the biologically based definition of ''significant'', such portions will not warrant further consideration.

The most serious of the potential threats to California golden trout discussed above in the Summary of Information Pertaining to the Five Factors section are livestock grazing, predation and competition from brown trout, and hybridization issues with rainbow trout. These potential threats generally occur across the species range and are not concentrated in any areas. Even areas that may currently lack one or more of these potential threats remain at some risk from them. The level of risk presented by each of these potential threats has, in the past, been highest in the South Fork Kern watershed. However, recent management actions and restoration activities have ameliorated the risks presented by these potential threats to the extent that they do not present a concentrated level of risk to California golden trout anywhere in its range, including the South Fork Kern watershed. Efforts in place to address these potential threats include the development and implementation of the Conservation Strategy, with its associated management and monitoring requirements (CDFG *et al.* 2004a, pp. 1–4; McGuire *et al.* 2009, entire; Lentz 2011, pp. 1, 2); the ongoing development of a genetics management plan scheduled for completion in June 2012 (Lentz 2011, p. 2); the construction and renovation of the three fish passage barriers restricting movement of brown trout and hybridized fish (Lentz 2011, pp. 1, 2); the eradication of brown trout above the Templeton barrier (Lentz 2011, p. 2); the curtailment of stocking of brown and rainbow trout (with the exception of sterile triploid rainbow trout at Kennedy Meadows) (CDFG *et al.* 2004a, p. 52; Lentz 2011, p.1); and extensive grazing restrictions and effects-monitoring across the range (USFS 1988a, pp. 78–79, 236; USFS 1995, pp. 2, 27; Knapp and Mathews 1996, pp. 816, 817; CDFG *et al.* 2004a, p. 34; McGuire and Sims 2006, p. 17; Ettema and Sims 2010, pp. 58–64).

Of the additional potential threats to California golden trout discussed above under the Summary of Information Pertaining to the Five Factors section, some are more applicable to the South Fork Kern watershed (recreation, fish barriers, beavers, angling, illegal trout transplants, fish stocking, and the New Zealand mud snail), while others are equally applicable to both watersheds (pack stock use, collection of fin tissue samples, whirling disease, fire suppression activities, and climate change). However, for the reasons discussed above in relation to the entire range of the subspecies, none of these activities (either singly or in combination) constitute a level of risk serious enough to bring a local population to the point where it would be in danger of extinction, either now or in the foreseeable future. Accordingly, based on the best available scientific and commercial information, we conclude that the California golden trout is not threatened or endangered in a significant portion of its range. Moreover, the subspecies currently exists throughout its historical range (see Distribution section above), so there is no need to address the question of whether lost historical range is a significant portion of the species' range.

Conclusion of 12-Month Finding

We do not find the California golden trout (or any DPS) to be in danger of extinction now, nor is this species likely to become endangered within the foreseeable future throughout all or a significant portion of its range. Therefore, listing this species as threatened or endangered under the Act is not warranted at this time.

We request that you submit any new information concerning the status of, or threats to, the California golden trout to our Sacramento Ecological Services Field Office (see **ADDRESSES** section) whenever it becomes available. New information will help us monitor the California golden trout and encourage its conservation. If an emergency situation develops for the California golden trout or any other species, we will act to provide immediate protection.

References Cited

A complete list of references cited is available on the Internet at *http://www.regulations.gov* and upon request from the Sacramento Fish and Wildlife Office (see **ADDRESSES** section).

Authors

The primary authors of this notice are the staff members of the Sacramento Fish and Wildlife Office.

Authority

The authority for this section is section 4 of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: September 22, 2011.

Rowan Gould,

Acting Director, Fish and Wildlife Service.

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Part VII

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Drug Enforcement Administration

Carlos Gonzalez, M.D., Decision and Order; Notice

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 11–33]

Carlos Gonzalez, M.D., Decision and Order

On July 18, 2011, Chief Administrative Law Judge (ALJ) John J. Mulrooney, Jr., issued the attached recommended decision (also ALJ). Thereafter, the Government filed Exceptions to the ALJ's decision.[1]

Having reviewed the entire record and the Government's Exceptions, I have decided to adopt the ALJ's recommended rulings, findings of fact, conclusions of law, and recommended order except as discussed below.[2] I will therefore order that Respondent's registration be revoked and that any pending application to renew his registration be denied.

The Government's Exceptions

The Government's Exceptions fall within two categories. First, the Government takes exception to the ALJ's finding that it had not proved that Respondent violated Federal law (the Ryan Haight provisions) by issuing controlled substance prescriptions through the Internet without having conducted ''at least one in-person medical evaluation'' of the patients. Exceptions at 3; *see also* ALJ at 69–71. Second, the Government takes exception to the ALJ's declination to give weight to testimony it elicited regarding several hearsay statements which it offered to prove various material facts (including the alleged violations of the Ryan Haight provisions).

The Ryan Haight Violations

With respect to its first contention, the Government points to various controlled substance prescriptions (typically for steroids) found during an inspection of a Florida pharmacy which list Respondent as the prescriber and the patients as residents of some fourteen States outside of Florida; the prescriptions are on forms bearing the letterhead of three separate entities, which were internet sites through which a person could obtain a prescription for a controlled substance which the pharmacy filled. Exceptions at 2; GX 37. The Government contends that the prescriptions by themselves constitute substantial evidence to support a finding that Respondent violated the CSA, which following the passage of the Ryan Haight Act, prohibits the distribution or dispensing of ''a controlled substance by means of the Internet without a valid prescription,'' and requires that such a prescription be ''issued for a legitimate medical purpose in the usual course of professional practice by * * * a practitioner who has conducted at least one in-person medical evaluation of the patient.'' 21 U.S.C. 829(e).

This is so, the Government argues, because none of the patients who received the prescriptions in GX 37 reside in Florida, and ''it is unlikely that [Respondent] traveled all over the country to conduct physical examinations with these patients'' and ''it is also highly unlikely that these patients traveled from all over the country to see [Respondent] in Florida.'' Exceptions at 3. Based on the respective geographic locations of Respondent and the patients, the Government argues that ''it is clear that these controlled substance prescriptions were issued outside of the usual course of professional practice and lacked a legitimate medical purpose because these patients were not examined by'' him. *Id.* at 4.

Contrary to the Government's position, the prescriptions alone are insufficient to establish that Respondent failed to perform an in-person medical evaluation of the patients. Notably, the Government provided only thirty-seven prescriptions, which were issued to twenty-eight patients, over a period of nearly six months. Thus, this case bears none of the hallmarks of the assembly-line prescribing methods which DEA has frequently encountered in other internet prescribing schemes and the small number of prescriptions does not foreclose the possibility that the patients traveled to Florida to be evaluated by him.[3] *See Sun & Lake Pharmacy, Inc.,* 76 FR 24523 (2011); *William R. Lockridge,* 71 FR 77791 (2006). Moreover, in contrast to other internet cases, the Government did not introduce any evidence showing how the websites functioned (such as an undercover buy) and whether persons were able to obtain controlled substances without undergoing an in-person examination. Nor did the Government produce any other evidence which might have been probative of the issue and met the Administrative Procedure Act's standard of reliability, *see* 5 U.S.C. § 556(d), such as evidence regarding how the websites promoted their service, the lack of documentation of an in-person examination in patient records, or the lack thereof of any patient records. Thus, the prescription evidence alone does not create a permissible inference that Respondent did not physically examine the patients.

The Government further argues that the ALJ erred in holding ''that additional evidence was needed * * * to prove that'' Respondent did not physically examine the internet patients because the evidence stands unrefuted. Exceptions at 4. In support of this contention, the Government also noted that Respondent was subpoenaed and invoked his Fifth Amendment privilege and refused to testify. *Id.* at 4. Unclear is whether the Government believes that Respondent's invocation of his Fifth Amendment privilege entitles it to the adverse inference that he did not physically examine the patients.

As for its contention that Respondent's failure to refute its evidence (in any manner whatsoever) entitles it to a finding that he did not physically examine the patients, the argument ignores that the Government has the burden of proof on the issue. Because its evidence does not create even a permissible inference that Respondent did not physically examine the patients, Respondent had no obligation to refute it.

As for whether Respondent's refusal to testify entitles the Government to an adverse inference that he failed to physically examine the patients identified in GX 37, it is noted that the Government subpoenaed him to testify and obviously Respondent has knowledge of whether he did so. However, in neither its original nor its supplemental pre-hearing statement did the Government state that it intended to elicit testimony from him on this issue. *See* ALJ Exs. 5 & 6. Moreover, at the hearing, when Respondent's counsel informed the tribunal that Respondent intended to assert his Fifth Amendment privilege, the Government did not make an offer of proof. Thus, there is no basis to conclude that the Government would have questioned him about the internet prescriptions, and thus, an adverse inference cannot be drawn on the issue of whether he physically examined the patients.

[1] All citations to the ALJ's decision are to the slip opinion as originally issued on July 18, 2011.

[2] Because it is dictum, I do not adopt the first sentence of the last paragraph which begins on page 56 of the slip opinion and continues on to the following page.

[3] While there was evidence that it exceeds the bounds of professional practice to prescribe narcotics to a pain patient who had not been seen in six months without doing a new history and physical exam, no evidence was presented as to what constitutes a legitimate medical purpose for prescribing steroids and the standards of medical practice for prescribing them. Moreover, that most of the pharmacy's steroid prescriptions were mailed to the patients does not foreclose the possibility that the patients had previously been examined by Respondent.

The Government further argues that its evidence supports the conclusion that Respondent did not physically examine the patients because it also elicited the testimony of a Diversion Investigator (DI) that the prescriptions ''were 'absolutely' the result of the Internet drug-based process used by'' the pharmacy. Exceptions at 4 (citing its Post-Hearing Br. at 29). In its Exceptions, the Government acknowledges that this testimony was hearsay as it was based on the unsworn statements made by two employees of the pharmacy which filled the Internet prescriptions. Exceptions at 5.

Under DEA regulations, a party's exceptions ''shall include a statement of supporting reasons for such exceptions, together with evidence of record (*including specific and complete citations of the pages of the transcript and exhibits*) * * * relied upon.'' 21 CFR 1316.66(a) (emphasis added). The Government's citation to its post-hearing brief does not comply with this requirement, which DEA has previously applied in rejecting the exceptions filed by a respondent. *See Paul H. Volkman,* 73 FR 30630, 30640 (2008), *pet. for rev. denied* 567 F.3d 215 (6th Cir. 2009). Because the Government did not identify which specific hearsay statements it believes should be given weight, this alone provides reason to reject the exception.[4]

The ALJ's Declination to Give Weight to Various Other Hearsay Statements

In addition to the hearsay testimony related above, the Government also takes exception to the ALJ's failure to give weight to hearsay statements made by several other persons. More specifically, these statements included: (1) Those made by four patients of the pain clinic where Respondent practiced, which were related by a Task Force Officer (TFO) who interviewed them; (2) the statements made to the TFO by the co-owners of the clinic; and (3) the statements made by a former employee who had been fired by the pain clinic which were related by the DI.

As for the first category of statements, the Government cites more than 100 pages of transcript and argues that the patients' statements, which were unsworn, were supported by the patient files; however, the Government does not identify the specific statements it believes should have been ''given substantial weight.'' Exceptions at 6. Here again, the Government has not complied with the Agency's regulation and properly presented the exception for review. Beyond that, the Government's contention that the Agency should give weight to these unsworn statements because ''there would be nothing to gain through cross-examination of these * * * clinic patients because [Respondent], in his absence left the clinic operation and the issuing of controlled substances prescriptions to the [clinic] staff and therefore [has] no idea as to what occurred with these patients,'' Exceptions at 6–7, ignores that one of the fundamental purposes of cross-examination is to show that witnesses lack credibility or an accurate recollection of the event. *See McCormick on Evidence* § 19, at 47 (3d ed. 1984) (''For two centuries, common law judges and lawyers have regarded the opportunity of cross-examination as an essential safeguard of the accuracy and completeness of testimony.''). The APA specifically protects this critical right in 5 U.S.C. 556(d), which states in relevant part that ''[a] party is entitled * * * to conduct such cross-examination as may be required for a full and true disclosure of the facts.''

As for the hearsay statements of the clinic's owners and the former employee, the ALJ cited extensive judicial authority discussing when hearsay statements constitute substantial evidence, including two cases which are binding precedent in the Eleventh Circuit. *See* ALJ at 37 (citing *Basco* v. *Machin,* 514 F.3d 1177, 1182 (11th Cir. 2008) and *J.A.M. Builders* v. *Herman,* 233 F.3d 1350, 1354 (11th Cir. 2000)).[5] As the ALJ explained, while hearsay evidence is admissible in administrative proceedings, the weight that can be given such evidence and whether it constitutes substantial evidence ''is an entirely different matter'' and is dependent upon ''the underlying reliability and probative value of the evidence.'' *Basco,* 514 F.3d at 1182 (quoting *U.S. Pipe and Foundry Co.* v. *Webb,* 595 F.2d 264, 270 (5th Cir. 1979)). As set forth in the ALJ's decision, the Eleventh Circuit has held that four factors should be considered in assessing whether hearsay statements are sufficiently reliable. These are: (1) Whether the declarant was unbiased and had no interest in the outcome of the case; (2) whether the opposing party could have obtained the hearsay information prior to the hearing and subpoenaed the declarant for cross-examination; (3) whether the information was inconsistent on its face; and (4) whether the information has been recognized by the courts as inherently reliable. ALJ at 37 (discussing *J.A.M. Builders,* 233 F.3d at 1354).

In its Exceptions, the Government does not even acknowledge either *J.A.M. Builders* or *Basco,* let alone offer any argument that the ALJ misapplied the relevant factors. Indeed, the Government does not cite a single judicial authority that supports its position that unsworn hearsay statements can constitute substantial evidence. However, even if it had, DEA is bound by the precedential authority of a United States Court of Appeals which would have jurisdiction over a subsequent petition for review of the Agency's final decision under 21 U.S.C. 877.

The Government nonetheless argues that other evidence, which is also hearsay, corroborates the testimony at the hearing. More specifically, with respect to the TFO's testimony as to the statements made by the clinic owners in two interviews, the Government argues that audio recordings and supporting transcripts corroborate the TFO's testimony. Exceptions at 7.

This misses the point entirely because the ALJ did not decline to give weight to the TFO's testimony regarding the interviews of the clinic owners because he found the TFO to lack credibility. To the contrary, the ALJ found the TFO to be credible. ALJ at 41. However, the ALJ

[4] In his decision, the ALJ noted that ''[i]t would not be unreasonable for the Agency to interpret the [Ryan-Haight Act] in such a way that a clear and convincing demonstration on the part of the Government that a practitioner has caused controlled substances prescribed and/or dispensed under his or her [registration] to be shipped to a remote, out-of-state location from the * * * registered address would result in a burden of production on the part of the registrant to demonstrate that an in-person physical examination had been conducted.'' ALJ at 71 n.109. I conclude, however, that such a rule is not justified given that the Government has ample means available to it to prove that a registrant failed to perform a physical examination, including by introducing the physician's patient records which it has the power to obtain through either subpoena or an administrative warrant; where such process is issued and no records are provided or a warrant is issued and no records are found, the Government would be entitled to the inference that the registrant failed to perform a physical exam. In addition, the Government can call the registrant as a witness and elicit testimony on the issue, and as explained above, where the registrant invokes his Fifth Amendment privilege, the Government would be entitled to an adverse inference. Finally, the Government can either call patients as witnesses (as it has done in several cases) or obtain sworn statements from them. In the event a potential witness resides more than 500 miles from the place of the hearing, and either the Government seeks to call the witness to provide live testimony or a respondent seeks to cross-examine the witness, the ALJ has authority to move the hearing so that a subpoena can be issued to compel the attendance of the witness and the ALJ can take such testimony through telephone or videoconferencing.

[5] To make clear, the ALJ also relied on the principles set forth in these two cases in declining to give weight to the some of other hearsay evidence such as the statements of the four patients to the TFO.

declined to give weight to this portion of the TFO's testimony because he found the statements of the clinic owners to be inherently unreliable based on the high likelihood that they were motivated by the owners' instinct for ''self-preservation'' and interest in shielding themselves from criminal liability; moreover, because the statements were not sworn, they are not the type which the courts have recognized ''as inherently reliable.'' ALJ at 39. Thus, that the transcripts and audio recording corroborate the TFO's testimony does not cure the fundamental flaws with the underlying hearsay statements to which he testified.[6]

It is acknowledged that the TFO testified that the owners had stated ''that the physician assistants were in charge of seeing patients and prescribing medications, although it was possible that they to some degree communicated with the Respondent through computer equipment at times * * * for him to approve prescriptions,'' *id.,* and that this is corroborated by the testimony at the hearing of the two UCs as to how they obtained their prescriptions. Nonetheless, this does not support reliance on the statement because the third *J.A.M. Builders* factor does not ask whether the hearsay statement is inconsistent with other evidence in the case, but only whether the hearsay statement is inconsistent on its face. Moreover, even if the owners' statements are internally consistent, and the owners could have been subpoenaed, the other factors still counsel against the Agency's reliance on the statements. Thus, the ALJ properly concluded that the statements of the clinic owners could not be relied upon. *Id.*

For similar reasons, the ALJ properly declined to give any weight to a DI's testimony regarding an interview she conducted with a former clinic employee who had been fired. Here again, while there is no evidence that the employee's statement was inconsistent on its face and the employee likely could have been subpoenaed (although the Government offered no evidence as to her whereabouts, notwithstanding that it was the proponent of the evidence), the other factors strongly support the ALJ's declination to give weight to this evidence. Having been terminated, the employee could well have been biased (again, while the Government was the proponent of statement, it did not produce any evidence that she was unbiased), and in any event, her unsworn interview with the DI is not the type of hearsay statement which the courts have recognized is inherently reliable. *See* ALJ at 42.

Accordingly, I reject the Government's various Exceptions to the ALJ's Recommended Decision. However, I agree with the ALJ's findings and legal conclusions that: (1) ''Respondent's prescribing practice fell well below the applicable standard in Florida regarding the controlled substances prescribed and dispensed to the undercover agents, as well as to the patients whose charts'' were reviewed by the Government's Expert, ALJ at 69; (2) ''Respondent employed his [registration] and/or allowed/enabled others to do so in a manner where controlled substances were prescribed and dispensed for other than a legitimate medical purpose or outside the usual course of professional practice,'' *id.,* and thus allowed controlled substances to be ''provided to individuals he never met,'' *id.* at 72; and (3) Respondent's charts include ''out-and-out falsehoods'' and ''failed to provide even the most basic documentation to support his prescribing and dispensing.'' *Id.*

I therefore conclude that Respondent has committed acts which render his continued registration ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). Because Respondent has offered no evidence to rebut this conclusion, I adopt the ALJ's recommended Order and revoke his registration and deny any pending applications.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration BG8251845, issued to Carlos Gonzalez, M.D., be, and it hereby is, revoked. I further order that any pending application of Carlos Gonzalez, M.D., to renew or modify his registration, be, and it hereby is denied. This Order is effective immediately.[7]

Dated: September 29, 2011.

Michele M. Leonhart,

Administrator.

Theresa Krause, Esq., for the Government

Michael Metz, Esq., for the Respondent

RECOMMENDED RULINGS, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

John J. Mulrooney, II, Chief Administrative Law Judge. On February 18, 2011, the Administrator of the Drug Enforcement Administration (DEA or Government), issued[1] an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) immediately suspending the DEA Certificates of Registration (COR), Numbers BG8251845, FG1242471, and FG2021804, of Carlos Gonzalez, M.D. (Respondent), as a practitioner, pursuant to 21 U.S.C. § 824(d) (2006), based on the Administrator's assessment of an imminent danger to the public health and safety. The OSC/ISO also seeks revocation of the Respondent's registrations, pursuant to 21 U.S.C. § 823(a)(4) (2006 & Supp. III 2010), and denial of any pending applications for renewal or modification of registration, pursuant to 21 U.S.C. § 823(f), alleging that the Respondent's continued enjoyment of the privileges vested in those registrations is inconsistent with the public interest, as that term is used in 21 U.S.C. § 823(f). On March 16, 2011, the Respondent, through counsel, timely requested a hearing, which was conducted in Miami, Florida on May 17–19, 2011. The immediate suspension of the Respondent's COR has remained in effect throughout these proceedings.

The issue ultimately to be adjudicated by the Administrator, with the assistance of this recommended decision, is whether the record as a whole establishes by substantial evidence that Respondent's registration with the DEA should be revoked as inconsistent with the public interest as that term is used in 21 U.S.C. §§ 823(f) and 824(a)(4). The Respondent is the holder of DEA practitioner registration, No. BG8251845, which expires by its terms on September 30, 2011. The Respondent surrendered two other registrations, Nos. FG1242471 and FG2021804, prior to requesting a hearing.

After carefully considering the testimony elicited at the hearing, the admitted exhibits, the arguments of counsel,[2] and the record as a whole, I

[6] Here again, the Government did not identify which of the numerous statements made by the clinic owners it believes the ALJ should have given weight to. Exceptions at 7.

[7] For the same reasons which led me to order the Immediate Suspension of Respondent's Registration, I conclude that the public safety requires that this Order be effective immediately. 21 CFR 1316.67.

[1] The Government served the OSC/ISO upon the Respondent on February 23, 2011.

[2] The parties were afforded the opportunity to file post-hearing briefs in this matter. The Government's brief was timely filed on June 14, 2011, but no brief was filed on behalf of the Respondent. The decision to forgo filing a brief has resulted in a record that contains no position from the Respondent on the

have set forth my recommended findings of fact and conclusions of law below.

The Allegations

The OSC/ISO issued by the Government alleges that during the approximate time period of October 2009 through September 2010, the Respondent ''distributed * * * oxycodone, a Schedule II controlled substance, and alprazolam, a Schedule IV controlled substance by issuing prescriptions to several undercover law enforcement officers for other than a legitimate medical purpose or outside the usual course of professional practice.'' ALJ Ex. 1 at 2 (internal quotation marks and parentheses omitted). Furthermore, the OSC/ISO alleges that patients at the Respondent's practice were able to procure similarly illegitimate prescriptions in a similarly illegitimate manner as the undercover officers. *Id.*

Interactions with two undercover officers are alleged in the OSC/ISO. The first undercover officer (UC1),[3] allegedly obtained prescriptions for various controlled pain medications issued from the Respondent's registration despite the Respondent's absence from the office and notwithstanding the fact that he never personally examined him. *Id.* The OSC/ISO also alleges that ''a nurse practitioner who was represented as being a doctor'' examined UC1 cursorily in the Respondent's stead, despite UC1's admission to the nurse practitioner that he had illicitly acquired controlled substances from a friend. *Id.*

The OSC/ISO also alleges that upon a subsequent visit, UC1 obtained prescriptions for, and distributions of, controlled pain medications without the Respondent conducting a physical examination, reaching a diagnosis, or providing a justification for the increase in dosage units and in the face of the UC's admission that he illegally obtained controlled substances from another person prior to the visit. Furthermore, the OSC/ISO charges that on two or more subsequent occasions, controlled substance pain prescriptions emanated from the Respondent's COR to UC1, even though UC1 was not personally examined by anyone and during a time wherein the Respondent was purportedly absent from the office. *Id.*

Regarding the second undercover officer (UC2),[4] the OSC/ISO alleges that while the Respondent was out of the office, UC2, after a cursory examination performed by a physician's assistant, was prescribed controlled pain medications through the Respondent's COR. *Id.* According to the Government, UC2 was issued the prescriptions even in the face of his admission to the physician's assistant that he had illegally obtained controlled substances from his girlfriend. *Id.*

The OSC/ISO also alleges that from February 2009 through December 2009, the Respondent allegedly procured 238,000 dosage units of oxycodone, and from January 2010 through June 2010, he allegedly obtained through purchase 259,000 dosage units of oxycodone at his registered location in Lake Park, Florida.[5] *Id.* at 3.

Subsequent prehearing and supplemental prehearing statements alleged additional facts, including (but not limited to) recordkeeping deficiencies and the illegal prescribing of controlled substances over the Internet in violation of the Ryan Haight Act.[6] ALJ Ex. 6 at 6.

The Stipulations of Fact

The parties, through their respective counsel, have entered into stipulations regarding the following matters:

Stipulation A: The Respondent is registered with the DEA as a practitioner in Schedules II through V under DEA registration number BG8251845 at 7108 Fairway Drive, Suite #120, Palm Beach Gardens, Florida 33418. Respondent's DEA registration number BG8251845 expires by its terms on September 30, 2011.

Stipulation B: On February 23, 2011 the Respondent was personally served with an Order to Show Cause and Immediate Suspension of Registration and was simultaneously arrested on state drug-related felony charges. The state criminal trial is pending.

Stipulation C: Oxycodone is a Schedule II controlled substance pursuant to 21 C.F.R. § 1308.12(b)(1)(xiii) (2010).

Stipulation D: OxyContin is a brand of oxycodone, a Schedule II narcotic controlled substance pursuant to 21 C.F.R. § 1308.12(b)(1)(xiii) (2010).

Stipulation E: Roxicodone is a brand of oxycodone, a Schedule II narcotic controlled substance pursuant to 21 C.F.R. § 1308.12(b)(1)(xiii) (2010).

Stipulation F: Alprazolam is a Schedule IV controlled substance pursuant to 21 C.F.R. § 1308.14(c)(1) (2010).

Stipulation G: Xanax is a brand of alprazolam, a Schedule IV controlled substance pursuant to 21 C.F.R. 1308.14(c)(1) (2010).

Stipulation H: Vicodin is a brand of hydrocodone combination product, a Schedule III narcotic controlled substance pursuant to 21 C.F.R. § 1308.13(e)(1)(iv) (2010).

Stipulation I: Soma is a brand of carisoprodol which is a non-controlled muscle relaxant.

The Evidence

At the hearing, the Government presented the testimony of several witnesses on the issue of the Respondent's medical practice, recordkeeping, and controlled substance prescribing practices. The testimony received during the Government's case-in-chief revealed that three undercover (UC) law enforcement officers infiltrated the North Palm Pain Management Clinic (NPPM) where the Respondent was employed and were able to obtain controlled substances issued under his COR. The Government also presented the testimony of an expert witness who reviewed the files maintained by NPPM on two of the UC officers as well as four charts maintained on other patients of the clinic who voluntarily consented to speak with law enforcement and to have their files examined.

UC Patient Rix

Task Force Officer (TFO) William Schwartz, a sixteen-year veteran of the Sheriff's Office in Broward County, Florida, testified that he has served as a detective for thirteen years,[7] been a designated DEA TFO since 2009, and has participated in thousands of drug diversion investigations.[8] Tr. 592–93, 752. Schwartz made multiple undercover visits to the North Palm Pain Management Clinic (NPPM) under the assumed name Bill Rix (UC Patient Rix). Schwartz wore a wire, the UC

weight that should be accorded the evidence admitted during the proceedings, beyond the arguments made at the hearing in connection with objections. Neither party filed any exceptions or proposed corrections to the transcript, notwithstanding being afforded the opportunity to do so.

[3] Evidence received at the hearing establishes that UC1, as referred to in the OSC/ISO, refers to Task Force Officer (TFO) William Schwartz. TFO Schwartz employed the fictitious name ''Bill Rix'' during his undercover office visits.

[4] Evidence received at the hearing establishes that UC2, as referred to in the OSC/ISO, refers to Special Agent (SA) Jack Lunsford. SA Lunsford assumed the fictitious name ''David Hays'' during his undercover visits.

[5] COR No. FG1242471 is the corresponding registration with this address.

[6] On October 15, 2008, the President signed into law the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act), Pub. L. No. 110–425, 122 Stat. 4820 (2008), which became effective on April 13, 2009 and is codified at 21 U.S.C. § 829(e).

[7] Tr. 656.

[8] TFO Schwartz also testified that he completed the DEA Diversion Investigators Course in 2002 and the Federal Bureau of Investigation (FBI) School in 2007. Tr. 751–52.

visits were recorded, and the recordings and transcripts were received into evidence.

TFO Schwartz testified that he made his first UC visit to NPPM as UC Patient Rix on October 21, 2009 (October 21st visit).[9] Upon arrival, Rix encountered an armed security guard and Donna Palemire, one of two non-physician owners of NPPM. Tr. 598–99. In response to an inquiry from UC Patient Rix, Palemire assured him that a one-and-a-half-year-old MRI report would be sufficient to be admitted to the practice for treatment,[10] asked him to make efforts to locate past pharmacy profile documentation, and referred him to her husband, non-physician NPPM co-owner Anthony Laterza, to discuss ''rejuvenation'' therapy. Tr. 599–600.

The wire transcript and audio recording received in evidence regarding the October 21st visit are consistent with Schwartz's recollection. *See* Gov't Ex. 13. Like Schwartz's testimony, the transcript reflects that in seeking admittance to the clinic as a new pain management patient, UC Patient Rix encountered Palemire, and that she instructed Rix that he needed to furnish an MRI report as a condition precedent to begin treatment. *Id.* at 4. Although UC Patient Rix asserted that he already had a year-and-a-half-old MRI somewhere in his possession, Ms. Palemire advised that the dated MRI would be fine ''for now'' but that he would need to procure a recent one. *Id.* Palemire referred UC Patient Rix to an imagining place for another MRI, and told him to ask for ''Rose.'' *Id.* at 6; *see* Gov't Ex. 40 at 1 (MRI referral). Additionally, Palemire recommended that UC Patient Rix bring in a pharmacy profile and copies of prescriptions that he had received in the past. Gov't Ex. 13 at 7. When UC Patient Rix told Palemire that he did not want the doctor to be put off by his history of having taken 80 mg oxycodone, Palemire reassured UC Patient Rix that the doctor would not be alarmed on that account. *Id.* Palemire explained, ''He * * * I mean she [sic] doesn't have a problem with [o]xycodone, but with [m]ethadone she does. But, if you come on [m]ethadone, she'll probably give it to you, but then kind of wean you off.'' *Id.* UC Patient Rix stated that he was seeking the 30 mg dose, which inspired Palemire to issue a warning that while the Respondent is ''cool'' and ''awesome,'' that Rix should not get himself caught in a lie because the doctor ''doesn't like it.''[11] *Id.* at 7–8. The referral to Laterza for rejuvenation therapy in the form of human growth hormone (HGH)[12] and testosterone is also confirmed by the transcript. *See id.* at 5, 10–11.

TFO Schwartz testified that he again presented to NPPM as Rix two days later on October 23, 2009 (October 23rd visit).[13] Tr. 603. According to Schwartz, Ms. Palemire explained some NPPM paperwork procedures, accepted the fictitious lumbar/thoracic MRI and pharmacy profile he offered as UC Patient Rix, and instructed him to wait for the Respondent's assistant. Tr. 605. According to Schwartz, while waiting to be seen by the assistant, Laterza coached him through the preparation of some paperwork, and advised him to indicate as many health issues as he could. Tr. 605–08. Specifically, the wire transcript indicates that Laterza advised Rix ''to have as many complaints as possible.'' Gov't Ex. 14 at 18.

It was at this point that UC Patient Rix encountered a female identified by Laterza as ''Dr. Betsy.'' Tr. 608. Schwartz later ascertained that ''Dr. Betsy''[14] is not really a doctor at all, but a nurse practitioner named Betsy Sanchez. *See* Tr. 777. Sanchez asked Rix if he had ''[a]ny medical history,'' Gov't Ex. 14 at 62, checked his heart rate and respiration, and applied pressure with her fingers below his navel, Tr. 609–10; Gov't Ex. 14 at 62–63. Nurse Sanchez told Rix that it would not be necessary for him to remove his shirt for the examination. Gov't Ex. 14 at 62. Laterza then left Rix alone with Nurse Sanchez, explaining that his rejuvenation portion of the visit was complete, and that Sanchez was going to ''triage [him] for [his] pain.'' *Id.* at 63.

Sanchez asked UC Patient Rix some questions about his reasons for seeking pain management. Intentionally omitting any reference to ''pain,'' Tr. 790, Rix told her that he was a stunt man, that he experienced some ''stiffness,'' and that as he's getting older he does not ''recover'' as quickly from workouts as he did when he was young, Gov't Ex. 14 at 65; Tr. 618. Rix also told Sanchez that his previous pain clinic had closed up suddenly, rendering his prior charts unavailable.[15] Gov't Ex. 14 at 65, 68. In response to questioning from Sanchez, Rix indicated that his pain was zero out of ten with pain medications, and four or five without. *Id.* at 67; Tr. 784. In this interview with Sanchez, as in the paperwork he filled out, Rix asserted that his discomfort was focused on his neck. Tr. 613; Gov't Ex. 14 at 69. Thus, inasmuch as the fictitious MRI[16] he provided related only to the lumbar/thoracic regions of his back, no objective evidence related to any neck malady was ever presented by this patient. The forms Rix completed also represented his pain levels between zero and a maximum of three and restricted the complaints to his neck.[17] Tr. 613; Gov't Ex. 4 at 5–6. Notwithstanding Rix's written and oral complaints centered on his neck, and his lumbar/thoracic MRI, neither his neck nor his back were examined by Sanchez, Laterza, or anyone else during the visit. Tr. 620–22.

In another, intentionally-engineered anomaly,[18] UC Patient Rix provided Sanchez with a physician name that conflicted with the information he provided on the fictitious pharmacy printout to see if it would generate a reaction from her. Tr. 619, 788–89; Gov't Ex. 14 at 70. It did not. *Id.* Sanchez told Rix that she would review his case ''with the doctor,'' and would ''find out[] when he's coming.'' Gov't Ex. 14 at 70, 72. In the waiting room, Palemire told Rix that the Respondent was in surgery and that Sanchez would ''call [the Respondent], review the chart over

[9] An audio recording and a corresponding transcript were received into evidence. Gov't Ex. 13; Tr. 596.

[10] According to Schwartz, Palemire told UC Patient Rix that she could refer him to an MRI facility if his efforts to locate his 18-month-old MRI proved fruitless. Tr. 600; *See* Gov't Ex. 40 at 1 (MRI referral).

[11] Confusingly, this transcript reflects that Palemire used the terms ''he'' and ''she'' interchangeably.

[12] HGH is not a controlled substance, and under current Agency precedent, a consideration of its handling by the Respondent is irrelevant to the public interest determination that must be made in these proceedings. *See Tony T. Bui, M.D.,* 75 Fed. Reg. 49979, 49988 (2010) (''Because it is not a controlled substance, Respondent's prescribings of [HGH] could not have violated the CSA's prescription requirement.''). Testosterone, by contrast, is an anabolic steroid and a Schedule III controlled substance. 21 C.F.R. § 1308.13(f)(1); *see* 21 U.S.C. § 802 (41)(A); 21 C.F.R. § 1300.01.

[13] A transcript of the wire recording of the visit was received into evidence. Gov't Ex. 14; Tr. 604.

[14] An examination of the wire transcript reveals that Laterza and Palemire go to considerable lengths to refer to Nurse Sanchez as ''Dr. Betsy,'' *see* Gov't Ex. 14, and Nurse Sanchez never corrects anyone in UC Patient Rix's presence or intimates to Rix that she is not a physician, Tr. 823. There is no indication in the record, however, that this was done at the direction of the Respondent. Further, during Sanchez's interaction with UC Patient Rix, she tells him that she is ''gonna review this with the doctor.'' Gov't Ex. 14 at 70; Tr. 796.

[15] Rix, as part of his undercover ruse, described his prior pain clinic to Sanchez as ''the kind of place where you had fifty (50) people in the waiting room, five (5) doctors, and whoever the doctor was available [sic] was who you went to see.'' Gov't Ex. 14 at 71. In fact, Rix told Sanchez that he was ''kinda glad they're closed.'' *Id.* By his description, UC Patient Rix unsubtly painted a picture of a pill mill. This description yielded no additional inquiry or corresponding chart note from Nurse Sanchez.

[16] Gov't Ex. 4 at 30.

[17] A copy of the NPPM patient chart prepared and maintained on UC Patient Rix was obtained by a signed release form and was received into evidence. Gov't Ex. 4; Tr. 613–15.

[18] *See* Tr. 762–63.

the phone and then * * * [Rix would be] good to go.'' *Id.* at 72. During his post-exam wait, Laterza counseled him that when he meets the Respondent (an event that ultimately did not occur during this UC visit), that he should ''[l]ook, talk, walk like you're in pain [and that] I want to see absolute suffering in you.'' *Id.* at 74.

Approximately an hour and a half later, Sanchez informed UC Patient Rix that the Respondent had approved prescriptions for controlled substances, but in lesser amounts than Rix's (fictitious) pharmacy report had indicated he had been receiving in past. *Id.* at 100; Tr. 622–23. Schwartz testified that he watched as Sanchez printed out controlled substance prescription scripts (as well as a script for physical therapy with no recommended or identified source for that modality) [19] that bore the Respondent's printed name. Tr. 624–25. Schwartz also testified that he saw Sanchez write something on or near the prescription scripts, but was unable to tell if she was signing them. *Id.* at 625. Schwartz testified that shortly after receiving the signed scripts (a remarkable development in light of the Respondent's absence from the room where the documents were printed and handed to Rix), he handed them to Palemire, who stepped into a dispensing area, filled the prescriptions, and handed the controlled substances over. Tr. 626–27, 715–16, 723–24; [20] *see* Gov't Ex. 38 at 1(a), 2(a); Gov't Ex. 39 at 4, 6–7. Schwartz left NPPM that day with the dispensed controlled substances and never encountered the Respondent, who he was told, was performing surgery. Gov't Ex. 14 at 71, 99. TFO Schwartz testified that during those visits to NPPM where he did not encounter the Respondent, the layout of the clinic and the open doors (except for the restroom door) gave him confidence that if the Respondent had been on premises, Schwartz would have seen him. Tr. 775–77.

Schwartz returned to NPPM as UC Patient Rix to pick up a lab requisition form on November 2, 2009.[21] There was also a visit where Schwartz introduced another undercover officer to Laterza as part of the operation, and some telephone exchanges related to the logistics of picking up medications. Tr. 638–43; Gov't Ex. 18.

UC Patient Rix finally got to meet the Respondent during the course of his fifth UC visit to NPPM, which occurred on November 21, 2009 (November 21st visit).[22] The November 21st visit started with Laterza opening and explaining the hormone therapy medications and enthanate (a Schedule III controlled substance testosterone medication) that were shipped to Rix in care of NPPM. Tr. 644–46. Laterza agreed to keep the delivered medications refrigerated while Rix was seen by the Respondent. Tr. 644–45.

After a short wait, the Respondent called UC Patient Rix into an examination room. Tr. 646–47. Schwartz testified that the Respondent had the Rix patient chart as the two men entered the examination room. *Id.* at 647. UC Patient Rix explained to the Respondent that he had been seen by ''Dr. Betsy'' and Laterza during his prior visit to NPPM, and that he received controlled pain medications from the former and controlled testosterone from the latter. *Id.* at 647–48. Furthermore, Rix informed the Respondent that ''Dr. Betsy'' had provided him with pain medication at a reduced level from what he had been prescribed by his former pain clinic. *Id.* Rix asked the Respondent about obtaining additional medication for breakthrough pain, acknowledged that he had run out of the pain medication that had been previously issued to him by ''Dr. Betsy'' at his last visit to NPPM, and confessed that he had procured more pain medicine ''from some people.'' *Id.* at 647; Gov't Ex. 19 at 19. Rix also mentioned to the Respondent that his last pain clinic was frequented by ''shady people'' and closed after a Molotov cocktail was thrown through a clinic window. Gov't Ex. 19 at 19. Additionally, UC Patient Rix inquired as to whether the Respondent (his pain management physician) thought that two years was enough for him to train to compete in a triathlon. Tr. 648; Gov't Ex. 19 at 22.

The Respondent, who had the Rix patient chart in hand, absorbed Rix's representation that he had received controlled substances from Laterza and ''Dr. Betsy'' without comment or discernible reaction. Tr. 647–48. Likewise, he did not question Rix about which ''people'' supplemented his controlled substance pain medications when he ran out, why he had previously frequented an unsavory pain clinic, or even why he needed pain medication at all if he felt fit enough to commence a truncated triathlete training regimen. Tr. 647–49. To the contrary, the Respondent's reaction to the input he received from Rix was to issue a script (that was filled by NPPM) increasing his Roxicodone dosage by one additional pill a day from the level set the previous month by Nurse Sanchez, with the reassurance that he generally commences prescribing medication for breakthrough pain at the third visit. Tr. 649, 718, 725; Gov't Ex. 19 at 20; Gov't Ex. 4 at 24; Gov't Ex. 38 at 4(a); *compare* Gov't Ex. 4 at 24 (script for #150 Roxicodone 30 mg issued November 21, 2009), *with* Gov't Ex. 4 at 27 (script for #120 Roxicodone 30 mg issued October 23, 2009). During this November 21st visit, UC Patient Rix was not asked to fill out any additional questionnaires or other paperwork,[23] he was not examined (or even touched) by the Respondent or anyone else at NPPM, no vital signs were taken, and he was never asked about side effects or pain issues. Tr. 649–50. There was no discussion about Rix's fictitious MRI and its facial inconsistencies with his paperwork (neck versus back), and no treatment plan, goals for treatment, risks and benefits, or alternative treatments found their way into the discussion. Tr. 651. In fact, according to Schwartz, during the entire brief encounter, the Respondent was writing in the Rix patient chart or typing on the computer, and only even made eye contact with Rix ''for a few seconds at most.'' Tr. 649. The November 21st UC visit clearly established that the Respondent knew, or should have known (in the unlikely event that he did not already know), that UC Patient Rix was receiving controlled substances at NPPM issued on scripts over his printed name.

Schwartz returned to NPPM on December 18, 2009 (December 18th UC visit) [24] and was seen by Nurse Sanchez. Tr. 661. UC Patient Rix told Sanchez that he had been hospitalized with the flu, lost weight, was working out, and only had three out of ten pain, but would like some breakthrough medication based on the Respondent's previous encouragement that breakthrough pain medication prescribing could commence at the third visit. Tr. 661; Gov't Ex. 24 at 8–11. When questioned on the issue of pain level, UC Patient Rix told Sanchez that ''[i]t's not that it gets so bad, it's just that

[19] Tr. 627.

[20] While later in his testimony TFO Schwartz misidentified pictures depicting a bottle of 2 mg alprazolam tablets as dispensed to him on December 21, 2009, the photographs clearly show a dispense date of October 23, 2009. *Compare* Tr. 724, *with* Gov't Ex. 38 at 2(a).

[21] An audio recording and corresponding transcript were received in evidence. Gov't Ex. 15; Tr. 631.

[22] An audio recording and corresponding transcript were received in evidence. Gov't Ex. 19; Tr. 644.

[23] Schwartz testified that as UC Patient Rix, he was never asked to fill out another form after the October 23rd visit. Tr. 649.

[24] An audio recording and corresponding transcript were received in evidence. Gov't Ex. 24; Tr. 660.

I run out.'' Gov't Ex. 24 at 10. Rix even asked if the three of ten number pain assessment he provided was appropriate. *Id.;* Tr. 662. Sanchez demurred on Rix's request for breakthrough pain medication, emphasizing to Rix that the Respondent had just increased his dosage. Tr. 661–62, 800; Gov't Ex. 24 at 11. Again, this UC visit, like the visit before it, did not include any type of physical exam, treatment plan, objectives and goals discussion, medication risks and benefits discussion, alternative pain treatment modalities, or follow up on the previous script that recommended a physical therapy consult. Tr. 663–64. At Sanchez's command, the examination room printer yielded the same compliment of prescription scripts for controlled substances that had been produced by the Respondent on the previous visit. Tr. 665; *see* Tr. 719–20, 724, 727–28, 800–01; Gov't Ex. 38 at 2(a), 11(a), 12(a), 13(a); Gov't Ex. 39 at 22, 26. Sanchez wrote something on the prescription scripts, and the visit ended with controlled substance prescriptions being authorized and dispensed, and without the Respondent making an appearance.[25] Tr. 665.

The next NPPM visit by UC Patient Rix occurred on January 11, 2010.[26] Tr. 666. Upon UC Patient Rix's arrival at NPPM, Palemire told him that the Respondent was not in the office because his wife was in the hospital giving birth, but that because Rix was ''an established patient,'' he would not need to see the Respondent to get his controlled substance prescriptions. Tr. 671; Gov't Ex. 26 at 6. At Palemire's direction, Rix left the clinic and telephoned back on two occasions to query when he could return. Tr. 668; Gov't Ex. 25. On the second call, Palemire told Rix that he could come in. Gov't Ex. 25 at 3; Tr. 668. Palemire handed Rix two controlled substance prescription scripts and dispensed the medications. Tr. 671–72, 728–29; Gov't Ex. 26 at 15; *see* Gov't Ex. 4 at 18; Gov't Ex. 38 at 13(a), 14(a).

Schwartz did not return to NPPM for six months. On July 22, 2010, UC Patient Rix visited NPPM and told Palemire he has been away in California starring in films.[27] Tr. 679. After a brief conversation, Palemire handed UC Patient Rix three controlled substance prescriptions. Tr. 680. Although Rix conversed with an individual named ''Ted'' regarding rejuvenation therapy, he never met with any medical professional during this UC visit. Tr. 681. He was not asked anything further about his extended absence from the practice or what treatments and/or medications he received during the hiatus. No one asked if he had been taking medication during that time, or if not, how well (or poorly) he was able to manage his activities of daily living without the benefit of controlled substance medications.

The testimony presented by TFO Schwartz was sufficiently detailed, consistent, and plausible to be found fully credible. Schwartz's demeanor appeared forthright and candid, and although his recollection of the relevant events was excellent, he demonstrated a consistent readiness to not acknowledge elements of the case where he was in any way unsure (*e.g.,* whether Nurse Sanchez was affixing a signature to prescription scripts in his presence).

A patient chart maintained by the Respondent's practice on UC Patient Rix was received into evidence. Gov't Ex. 4. The chart contained what the evidence established to be a compliment of forms and documents that are generally common to other patient charts from the Respondent's practice that were also admitted into evidence. These forms are collected, completed, and/or executed by the patient during initial intake procedures. *See* Tr. 617. These intake documents include: (1) A patient sign-in sheet; (2) a patient information form (Patient Intake Form); (3) a consent to treat and guarantee of payment form; (4) a Brief Pain Inventory (Pain Inventory); (5) a Patient Medication Management Agreement (Pain Med Contract); (6) a Contract for Long-Term Use of Opioid Analgesic (Opioid Contract); (7) an advisal to patients regarding possible criminal consequences under state law associated with acts of drug-diversion-related activity and consent for the Respondent's practice to cooperate in law enforcement efforts associated with diversion; (8) an advisal to patients regarding possible consequences of lost medication; (9) a HIPAA [28] notice to patients; and (10) a driver's license photocopy. Gov't Ex. 4 at 2–14, 34, 36; Tr. 615–17. Additionally, the chart contained forms that were completed by the Respondent and/or personnel at the practice, such as a Patient Reassessment Opioid Analgesic 4–A's+ Chart Note (Chart Note), as well as progress note pages (Progress Note Form), imaging reports, and copies of prescription scripts. Gov't Ex. 4 at 15–33, 35; *see* Tr. 17–18, 21.

In the Patient Intake Form, UC Patient Rix listed his occupation as an actor, described the purpose of the visit simply as ''pain,'' and he wrote that he heard of the Respondent's practice through a ''friend/word of mouth.'' *Id.* at 3. Rix responded on the form that he was not involved in an auto accident. *Id.* Under a section labeled ''MEDICAL HISTORY: (CHECK ALL THAT APPLY),'' concerning a legion of listed medical ailments, conditions, diseases, and symptoms, Rix declined to identify a single malady, and responded that he had no allergies. *Id.*

The Pain Inventory consists largely of questions prompting the Respondent to rate his pain and how it interferes with daily activities and quality of life on a ten-scale (with zero representing no pain and ten amounting to ''pain as bad as you can imagine''). *Id.* at 5–6. UC Patient Rix affirmatively indicated therein that he experienced pain on the same day different from ''everyday'' pain, and signaled that he experienced neck pain by circling the corresponding anatomical representation on a diagram. *Id.* Underneath the diagram, Rix expressed that his pain in the last twenty-four hours had been constant, to wit: he rated his pain at its least, worst, average, and at present all as a three. *Id.* Also within the last twenty-four hours, Rix marked that he had experienced no pain relief (zero percent) from pain treatments or medications, despite reporting in an adjacent area that he was receiving oxycodone 30 mg, oxycodone 15 mg, and Xanax for his discomfort. *Id.* The next array of seven questions inquired into the level of interference that the patient's pain caused with routine functions. *Id.* The scale employed also ranges from zero (does not interfere) to ten (completely interferes). *Id.* To these metrics, UC Patient Rix variably fixed his pain between one and three on a ten scale, and in another portion of the form, characterized his pain as ''aching'' that has lasted more than a month. *Id.* at 6. Regarding the kinds of things that improve his pain or make it worse, Rix wrote in respectively ''medication'' and ''no medication.'' *Id.* At another part of the form, Rix declined to circle any of a large number of symptoms. *Id.*

The fictitious reports supplied to NPPM by Schwartz are in the Rix chart.

[25] Schwartz testified that he did not know if any of the scripts issued to him during any of his visits to NPPM were pre-signed. Tr. 812.

[26] An audio recording and corresponding transcript were received in evidence. Gov't Ex. 26; Tr. 670. An audio recording and transcript of a phone call to NPPM by UC Patient Rix wherein he attempted to negotiate an earlier refill visit date was also introduced into evidence. Gov't Ex. 28; Tr. 676. Rix convinced Palemire to advance the visit from January 16th to the 11th. *Id.*

[27] An audio recording and corresponding transcript were received in evidence. Gov't Ex. 31; Tr. 678.

[28] Health Insurance Portability and Accountability Act of 1996.

The fictitious MRI report reflects some multilevel mild thoracic and lumbar spondylosis, that there is no evidence of cord injury, and that there was no evidence of fracture history. *Id.* at 31. The fictitious pharmacy history indicates five prescriptions for controlled substances filled on two occasions during non-consecutive months and prescribed by two different doctors.[29] Gov't Ex. 4 at 33. A handwritten note across the bottom of the report reads ''South FL Pain,'' ''Moved to Pain Manager,'' ''Broward Co.'' *Id.*

During the October 23rd examination, Nurse Sanchez prepared a Chart Note. Gov't Ex. 4 at 28–29. Under a section denoted ''Current Analgesic Regimen,'' Sanchez wrote oxycodone 30 mg #210, oxycodone 15 mg #90, and Xanax 2 mg #30, with a note in the left margin signifying that they were all last filled in September 2009 (the month before this visit). *Id.* Under a section styled ''Analgesia (average/best/worst pain intensity; % pain relief),'' is found ''best 0/10'' and ''worst 4/10.'' An ''Activities of Daily Living (functional status/relationships/mood)'' section does not list any activities of daily living, but does contain the phrase ''stunt man.'' *Id.* Zeros are entered in sections entitled ''Adverse Events (type/severity),'' and ''Aberrant Drug-Related Behaviors (type/severity).'' *Id.* ''MRI 5/08 -> mild spondylosis'' are inscribed under ''Monitoring Tests/Reports (urine screen/pill counts/other).'' *Id.* at 29. UC Patient Rix's physical and psychological assessment does not contain any diagnoses, but does state that Rix is ''pleasant.'' *Id.* Sanchez's notes related to the physical examination are not entirely legible, but do include a notation that UC Patient Rix is 38 years old, is in no apparent distress, and has clear lungs. *Id.* Below the physical examination findings is a front and back body sketch, with X's drawn upon the neck and lower back of the posterior depiction. *Id.* Further below the sketches is a section entitled ''Action Plan (continue/adjust/discontinue therapy),'' wherein the controlled substances that were ultimately prescribed to Rix that day (''Roxi 30 mg #120'' and ''Xanax 2 mg #30'') are indicated. *Id.* In a space designed for the medical professional to enter additional comments, Sanchez wrote the word ''obtain.'' *Id.*

The Government presented testimony and a written report from Mark A. Rubenstein, M.D., FAAPMR, FAAEM. Tr. 24–25; Gov't Ex. 11. Dr. Rubenstein, a Florida-licensed physician and academic, whose qualifications include a board certification in Physical Medicine and Rehabilitation with a subspecialty certificate in Pain Medicine, as well as extensive experience serving as a medical expert to multiple entities in varied litigation forums,[30] was offered and accepted as an expert in the area of pain management. Tr. 21, 129; *see* Gov't Ex. 10. Rubenstein testified that he was compensated at a rate of $750.00 per hour for his testimony, $500.00 per hour for his preparation time, and that there was no cap fixed on the compensation arrangement. Tr. 118.

Dr. Rubenstein's report and testimony set forth his professional evaluation of six patient charts seized from the Respondent's practice, including the chart maintained on UC Patient Rix. Tr. 27. As a preliminary matter, it is worthy of note that the format of Dr. Rubenstein's report was confusing and singularly unhelpful. While a critical objective of securing expert assistance is to aid the trier of fact in analyzing and processing material that can benefit from expertise beyond the ken of the ordinary citizen, Dr. Rubenstein's report is disorganized, unfocused, and written in a manner that bespeaks a free association narration of documents and other items provided to him by the Government in no particular order. A principal reason for the difficulty in utilizing the report undoubtedly comes from the manner of its genesis. Rubenstein testified that over time he has developed a relationship with the Florida State Attorney's Office wherein he would review files and provide whatever opinions he felt the documents warranted, with scarce guidance regarding a specific mandate. Tr. 28–29. Moreover, Rubenstein was asked to review a mass of paper wherein patient charts that were eventually properly admitted into evidence are interspersed with DEA investigative reports and other documents that were not. Tr. 35; Gov't Ex. 12. The exhibit that contained the documents reviewed by Dr. Rubenstein was admitted into evidence in these proceedings as a single exhibit (Expert Review Package), Tr. 28–29, for the singular purpose to enable a review over whether particular facets of his opinions regarding the UC operations were informed by properly admitted evidence, Tr. 34–35. In reviewing Rubenstein's report, it was often difficult to determine whether he was relying upon information procured from a patient chart, a UC visit recording, a DEA investigatory report, or even a conversation with an agent[31] that was not an admitted part of the record in this case, and expert opinions were drafted in a manner that made it challenging to ascertain whether a single patient, several patients, or overall trends were the object of the opinion. The absence of focus that defines the pages that were submitted by the Government as the purported report of an expert severely detracted from the benefit that Dr. Rubenstein's expertise could have yielded. The disjointed nature of the report was certainly not ameliorated by Dr. Rubenstein's almost perpetual need to refer to it during his testimony.

An example of the difficulty in the manner in which Dr. Rubenstein's analysis was procured, evaluated, and presented was his observations and conclusions on the UC Patient Rix chart regarding what he perceived to be a 50-second physical exam during the October 23rd UC visit that was limited to a pupil examination. Gov't Ex. 11 at 1. Nowhere in the admitted exhibits or testimony (beyond the Expert Review Package) is the October 23rd UC visit limited to this time period and scope. Thus, this opinion cannot be used here to determine whether the Respondent's controlled substance prescribing practices were unsatisfactory.

On the UC Patient Rix chart, Rubenstein's report and his testimony criticized the practice at NPPM for introducing Nurse Sanchez as ''Dr. Betsy.'' Tr. 30. Rubenstein found this to be misleading. *Id.* As discussed elsewhere in this recommended decision, the record is not sufficiently developed on this point to ascertain the extent (if any) that this feature should impact the decision as to whether the revocation of the Respondent's COR is in the public interest. While true, as discussed above, that Rix did indicate to the Respondent that he had been previously seen and was issued controlled substances by ''Dr. Betsy,'' and was not corrected on the issue of her title, it is not clear that this was a matter that reflected controlled substance prescribing at or below the standard recognized in Florida. Stated differently, it is not Sanchez's moniker among NPPM patients that is as important here as whether the Respondent was permitting her to make controlled substance prescription decisions under his COR number. Dr. Rubenstein was unambiguous on his expert opinion that the prevailing medical standard in Florida requires

[29] This is yet another none-too-subtle reference to possible doctor shopping and a potential red flag of possible diversion that received no discernible heightened scrutiny during the visit or in the patient chart.

[30] Tr. 129.

[31] *See* Tr. 37.

that a physician must actually meet a patient prior to prescribing controlled substances, and must be physically present at a facility where controlled substances are being prescribed. Tr. 36–43. This is so, according to Dr. Rubenstein, even where medical professional ''extenders'' such as nurse practitioners or physician's assistants are utilized to take vital signs and/or conduct portions of physical examinations. Tr. 41–42.

According to Schwartz's credible testimony, he made ten visits to NPPM and received controlled substances on five of those. He met with Nurse Sanchez (not the Respondent) for the first time during the (2nd) October 23rd UC visit and got controlled substances; he met with the Respondent (for the first and only time) on the (5th) November 21st UC visit and got controlled substances; he met again with Nurse Sanchez on the (6th) December 18th UC visit and got controlled substances; he met only with Palemire on the (7th) January 11th visit and got controlled substances; and on the (10th) July 28th visit, Rix met with a non-medical office staffer named ''Ted'' and once again got controlled substances. Thus, Dr. Rubenstein's professional opinion that the controlled substance prescribing realized under the Respondent's COR was done without the Respondent present and fell below the Florida medical standards is clearly factually supported in the current record, and as discussed, *infra,* stands unrebutted. It is likewise clear that (at least) as of Rix's fifth visit where he met the Respondent for the first and last time, the Respondent knew that Rix was a patient who was procuring controlled substances under his COR by meeting with Nurse Sanchez and Mr. Laterza. The only reasonable factual inferences that can be drawn are that either the Respondent was aware that Nurse Sanchez was prescribing under his COR, or that on the fifth visit he learned about that situation and voluntarily endured it for the subsequent visits. Accordingly, the Respondent knew or should have known that Nurse Sanchez and others at NPPM were authorizing controlled substance prescriptions under his COR. In light of the fact that no surprise was expressed by the Respondent to UC Patient Rix when the latter explained to the former that he had seen ''Dr. Betsy'' and Laterza for his prior visit and received controlled substances (in the unlikely event that these statements from Rix presented an unexpected anomaly or concern to the Respondent), a glance at the Rix patient chart that the Respondent had in his hand would have provided absolute clarity.

In his testimony, Rubenstein characterized the physical exam performed on Rix as ''suboptimal.'' Tr. 36. In particular, Rubenstein noted that although ''the patient complained of neck and back stiffness * * * the neck and back were never palpated or even examined and * * * no detailed neurologic or musculoskeletal examination was performed.'' *Id.* Similarly, Rubenstein's report noted that ''no neurologic or musculoskeletal examination [was] performed,'' and that ''no objective abnormality [was] ever identified during the limited, brief and suboptimal physical examination.'' Gov't Ex. 11 at 2. The brevity and scarce content of the physical examination were credibly detailed by TFO Schwartz, thereby equipping this unrebutted expert opinion with a sufficient factual evidentiary basis in the record for reliance.

Rubenstein's report also observed that although the chart reflected a prescription for physical therapy, ''there was no recommendation to a specific therapist, a diagnosis, a type of physical therapy, frequency, duration, goals, etc.'' *Id.* In his report, Dr. Rubenstein concluded that the treatment observed during the October 23rd Rix office visit

> Does not represent even minimal standards to justify controlled substances, and there would be no basis to prescribe highly addictive medications such as oxycodone 30 mg in large quantities as well as Xanax 2 mg based on the history provided or the physical examination performed [and that] [t]his represents a deviation from the standard of care.

Id.

Dr. Rubenstein also opined that having UC Patient Rix execute a pain contract, medical management agreement, and an advisal regarding safeguarding opioids at the outset of treatment, before a determination could be made by a physician that opiates were even appropriate, is a practice that falls below the standard of care in Florida. Tr. 43–46; Gov't Ex. 4 at 7–11.

The Rix patient chart also contains progress notes [32] pertaining to Rix's (5th) November 21 UC visit, the first and only time the Respondent was in the same room with UC Patient Rix. Gov't Ex. 4. Rix was seen only by the Respondent, and the handwritten progress notes are signed with the letter ''g.'' *Id.* at 26. The progress notes reflect marks on the form denoting inquiries regarding medication side effects (constipation, loss of appetite, and insomnia checked off), social history (single and living with spouse oxymoronically checked off), daily substance intake (half pack of cigarettes and no alcohol checked off), and physical examination (reflects examination of head, ears, eyes, nose, throat, and abdomen, and that Rix was pleasant and appeared in pain). *Id.* at 25. The form also indicates negative psychological history findings for eight mental health symptoms and ''rarely'' designated for three others. *Id.* at 26. Additionally, the form indicates that Rix had been ''counseled on risks/benefits of [the prescribed medications and] will take exactly as prescribed,'' that ''fish oil/omega 3 was recommended [in a dosage of] 3–6 grams per day,'' that alcohol and soda avoidance was urged ''@ length [sic],'' that Rix was ''strongly advised'' to stop smoking, and responded negatively when asked whether he has used recreational drugs while taking pain medication. *Id.* Schwartz's credible testimony and the transcript of the wire he wore show that none of those areas were the subject of any discussion or examination during the brief encounter. Gov't Ex. 4 at 25–26; Gov't Ex. 18 at 17–22; Tr. 647–53. Thus, to the extent that the progress notes reflect these events, questions, and examination results, they are plainly fabricated.

Under the section labeled ''plan,'' six controlled and non-controlled substances are preprinted in predetermined strengths. The list contains Roxi 30 mg, Roxi 15 mg, Valium 10 mg, Xanax (with a blank next to the strength), Mobic 7.5 mg (non-controlled), and Soma (non-controlled with a blank next to the strength). *Id.* Next to each drug is a corresponding area with a blank field and the words ''continued as prescribed'' next to it. *Id.* Handwritten by the Respondent is a check next to Roxi 30 mg and an ''up'' arrow with the number 150 next to ''continued as prescribed.'' *Id.* Also marked is Xanax for 2 mg. *Id.*

In evaluating this November 21st UC visit, Dr. Rubenstein's report notes that although no physical examination was conducted on Rix during this visit, the office visit form has no patient name and falsely reflects that an examination of the patient's head and other enumerated body parts and organs occurred. Gov't Ex. 11 at 3. Hence, based on the credible testimony of TFO Schwartz and the corroborating transcript received into evidence, these chart notes are plainly untrue.

The UC Patient Rix patient chart contains a progress note prepared in

[32] Although the patient name on this page is left blank, there is adequate, unchallenged record evidence to support a finding that this page was contained in the Rix patient chart provided to TFO Thomas by NPPM. *See* Gov't Ex. 4 at 1.

connection with Schwartz's (6th) December 18th UC visit. Gov't Ex. 4 at 22–23. Consistent with Schwartz's credible testimony that his procurement of controlled substances on this occasion was preceded by contact with Nurse Betsy Sanchez and not the Respondent, the progress notes are signed with the letter ''B.'' *Id.* at 23. Suffice it to say that the progress notes prepared by Nurse Sanchez during this UC visit are as distant from the reality of what happened as were the Respondent's recorded recollections of the November 21st visit. In short, the observations set forth in these chart notes are as phony as those concocted by the Respondent regarding the November 21st UC visit.

Dr. Rubenstein's report on the December 18th UC visit notes that this visit also resulted in the issuance of controlled substance prescriptions issued under the Respondent's COR although he was nowhere in sight, and that this visit included neither a physical examination nor even the taking of vital signs. Gov't Ex. 11 at 3. These are factual predicates that find support in the record in Schwartz's credible testimony. Tr. 660–65. The absence of any examination and vital readings did not result in the absence of values regarding those aspects from appearing in the progress notes, which Rubenstein characterizes as ''fraud in the examination scenario.'' Gov't Ex. 11 at 3. Rubenstein also found it remarkable that UC Patient Rix told them his pain was ''not bad'' so long as he has his medication and that Rix asked for advice about what number to volunteer on the pain scale and whether a three would be too low. *Id.* Although Patient Rix informed the practice that he had been in the hospital for a week, lost ten pounds, and had been unable to keep food down, conditions that could have precluded his ability to finish the medication that had been prescribed on the prior visit, Nurse Sanchez presented him with prescriptions for #150 Roxicodone 30 mg and #30 Xanax 2 mg, both of which were dispensed by Ms. Palemire. *Id.* at 3–4.

The Rix patient chart contains a progress note prepared in connection with the (7th) January 11 UC visit by UC Patient Rix. Gov't Ex. 4 at 19–20. Although, according to the credible testimony of TFO Schwartz, UC Patient Rix was issued controlled substances after consultation with only Palemire (and no medical professional), Tr. 681, the progress note reflects recorded observations, history, advice, and counseling reminiscent of previous (equally false) versions prepared in connection with other visits by the Respondent and Nurse Sanchez. The form is signed with the letter ''g.'' Gov't Ex. 4 at 20.

The progress note documentation maintained in the chart in connection with the (8th) July 22nd UC visit was unnamed, incomplete, and unsigned. Gov't Ex. 4 at 16–17. Like the UC visit that preceded it by six months, the credible testimony of TFO Schwartz established that he encountered no medical professional during that visit, no history of any kind was taken, and no examination took place—the false entries on the form to the contrary notwithstanding. Tr. 681. The progress note bore no reference to the fact that Rix had not been to the practice in six months. Gov't Ex. 4 at 16–17.

Regarding this final UC visit to NPPM by Rix as a pain patient[33] and the lengthy hiatus that preceded it, Dr. Rubenstein testified that after such a long absence from the practice, that a detailed history and inquiry must precede a determination by the physician that controlled substances are an appropriate course, and that the documentation in the chart did not support such steps. Tr. 48–54. Not only did Schwartz's credible testimony and the chart note support the absence of such a probing inquiry, Schwartz's testimony establishes that the decision to prescribe controlled substance pain medication on the Respondent's COR was made by, or with input from only, Palemire, who is not a medical professional. Rubenstein opined that ''based on the records presented * * * there was no basis to prescribe oxycodone or Xanax based on the history provided or the physical examination performed.'' Tr. 50. Dr. Rubenstein elaborated that this was of particular importance in a case such as Rix presented, where the two medications have potentially dangerous interactions that can result in respiratory depression, and that a determination as to whether a patient has been off opioids for that period of time (and by virtue of that abstinence would be treated as opioid naïve) must be made by a qualified practitioner. Tr. 51–54.

Addressing the controlled substance prescribing regarding UC Patient Rix, Dr. Rubenstein testified that the amount of controlled substances prescribed was inconsistent with the relatively low levels of pain complaints. Tr. 55. According to Rubenstein, the conflict between the complaints in the neck and the MRI addressing the back made it unclear as to what body part was even being treated for pain. Tr. 56. Moreover, Rubenstein was troubled by the absence of any indication that in the face of stated back and neck complaints, no neurologic or musculoskeletal exam had been performed and that there was no evidence that UC Patient Rix's back and neck had been palpated. Tr. 56–57. Dr. Rubenstein testified that after reviewing the patient chart prepared on UC Patient Rix, it was his opinion that the care rendered to Rix at NPPM did not meet the standard of care required in pain management for the following reasons:

> There was not an adequate physician/patient relationship. The medications were excessive given the lack of appropriate history or physical examination, the lack of identified pain generators and the lack of patient complaints or objective abnormality that would have correlated to the requirement or consideration of said medications. The medications were excessive in dose and frequency given the underlying problem and there were issues with who performed the evaluation of the patient.

Tr. 59.

UC Patient Hays

Retired Special Agent (SA) Jack Lunsford testified that prior to his retirement, he had served over twenty-two years as a DEA special agent. Tr. 136. Lunsford testified that he made two UC visits to the Respondent's practice, on June 29, 2010 and July 27, 2010, respectively, under the assumed name David Hays (UC Patient Hays), and that (like TFO Schwartz's visits as Rix) both visits were recorded through the use of a bodywire and transcribed. Tr. 137, 139, 176.

SA Lunsford testified that at his initial visit to NPPM, which occurred on June 29, 2010,[34] he was greeted by an armed security guard who told him that the Respondent was not in and that he did not know whether the Respondent would return. *Id.* SA Lunsford testified that he lined up at the reception counter. Tr. 138–40. The attendant at the reception counter likewise informed UC Patient Hays that the Respondent was not available, but stated that a ''Dr. Derrick'' could see him instead.[35] Tr. 140. He was then instructed to produce his MRI report and driver's license and was asked to sign a log and fill out paperwork while he waited for his examination. Tr. 140–41.

A copy of the patient chart maintained by the Respondent's office on UC Patient Hays reveals the same

[33] TFO Schwartz returned two more subsequent times, on July 23rd and July 28th, to order and pick up anabolic steroids.

[34] An audio recording and corresponding transcript were received in evidence. Gov't Ex. 30; Tr. 176.

[35] Derrick Davis is a physician's assistant who was employed by NPPM. Tr. 893.

compliment of standard forms present in the other patient charts received into evidence [36] and has chart entries reflecting his initial June 29th UC visit. Gov't Ex. 8. On the Patient Intake Form, UC Patient Hays indicated that he was referred to the practice by his ''friend Mark,'' and that the purpose of his visit was ''to see about medication.'' *Id.* at 2. The Pain Inventory reflects a range of pain from only 1–3 on a 10 scale, that he has endured this discomfort for ''more than a month,'' that he treats his pain with rest, hot showers, and over-the-counter Advil and Motrin, and that remedies have provided him with 30% relief (from his 1–3 out of 10 pain). *Id.* at 4–5. Diagonal lines were drawn on a Pain Med Contract that was provided to Hays, thereby alerting the patient that it is not necessary to provide either his ''[g]oals for taking opioid medications'' or ''[m]edication and proposed duration of use.'' [37] *Id.* at 6. Similar lines were pre-drawn on the provided Opioid Contract through areas designated for the patient to list ''[t]he reasons [he] has pain,'' and the specific opioid medications and doses prescribed. *Id.* at 10. Lunsford testified that these diagonal marks were not made by him. Tr. 143.

A review of the transcript prepared in connection with the June 29th UC visit,[38] to which SA Lunsford's testimony largely parallels, reveals that UC Patient Hays never interacted with the Respondent, but was seen by a physician's assistant (PA) who identified himself as ''Derrick.'' [39] Gov't Ex. 30 at 9. When, in response to an inquiry from the PA, Hays informed that he ''had not really injured'' his back, the PA told him that he was mistaken and that his back was injured, and pointed to his MRI report. *Id.;* Tr. 164. The lumbar MRI report found within the UC Patient Hays chart reflects ''[s]mall disc protrusions at L4–5 and L5–S1 with bulging of the annulus [with] [n]o nerve root effacement * * * identified at either level'' and ''[r]ecommend[s] correlation with the clinical symptoms and neurologic exam to assess the significance of the * * * findings.'' Gov't Ex. 30 at 15.

UC Patient Hays told the PA that he was a pressure washer by occupation and that his employment, as well as the mechanic work he performs on his motorcycles, results in his lifting heavy items. Gov't Ex. 30 at 10. While Hays initially told the PA that he had never been in a motor vehicle accident, *id.,* he later admitted to rear-ending a car in a motor vehicle. *Id.* at 17.[40] Regarding medication, consistent with his responses on the Pain Inventory, Hays told the PA that he has been treating his back discomfort with ''Advil and Motrin sometimes.'' *Id.* at 11; *see* Tr. 163. When asked pointedly whether he had tried other medications ''whether you got it off the street or [from] a friend,'' UC Patient Hays conceded that his girlfriend has given him oxycodone in both 30 and 15 mg strength, as well as Xanax, but that this was causing a problem because his girlfriend actually had a legitimate need for her prescribed pain medication and Hays, by his own admission, only had ''you know, a few * * * I guess relatively minor health issues.'' *Id.* at 11–12; *see* Tr. 150, 153. As the discussion between patient and PA progressed, Hays made it clear that taking his girlfriend's medication has caused some relationship disharmony because she is happy ''[w]ell, because she's medicated [and] I haven't been so much.'' *Id.* Hays told the PA that his girlfriend ''wants us to get kind of on a even bases [sic].'' Gov't Ex. 30 at 12. An almost surreal exchange followed wherein the PA (none too discreetly) re-framed the patient's issue as based really in terms of the need for back pain relief, to which the patient finally replied ''You know, [I] haven't really thought about it that way but you may be right,'' and the PA ultimately announced ''Okay. Well, let's see what we could do to make you happier and make you guys really connect, okay?'' *Id.* at 12–14; *see* Tr. 150. The PA conducted a discussion with the patient regarding potential medication side effects and risks of addiction. Gov't Ex. 30 at 15–16, 24; *see* Tr. 151, 165. A discussion on pain level followed, wherein UC Patient Hays repeatedly confessed that his earthly existence has been virtually unknown to feeling or even observing genuine pain, and is finally coaxed into agreeing that without medication, his pain level is about a three out of ten. Gov't Ex. 30 at 17–18; *see* Tr. 151. When pressed on the issue of pain, UC Patient Hays explained to the PA that ''my back doesn't feel all that bad,'' that ''I mean * * * I've drove [sic] over here, I've been sitting around, I walked freely,'' that ''[w]hen I take Advil it works pretty good [and that when] I'm taking that other stuff * * * everything's just, you know * * * [k]inda flat.'' Gov't Ex. 30 at 18; *see* Tr. 151. The PA utters an audible sigh when Hays insists ''[w]ell, my back is really nothing to be worried about.''

The PA, in an obvious testament to his (albeit arguably misguided) perseverance, conducted a physical examination where he took the patient's blood pressure and had him conduct multiple postural pushing and twisting maneuvers, none of which caused the patient to issue any manner of complaint. Gov't Ex. 30 at 23–24; *see* Tr. 150–51. Interestingly, the chart notes in the file that correspond to this UC visit reflect numerous (+) signs that correspond to illegible words, notwithstanding the absence of any complaint by the patient as captured within the transcript. Gov't Ex. 8 at 28. The PA informed UC Patient Hays that he intended to ''talk to the doctor,''[41] and shortly thereafter, the NPPM office staff provided the patient with an appointment card and prescription scripts for #150 Roxicodone 30 mg, #30 Xanax 2 mg, as well as Naprosyn (not a controlled substance), and a prescription script where the word ''consultation'' appears next to the area designated ''drug name,'' and ''see ortho and physical therapy'' appears in the area designated for pharmacy label instructions. *Id.* at 26; *see* Tr. 154. SA Lunsford testified that he recalled the prescriptions being signed with ''some form of initials,'' either something resembling a ''C'' and ''G,'' or just a lone ''G.'' Tr. 154; *see* Gov't Ex. 40 at 25–26, 28–29. According to SA Lunsford's testimony, the issuing physician's name on the script belonged to the Respondent. *Id.* However, no testimony was elicited from Lunsford as to

[36] An exception being the addition in UC Patient Hays' medical file of a copy of a DEA regulation (21 C.F.R. § 1306.13) detailing the permissible conditions for the partial filling of a prescription for a Schedule II substance. Gov't Ex. 8 at 13.

[37] SA Lunsford testified that while he was not certain when the diagonal lines appeared in the chart, they were not added by him. Tr. 143.

[38] While the foundation laid for the introduction of the transcript was certainly not a model for clarity, the document was received into evidence after SA Lunsford testified that it might contain some inconsistencies that did not rise to the level of significant, such as him saying ''Whoa'' but it appearing as ''Wow'' in the transcript. Tr. 169–76. Whatever typos he thought the transcript may possess, SA Lunsford still felt that on balance it was fair and accurate as to what transpired on June 29, 2010. Tr. 171, 175. Moreover, although the tenor of Lunsford's testimony during the authentication evolution gave the impression that the transcript contained typographical errors, the substance of SA Lunsford's recollection of events as expressed through his credible testimony was substantially the same as the version depicted in the transcript.

[39] Although the office staff told UC Patient Hays that he was going to see ''Dr. Derrick,'' the physician's assistant made it clear at the outset of his interaction with Hays that he was a ''practitioner assistant.'' Gov't Ex. 30 at 9; Tr. 149.

[40] As discussed, *infra,* the chart note prepared by the PA in connection with this visit reflects that Hays told him that he had been in a motor vehicle accident; however, UC Patient Hays denied experiencing a motor vehicle accident on his intake form. *Compare* Gov't Ex. 8 at 27, *with* Gov't Ex. 8 at 2.

[41] Gov't Ex. 30 at 26; Tr. 153.

whether he was familiar with, or could identify, the Respondent's signature.[42]

In the evaluation of this UC visit that is set forth in his report, Dr. Rubenstein notes that UC Patient Hays received controlled substance prescriptions on the June 29th UC visit, even though he received only a ''brief exam in terms of cardiac and respirator auscultation'' by a physician's assistant, performed postural maneuver tests ''with full strength and flexibility,'' and was never seen by the Respondent. Gov't Ex. 11 at 5. The report notes that Patient Hays told the physician's assistant that over-the-counter Advil[43] ''works pretty good'' and that his back ''doesn't feel all that bad [and] is really nothing to be worried about.'' *Id.* Rubenstein also found it remarkable that when Patient Hays stated that his back was ''not really injured,'' that the physician's assistant pointed to the patient chart and told him that it was. *Id.* Interestingly, the MRI report that he had provided to NPPM as Patient Hays was actually a report done on SA Lunsford's back. Tr. 143–44, 217, 226. Thus, the diagnosis of a small disc protrusion reflected in the patient chart is actually a diagnosis for Patient Hays that is supported by objective medical evidence. Tr. 217–18.

SA Lunsford's second and final foray into the Respondent's practice as UC Patient Hays occurred on July 27, 2010.[44] Tr. 176. SA Lunsford testified to entering the clinic premises and having brief interactions with a uniformed security guard as well as a receptionist. He presented his Patient Hays driver's license, signed a sign-in sheet (the single paperwork evolution associated with the visit on his part), and paid an office visit fee. Tr. 176–77, 179–80. SA Lunsford then seated himself in the waiting area until called back to the reception counter about an hour later. Tr. 177–78. As revealed in the transcript and Lunsford's testimony, the interaction involved nothing more than a visit at the reception desk that took as much time as needed by the staff person to say, ''There you go,'' and Hays to reply, ''Thank you very much.'' Gov't Ex. 33 at 3. Hays thanked the staff person for wishing him ''a wonderful afternoon'' and the transaction, *id.,* which yielded an identical battery of prescription scripts as the first UC visit, was completed[45]—but for the paperwork. The chart entry reflects a somewhat more elaborate account that (falsely) details UC Patient Hays' denial of side effects and street drug use, his pain and the appearance of his pain, as well as Hays' abnormal posture (spelled ''postue'' in the form), all recorded without an examination of any kind. Gov't Ex. 8 at 24–25. According to Lunsford, he came and left the clinic, and received his controlled substance prescriptions, without suffering the inconvenience that might be caused by interaction with medical personnel of any variety. Tr. 177–78, 246. Lunsford testified that while he was in the waiting room awaiting the issuance of his prescriptions, he saw the Respondent enter the clinic and cross the threshold into the hormone treatment area. Tr. 178–79.

Regrettably, the only observations in Dr. Rubenstein's report relative to UC Patient Hays' second UC visit relate to the nature of the controlled substances dispensed and the fact that no patient name was written on the progress note page. Gov't Ex. 11 at 5. However, in his testimony, Rubenstein offered his conclusion that under the prevailing standards in Florida, the controlled-substance prescribing that was undertaken with respect to Hays was not justified by the information presented to the prescriber. When asked what was missing from the chart that should have been there to support the prescribing evidenced in the case of UC Patient Hays, Dr. Rubenstein responded this way:

> An adequate history and complete physical examination, with any other objective testing to formulate an appropriate treatment plan, which may or may not include medication. In this case, [SA Lunsford] was specifically downgrading his complaints of pain * * * telling the physician's assistant that his back was ''nothing to be worried about.'' Yet high doses of medications were being recommended that were not warranted based on the patient's history. So to justify prescriptions of the agents and any opioid agent at an initial visit, I would want an appropriate history or physical examination that would indicate that there is acute or chronic pain with an objective correlation that would justify such agents, and even so, the amounts and doses of medication would be excessive for an initial visit of the patient.

Tr. 65–66. Dr. Rubenstein opined that the medical care offered to UC Patient Hays (which, in this case was controlled substance prescribing and dispensing) fell below the established standards for medical care in Florida. Tr. 76–77.

Viewed in a vacuum, the controlled substance prescribing conducted at NPPM under the authority of the Respondent's COR was effected by persons other than the Respondent. The evidence presents no serious dispute on that issue. However, the direct, credible evidence from TFO Schwartz that the Respondent was directly informed that UC Patient Rix was previously seen by, and received controlled substances from, Laterza and ''Dr. Betsy,'' with an in-hand patient chart confirming that scenario, casts the NPPM staff interactions with UC Patient Hays in a different light. Under the circumstances presented here, it is reasonable, based on the evidence of record, to conclude that the Respondent was well aware (or should have been) that these and other controlled-substance prescribing actions like these were being taken by various NPPM staff persons under his COR. This is particularly true here, where the Respondent, although called as a witness by the Government at the hearing, asserted the Fifth Amendment and declined to testify. Although the Respondent was an employee of NPPM, he was the master of his COR. His status as an NPPM employee in no way diminished his responsibility to safeguard the authority associated with his COR.

UC Patient Barbaro

SA Joseph Annerino, an agent with two and a half years of experience with DEA, and with a decade of prior experience as a Chicago police officer, testified that he made two UC visits to the Respondent's practice using the name Joe Barbaro (UC Patient Barbaro), that he never met the Respondent or any other physician there, and yet received Testosterone Cypionate[46] under the authority of the Respondent's COR. Tr. 261–62, 287, 311. SA Annerino testified that UC Patient Rix introduced him to Mr. Laterza at NPPM to effectuate the sale of anabolic steroids. Tr. 263.

SA Annerino testified that shortly after being introduced to Mr. Laterza at the first visit on November 16, 2009,[47] Laterza provided quite a bit of information in response to questions he posed about testosterone and HGH, as well as explaining the benefits of hormone replacement therapy (HRT). Tr. 262, 264. The transcript of the first of the UC visits reflects a lengthy conversation with Laterza about

[42] The Government sought to elicit testimony regarding conversations between patients that were overheard by Lunsford as he sat in the waiting area, but inasmuch as there was no link between the Respondent and any of these purported conversations, the testimony was excluded as irrelevant. Tr. 158–63.

[43] Actually, the transcript of this interaction with the physician's assistant reflects that UC Patient Hays told him he had been treating his back with ''Advil and Motrin.'' Gov't Ex. 30 at 11.

[44] An audio recording and corresponding transcript were received in evidence. Gov't Ex. 33; Tr. 182.

[45] Gov't Ex. 8 at 23; Tr. 177–78.

[46] A Schedule III controlled substance.

[47] An audio recording and corresponding transcript were received in evidence. Gov't Ex. 17; 268.

purported benefits of testosterone and HGH treatment and an examination conducted by Nurse Sanchez, who, like in the case of UC Patient Rix, was introduced and answered to the moniker ''Dr. Betsy.'' Gov't Ex. 17 at 40–42; Tr. 273–74. As testified by SA Annerino, Laterza instructed him to complete a personal history form, upon which he declined to put down any physical ailments. Tr. 264–65. As a result, Laterza spent much of his time coaching UC Patient Barbaro on the most advantageous answers to questions asked in the patient information form, even to the point that Laterza personally changed answers provided by UC Patient Barbaro from ''no'' to ''yes.'' Gov't Ex. 17 at 17–19, 36–39; Tr. 265–66, 268–69. At one point, Laterza admonished him that ''if you say no to everything, then the doctor is not going to know what he's treating.'' Gov't Ex. 17 at 37; Tr. 268. SA Annerino testified that an examination was conducted by Nurse Sanchez. Tr. 273; Gov't Ex. 17 at 41. However, SA Annerino testified that none of his discussions with Nurse Sanchez bore upon the subject of testosterone. Tr. 274.

Laterza arranged for UC Patient Barbaro to have his blood drawn at a lab and left a phone message for him four days later wherein he attempted to arrange for a time to ''go over'' Barbaro's ''labs'' with him. Tr. 274, 278, 282; Gov't Ex. 20 at 3. Four days after the phone message, on November 24, 2009, UC Patient Barbaro telephoned Laterza, and the latter explained the blood analysis results to the former in great detail, ultimately advising that ''basically, you are going to need some testosterone'' due to ''deficiencies'' that Laterza identified in the results. Gov't Ex. 21 at 4; Tr. 282–84. On December 9, 2009, UC Patient Barbaro presented himself to the Respondent's practice [48] (following a voicemail from Laterza on November 30, 2009 to pick up his Testosterone Cypionate from the clinic, Tr. 284), and upon little more than stating his (fictitious) name and providing cash, was presented by Ms. Palemire with a box containing a vial of Testosterone Cypionate and a syringe, Tr. 287–88; Gov't Exs. 22–23. While vial of the controlled testosterone reflects that it was prescribed pursuant to the Respondent's COR, Tr. 304, 331–32; Gov't Ex. 38, at 7–A, Laterza made no representations to SA Annerino that he ever consulted with the Respondent about UC Patient Barbaro's treatment, that the Respondent had actual knowledge of his treatment, or that the Respondent personally prescribed the controlled substances or authorized Laterza to issue the prescriptions,[49] Tr. 284, 325–27, 332. Annerino testified that although he obtained controlled steroids issued under the Respondent's COR, the only medical professional he interacted with at NPPM was Nurse Sanchez, and that the first time he ever laid eyes on the Respondent was at the hearing. Tr. 311, 316.

Although Dr. Rubenstein did not review any patient chart associated with the Annerino's UC visits as Barbaro, his testimony was unequivocal that the issuance of controlled substance prescriptions without meeting a patient falls below the Florida prescribing standards. Tr. 36–43. If the evidence of record stood, thus, with no evidence of a direct connection between Laterza and the Respondent, there would be little to recommend wrongdoing on the part of the Respondent based on the testimony of SA Annerino. However, the Respondent's November 21st UC visit and interaction with UC Patient Rix, wherein the former was advised by the latter that he was receiving anabolic steroids through exchanges with Laterza, provides ample support for the proposition that the Respondent knew or should have known that Laterza was consulting and prescribing controlled steroids armed with the Respondent's COR. This is particularly so on this record wherein the Respondent asserted his Fifth Amendment right against self-incrimination and declined to testify although called as a witness by the Government.

Patient Chart Reviews

At the request of the Government, Dr. Rubenstein reviewed charts maintained on four of the Respondent's patients, prepared written comments in his report, and testified at the hearing about his conclusions. Each patient executed a written authorization for the release of their respective chart.

Chart Review: Patient SL[50]

Patient SL's chart reflects that he is a 35-year-old male patient who was treated by the Respondent from April to September of 2010. Gov't Ex. 5. On his Pain Inventory, which he completed and submitted on intake, SL signaled that he was experiencing pain in the 4–8 out of 10 range in his lower back, right knee, and left shoulder, that he had been experiencing the pain for ''over a month,'' and that his treatment with oxycodone 30 mg and Percocet 5 mg, coupled with Xanax for sleep issues, has afforded him relief at a level between 70–100%. *Id.* at 32. Further, the Pain Inventory reflects that while his discomfort is exacerbated by running, excessive walking, and prolonged sitting, that medicine, rest, and therapy provide relief. *Id.* at 33.

The SL patient chart maintained by NPPM contains, *inter alia,* multiple prescriptions authorized under the Respondent's COR for Roxicodone (30 mg) and Xanax (2 mg). *Id.* at 4–5, 11, 14, 23, 27. Dr. Rubenstein's report notes that a sign-in sheet included in the chart contains obviously discrepant dates, that the patient informed the practice that he had been referred ''by a friend,'' that no neurologic or musculoskeletal examinations were ever performed on him at the Respondent's practice, and that he traveled from a remote location to be treated by the Respondent without any obvious explanation for the commute present in the documentation. Gov't Ex. 11 at 15–16. Although at the hearing Dr. Rubenstein testified that there was no apparent reason this patient traveled a distance that Rubenstein guestimated to be about thirty to forty minutes[51] to be treated at NPPM, there was insufficient development of this issue to have the testimony bear on any issue that must be decided here. If thirty to forty minutes was a long distance, there was no evidence presented as to what a reasonable distance might be, or why the distance was or should be gauged in determining whether revoking the Respondent's COR is in the public interest.

Dr. Rubenstein testified that the SL patient file demonstrated what he characterized as a ''deficit in the standard of care.'' Tr. 81. Specifically, Rubenstein noted that the file lacked sufficient documentation to substantiate the need for the controlled substances prescribed, that there were no records from prior physicians, and that no indications that alternative treatments beyond the controlled substances prescribed were ever discussed with the patient. *Id.* at 80–81. Dr. Rubenstein summarized his conclusions in his report as follows:

[48] An audio recording and corresponding transcript were received in evidence. Gov't Ex. 23; Tr. 294.

[49] SA Annerino testified that although a search warrant was executed at the Respondent's practice pursuant to the ''round-up'' for Operation Pill Nation, he was not a part of that evolution and therefore lacks any knowledge as to whether a patient file corresponding to UC Patient Barbaro was ever identified, sought, or recovered. Tr. 272. Dr. Rubenstein's report did not contain an analysis of UC Patient Barbaro's encounters with the Respondent.

[50] Pursuant to a Protective Order issued in this case on May 2, 2011, initials have been substituted for the names of patients. ALJ Ex. 15.

[51] Tr. 82.

The records of [SL] are suboptimal. They clearly do not document the rationale or need for high doses of Roxicodone. At no point was a physical exam ever documented which would have warranted the use of these agents. There was no examination of the right knee or left shoulder consistent with the MRIs. There was absolutely no documentation in the file which would have warranted or substantiated the need for these medications. No other alternatives for treatment of these problems were reviewed. Clearly this represented simply visits to dispense medications. No other records from other providers to document the use and need of these medications [was] reviewed. In summary, this represents a deficit in the standard of care.

Id. at 16.

Chart Review: Patient CC

Patient CC's chart reveals that she was treated at NPPM from May to October of 2010, and that during that time she received multiple prescriptions for controlled substances, including (but not limited to) multiple prescriptions for Roxicodone (30 mg and 15 mg doses) and Xanax (2 mg). Gov't Ex. 6 at 5–7, 15–17, 40–41, 44–45, 48–49, 52–54. She initially presented to NPPM as an obese, 31-year-old patient with complaints of back and ankle pain that she rated between three and seven on a ten-scale. *Id.* at 20–23. The chart contains MRI reports for the ankle as well as the lumbar and thoracic areas of CC's back from 2007. *Id.* at 32–34. The back MRI reports describe anomalies that are consistently characterized as ''mild.'' *Id.* at 32, 34. The ankle MRI report includes references to an incomplete fracture, a partial tendon tear, as well as a ligament tear. *Id.* at 33. Dr. Rubenstein testified that the 2007 MRI reports could be relied upon in evaluating patient treatment, but were not current enough to justify the prescribing of pain medication. Tr. 88.

Although CC's chart shows that the controlled substance medication dosages were changed and titrated, there was no justification for the adjustments documented in the record as opined by Dr. Rubenstein. Tr. 90–91. Moreover, Rubenstein noted that CC was prescribed OxyContin in an 80 mg dose, which is a dosage indicated for opioid-dependent patients, absent a diagnosis of cancer or other terminal illness. Tr. 91–93. The chart has no indication that CC was diagnosed as having opioid dependence, a malignancy, or other terminal disease. Dr. Rubenstein testified that in his view, based on his review of the chart:

There is no basis for any of [the prescribed] medications based on lack of any neurologic or musculoskeletal exam abnormality. I * * * reviewed the imaging studies [and] noted that there were large quantities of multiple highly addictive medications prescribed without any objective abnormality other than [an] MRI from 2007 that had shown some mild abnormalities but no, in my opinion, nerve root displacement or spinal cord compression [and thus, a] [l]ack of objective correlation that would have been consistent with the patient's complaints that shepresented to [NPPM].

Tr. 86–87. This testimony was consistent with the conclusions set forth in Dr. Rubenstein's report. Gov't Ex. 11 at 7.

Chart Review: Patient CH

Dr. Rubenstein also reviewed the chart maintained on Patient CH, a 29-year-old female patient treated by the Respondent from August 2009 until October 2010,[52] when, according to a chart entry, she was discharged in a notice dated October 5, 2010 by a Dr. Randy Dean for ''Dr. Shopping.'' Gov't Ex. 7 at 1. An intake form completed by CH states that the purpose of her visit is pain management, and she claims having the diagnoses or symptoms of fibromyalgia, depression/anxiety, and neck/back pain in her medical history. *Id.* at 34. Patient CH wrote that she heard about the NPPM clinic from a business card. *Id.* At intake, CH reported on the Pain Inventory that she had pain in her neck, front and back shoulders, lower back, and quadriceps, and rates her pain between seven and ten. *Id.* at 36. She further represented that only medicine and rest improve her pain, whereas ''walking, playing [with] kids[,] standing, [and] riding in [a] car'' all aggravate her pain. *Id.* at 37. CH adds, ''[The pain] interferes with my life in everyway [sic]. I can't function to do everyday jobs when I'm in pain. It even interferes with my relationship [with] husband & kids.'' *Id.*

Among CH's documents provided at intake were an MRI report and two papers relating to prescribed controlled substances. *Id.* at 30–32. The MRI[53] is of the lumbar spine and reports minimal impressions. *Id.* at 30, 46 (''Very minimal degenerative changes in the low lumbar spine as described above. No fracture, no acute herniated nucleus pulposis. No significant facet arthritis.''). A prescription label of #56 alprazolam 1 mg by a Dr. Findley, dated May 20, 2009, is included, as well as a pharmacy profile from Orange Park Drugs between March 12, 2009 and July 9, 2009, which contains only either #120 oxycodone 30 mg or #90 Vicodin 10/500 mg, all prescribed by a Dr. Fowler. *Id.* at 31–32. It is noted that the alprazolam prescription is not included in the pharmacy profile, although it was prescribed within the same time period.

Regarding the progress notes and prescriptions for each visit, little changes each time. Usually few notes are taken or boxes checked. Controlled substances are consistently prescribed with explanations, notes on medication efficacy and results, activities of daily living, progress, or testing protocols consistently absent. Oft times, the progress notes are unsigned, un-named, and abjectly unintelligible. *See, e.g., id.* at 110–11.[54] At the initial visit on August 8, 2009, the unsigned chart contains a notation to drug test CH's urine at the next visit, although there is no documentation to suggest that this aspiration ever came to fruition during CH's year at the practice. *See* Gov't Ex. 7 at 81.

The chart reflects a more or less continuous stream of controlled substance prescriptions issued in the Respondent's name[55] throughout the year of treatment without follow up. Even should a notation appear to signal to follow up with the patient regarding a referral, *see id.* at 75–77 (August 2009 visit), no follow up is ever found or is evidenced anywhere in the chart during the months subsequent, *see, e.g., id.* at 72–74 (September 2009 visit), and instead the patient is supplied with prescriptions for greater amounts of controlled substances, *see id.* at 56–57, 59, 82, 92–93 (October 2009 visit with Roxicodone dosage increase). Furthermore, the chart reflects a pattern of premature visits during which controlled substances are prescribed every time without annotation to the medical record explaining why. *See, e.g., id.* at 75–77 (August 25, 2009 visit, 17 day cycle); *id.* at 56–57, 59, 82, 92–93 (October 17, 2009 visit, 22 day cycle); *id.* at 12–14 (December 7, 2009 visit, 18 day cycle).[56]

[52] A sign-in sheet included in the chart reflects that CH presented to NPPM on fifteen occasions from August 2009 through August 2010. Gov't Ex. 7 at 33.

[53] While the MRI refers to Patient CH as a ''man,'' this was apparently errata. *Id.* at 10.

[54] It would be difficult to imagine that any subsequent practitioner or reviewer would be able to discern the rationale employed to justify the medications prescribed that day or anything else that happed during that visit.

[55] CH also received controlled substances from times by a physician other than the Respondent. *See, id.* at 67 (Dr. Carlos Haro), 109 (same).

[56] For reasons not readily apparent or explained by testimony, the CH chart reflected another curious practice wherein the patient was provided split prescriptions. At CH's February 10 visit, which was conducted by Dr. Carlos Haro, two prescriptions were issued for Roxicodone 30 mg into two separate scripts, one for 50 dosage units and the other for 100 dosage units, but netting no difference of quantity from that prescribed the previous month. *Compare id.* at 67, 109, *with id.* at

Continued

Dr. Rubenstein's report noted the absence of neurologic examinations and multiple occasions where prescription scripts were issued without any indication of a corresponding office visit. Gov't Ex. 11 at 12. Dr. Rubenstein provided the following assessment of the patient file:

> Although at the initial visit an MRI study, physical therapy and EMG all [were] recommended[,] there was absolutely no reference anywhere in the records to suggest that specific referrals were given, that the patient completed these referrals, or even any documentation as to what occurred. There were no diagnostic studies listed in the file [and] [t]here was no neurologic exam ever performed. In summary, the records do not meet the standard of care to justify the prescriptions that were dispensed. There was no evidence of any objective abnormality[,] be it through diagnostic testing, physical examination, or even a detailed pain history that would warrant the medications.

Id. at 13. Similarly, when asked at the hearing if the chart reflects whether the standard of care was met for the prescribing of controlled substances in Florida, Dr. Rubenstein testified:

> The records did not meet with the standard of care to justify the prescriptions that were dispensed. There was no evidence of any objective abnormality, be it through diagnostic testing, physical examination or detailed pain history that would warrant the medication.

Tr. 96.

Chart Review: Patient PL

The patient file maintained by the Respondent on PL, a 48-year-old female patient who was seen by the Respondent from April to September 2010, at which time according to a chart entry she was discharged from the practice for ''Dr. Shopping,'' was also reviewed by Dr. Rubenstein.[57] Gov't Ex. 9 at 2.

PL's sign-in sheet indicates five visits in 2010, on April 10, May 7, June 10, July 19, and August 16, but curiously the only minimally-completed progress note contained in the entire chart is dated September 17 (a date subsequent to the final sign-in date). Gov't Ex. 9 at 3–8, 23.

The intake forms indicate that PL identified herself as a manager at a storage facility, represented that the purpose of her visit was to ''receive pain medications,'' and stated that she was referred by someone with an identical name to her emergency contact person. *Id.* at 9. PL indicated complaints of anxiety, neck pain, and arthritis. *Id.* On the Pain Inventory, PL drew X's on an illustration depicting pain running all along her shoulders and arms, down her legs, and on her neck. *Id.* at 11. On a ten-scale, PL rated her pain between six and ten. *Id.* PL wrote on the form that she had been prescribed #240 oxycodone 30 mg, #120 oxycodone 15 mg, #90 Xanax, and #90 Soma sometime in the last 40 days. *Id.* To describe the variety of pain she experienced, PL circled every adjective listed on the inventory form except for ''dull.'' *Id.* at 12. Medicine, rest, and ice all purportedly improved her pain, while lifting, standing, or even writing exacerbated it. *Id.*

A cervical spine MRI report dated March 11, 2008 is found within the PL chart exhibit. *Id.* at 21–22. It identified mild impingement of the left C4 and left C5 nerve roots caused by disc herniation at C3–C4 and C4–C5, and bone marrow edema associated with the C4 and C3 areas that was opined to be a secondary result of bone contusion. *Id.* at 22.

As discussed, *supra,* scantily-completed progress notes are found within the chart for the September 17 visit, only. *Id.* at 3–4. The marks upon it indicate PL was observed to exhibit abnormal posture, appeared in pain, and had pain in her abdomen. *Id.* at 3. The word ''denies'' is written near the section inquiring about recreational drugs. *Id.* Roxicodone in the 30 mg and 15 mg varieties are checked to be continued as described, as is Xanax 2 mg and Soma 350 mg. *Id.* at 4. The word ''Naprosyn'' is also written near the treatment plan area. *Id.* The rest of the form, in pertinent part, is left blank. *See id.* at 3–4. Prescriptions in the medical file issued on September 17 are for #60 Naprosyn 500 mg, #180 Roxicodone 30 mg, #30 Rocicodone 15 mg, #60 Soma 350 mg, and to see a neurologist and primary care physician for chronic pain, to obtain lab workups including liver function tests, and for medical records of an injury. *Id.* at 6–7.

In his report, Dr. Rubenstein notes that PL's emergency contact in her paperwork is the same person that she indicated as the person who referred her to the practice to ''receive pain medications,'' that chart documentation did not support the controlled substance prescriptions issued, and that the file was bereft of any indication that a neurologic or musculoskeletal examination was ever performed. Gov't Ex. 11 at 13. Dr. Rubenstein set forth his analysis of PL's care as follows:

> The records of [PL] are also beneath the standard of care. No attempt was actually made to review previous medical records. There was no documentation as to the need for Roxicodone at the doses prescribed, *especially at the initial visit and all subsequent visits.* No neurologic exam was ever documented. There was no focal objective deficit on exam or even any specific exam that would correlate with the MRI findings in the cervical spine that would have justified the prescriptions that were provided. No other [treatment] alternatives were reviewed in the file.

Id. at 14–15 (emphasis supplied). In like manner, when asked during the hearing whether he had an expert opinion about whether the controlled substance prescribing demonstrated in the PL patient chart met the standard of care required to be exercised in Florida, Dr. Rubenstein testified that:

> The records were beneath the standard of care, that no attempt was actually made to review the previous medical records, there was no documentation as to the need for Roxicodone at the doses prescribed, *especially at the initial visit and all subsequent visits,* no neurologic exam was ever documented, there was no focal objective deficit on exam or even any specific exam that would have correlated with [the] MRI findings of the cervical spine that would have justified the prescriptions provided. There were no other alternatives that I saw in the file to medication management offered.

Tr. 98 (emphasis supplied). Although Dr. Rubenstein specifically bases at least a portion of his expert opinion regarding the PL chart review on the controlled substances prescribed at the initial visit and subsequent visits, the patient file provided by the Government and accepted into evidence reflects a chart note relative to only a single visit (September 17, 2010). Dr. Rubenstein's report reflects events that purportedly occurred during visits that correspond to dates entered into the sign-in sheet. *Compare* Gov't Ex. 9 at 8, *with* Gov't Ex. 11 at 13–14. Inasmuch as the copy of the PL patient chart that was provided by the Government does not have the information regarding these visits beyond the sign-in sheet, it is likely that the Government-provided version is incomplete, or at a minimum, at some variance with the chart reviewed by Dr. Rubenstein. While this is an admittedly disconcerting inconsistency, no conclusions will be drawn in this recommended decision regarding those portions of the chart not in evidence.

The Expert Opinion of Dr. Rubenstein

In his report Dr. Rubenstein provided a synopsis of his overall evaluation of the charts from the Respondent's

17. This method was also employed the following month by the Respondent on a visit occurring March 6, 2010, whereby he provided dual prescriptions for Roxicodone 30 mg, one for 150 tablets and another for 75 tablets, resulting in a cumulative increase of 75 dosage units. *Id.* at 112–13. No evidence was developed in the record regarding the propriety of subdividing controlled substances prescribed by issuing multiple scripts, nor was comment drawn by Dr. Rubenstein in his review about the increase of oxycodone afforded by the Respondent through this technique.

[57] This entry was signed by Dr. Randy Dean, rather than the Respondent. Gov't Ex. 9 at 2.

practice that he was asked to review. According to Dr. Rubenstein, the reviews he conducted clearly suggest that medications are being prescribed and/or dispensed from North Palm Pain Management without objective abnormalities correlating with patient pain complaints. High doses of highly addicting medications in the form of Roxicodone and Xanax are prescribed to each individual, yet not one of the patients showed any objective abnormality. In fact, no new neurologic exam was performed on any of the patients at any of the visits, and there were multiple visits when the patient was not even examined. Even more alarming is the fact that prescriptions were dispensed from the office without even physician encounters or visits, and at times there was not even a medical paraprofessional present. There were also times when patients did not complain of any significant pain, yet [were] still provided with high doses of medications and weaning was not discussed. The patient specifically did not even complain of back pain, yet was given high doses of Roxicodone. This does not appear to meet with the standard of care of pain management. Clearly, these are visits designed to supply patients with Roxicodone, Xanax, and in one patient, Soma. Although physical therapy was mentioned for at least two of the patients, there was no formal physical therapy prescription ever written or even referenced. The patients that were referred to Neurology were never given the name of a consultant to see, nor even a diagnosis to consider. Gov't Ex. 11 at 7.

Notwithstanding the disjointed organization of Dr. Rubenstein's written report, his arguably inordinate dependence on prior notes while on the witness stand, and the discrepancy noted, *supra,* between the version of Patient PL patient chart he apparently reviewed and the copy of the chart received in evidence at this hearing, his testimony was sufficiently clear, cogent, and supported by identified elements in the charts and admitted evidence to be relied upon in this recommended decision. Dr. Rubenstein highlighted consistent themes in his generally well-reasoned conclusions that lend credibility to the opinions he offered. Perhaps most significantly here, Dr. Rubenstein's expert opinion stands unrebutted.

TFO Thomas

The Government also presented the testimony of TFO Robert Thomas. TFO Thomas testified that he has been a police officer in the City of Palm Beach Gardens since 1994, that he works as a field training officer for the city, and that he has also been cross-designated by DEA as a TFO since May of 2009. Tr. 837–38. TFO Thomas served as the case agent [58] for the investigation of the Respondent, which began around September 2009. Tr. 839.

TFO Thomas testified that he personally obtained the undercover patient files for TFO Schwartz and SA Lunsford at NPPM by presenting Mr. Laterza with signed Florida Department of Health (DOH) medical release forms and identifying himself only as a police officer at Palm Beach Gardens. Tr. 841. He testified that he was also responsible for securing the patient files for Patients CH and PL by observing them exiting the clinic at different times, following them to their next destination, and then approaching them after they stopped [59] by identifying himself as a TFO for DEA inquiring whether they would voluntarily answer questions. Tr. 844–46. Accordingly to TFO Thomas, both agreed to speak to him and to execute a DOH release form so that he could retrieve their medical records from NPPM. Tr. 844–46. Similarly, TFO Thomas testified that while conducting surveillance, he spied Patient SL leave NPPM and caused an officer in a marked patrol car to conduct a traffic stop on Patient SL for extreme window tint. Tr. 842, 900. TFO Thomas's testimony continued that at the conclusion of the stop and after Patient SL was informed that he was free to leave, Thomas approached him as a TFO, and during this encounter SL agreed to answer questions and to sign a DOH release form. *Id.* TFO Thomas testified that he used the executed form to obtain a copy of SL's patient file from Mr. Laterza. *Id.* Finally, Thomas testified that Patient CC, who was cooperating with Assistant State Attorney Christy Rogers at the Palm Beach County State Attorney's Office, furnished the prosecutor's office with a signed DOH medical release form, but TFO Thomas could not recall if he personally retrieved the patient file from NPPM or if possession of the file was the result of the fruits of some other agent's endeavors of the State Attorney's Office.[60] *Id.* at 842–43. Thomas also testified that CC had some outstanding criminal matter with the State Attorney's Office, but stated that he did not know the details, effectively short-circuiting any meaningful ability to cross-examine on that issue. Tr. 881–82, 885–86.

TFO Thomas presented testimony regarding an interview in which he participated of Patient CH. Tr. 848. The conversation was purportedly recorded, but neither the recording nor a transcript derived therefrom was offered into evidence. *See id.;* 902–03. TFO Thomas testified that Patient CH told him she had been treated at NPPM for the last twelve to fifteen months, yet she was only seen by the Respondent five or six times. Tr. 848–49. According to Thomas, Patient CH stated that she received prescriptions for oxycodone without ever seeing the Respondent or any medical professional at her last six office visits. Tr. 849. Still, according to TFO Thomas's testimony, she paid a $200 office visit fee each time and sat in the waiting room for fifteen minutes to an hour for her prescriptions. *Id.* During one of these visits, it was TFO Thomas's testimony that Patient CH stated that she received prescriptions for controlled substances after she observed the Respondent leave the clinic premises. *Id.* Furthermore, TFO Thomas provided testimony that during his interview of Patient CH, she represented that she once observed the Respondent pre-sign a fresh pack of blank prescription pads opened, in her view, by Ms. Palemire. *Id.* 850. Patient CH purportedly described to Thomas that she watched as Ms. Palemire then loaded a portion of the pre-signed prescriptions into the printer used by the office for writing out the scripts. *Id.* Later in his testimony, TFO Thomas denied ever seeing pre-signed prescriptions himself. Tr. 855–56, 935.

Hearsay evidence is admissible evidence in administrative proceedings. *Richardson v. Perales,* 402 U.S. 389, 402 (1971) (signed reports prepared by licensed physicians correctly admitted at Social Security disability hearing); *Keller v. Sullivan,* 928 F.2d 227, 230 (7th Cir. 1991) (insurance company investigative reports correctly admitted in Social Security disability hearing where sufficient indicia of reliability established); *Calhoun v. Bailar,* 626 F.2d 145, 149 (9th Cir. 1980) (hearsay affidavits correctly admitted where indicia of reliability established). However, the weight afforded such testimony and, *a fortiori,* whether that testimony can support substantial

[58] As described by TFO Thomas through his testimony, the case agent is in charge of a particular case and is primarily responsible for initiating the investigation, directing the course of the investigation, and documenting its developments. Tr. 869.

[59] TFO Thomas made contact with CH at a Burger King on North Lake Boulevard, Tr. 844, and with PL at a nearby gas station about a quarter-mile from NPPM, Tr. 845–46.

[60] TFO Thomas later clarified on cross-examination that the State Attorney's Office obtained CC's patient file prior to his being brought into her interview. Tr. 911.

evidence is an entirely different matter. As succinctly stated by the Eleventh Circuit:

> Although the rules of evidence are not strictly applied in administrative hearings, there are due process limits on the extent to which an adverse administrative determination may be based on hearsay evidence. As was held in *U.S. Pipe and Foundry Company* v. *Webb,* ''hearsay may constitute substantial evidence in administrative proceedings as long as the factors that assure the 'underlying reliability and probative value' of the evidence are present.'' 595 F.2d 264, 270 (5th Cir. 1979).

Basco v. Machin, 514 F.3d 1177, 1182 (11th Cir. 2008). Thus, the utility of hearsay evidence before an administrative tribunal is limited by its reliability and credibility. Divining the correct use of hearsay evidence requires a balancing of four factors: (1) whether the out-of-court declarant was not biased and had no interest in the outcome of the case; (2) whether the opposing party could have obtained the information contained in the hearsay before the hearing and could have subpoenaed the declarant; (3) whether the information was inconsistent on its face; and (4) whether the information has been recognized by the courts as inherently reliable. *Id.* at 1182; *J.A.M. Builders v. Herman,* 233 F.3d 1350, 1354 (11th Cir. 2000).

Timely, well-reasoned objections were interposed by the Respondent's counsel at the time this evidence was offered. Tr. 847–48. Although the Respondent's counsel conceded that he made no attempt to subpoena any of the patients with whom TFO Thomas spoke, including Patient CH, Tr. 847, all other factors militate against consideration of the hearsay evidence elicited through Thomas pertaining to this and other interviews he conducted which were offered as evidence by the Government. Regarding possible bias, CC had an open criminal case, and no foundation was laid by the Government regarding the absence of bias from the other interviewees. The information provided could not be tested for consistency as the propositions contained in the interviews is corroborated by no other evidence of record, and there is no case law or other authority recognizing this variety of evidence as inherently reliable. Simply put, the Government, as the proponent of the evidence, did not lay a foundation sufficient to permit this tribunal to consider, with any appreciable value, the hearsay testimony of TFO Thomas regarding Patient CH or the other individuals he interviewed, absent the information being subject to the crucible of cross-examination. The Government opted to elicit the relevant information from TFO Thomas rather than to examine Patient CH directly, and did so at its own peril. Without more of a foundation, such as a way to gauge Patient CH's degree of bias or the consistency of her recollection, the reliability of the testimony as it stands on the record has not been shown to be adequate to merit gainful consideration for any purpose. Hence, this testimony, as helpful as it may have been to support the Government's investigation, cannot be used to support the enforcement action it seeks or to support any Agency finding or action that requires the benefit of substantial evidence.

Similarly, TFO Thomas testified to participating in two meetings with Mr. Laterza and Ms. Palemire occurring on October 14, 2010 [61] and October 20, 2010,[62] which were also recorded by TFO Thomas and later transcribed. Tr. 851–53, 856–57; *see* Gov't Exs. 35, 36. Specifically regarding the Respondent's controlled substance prescription writing, TFO Thomas testified that Mr. Laterza and Ms. Palemire explained that the Respondent would come in to NPPM for close to nine hours per week to pre-sign blank prescriptions so that a physician's assistant or nurse practitioner could print and issue prescriptions under his signature while he was not in the office. Tr. 854. TFO Thomas testified that he was told that the Respondent would be contacted to come back to the clinic if the clinic ran out of pre-signed scripts as its throughput could be as many as one hundred patients per day. Tr. 854. As conveyed to him by Mr. Laterza, TFO Thomas testified that the physician assistants were in charge of seeing patients and prescribing medications, although it was possible that they to some degree communicated with the Respondent through computer equipment at times, owned by the Respondent, for him to approve prescriptions.[63] Tr. 854–55, 861.

Thomas's recollection was that Laterza informed him that he was motivated to come forward about the Respondent by an ''internal investigation'' conducted by NPPM's attorney at the company's own initiative, and that this was commenced on suspicion that the Respondent was self-prescribing anabolic steroids and other medications by proxy through his father, and defrauding the clinic of thousands of dollars in the process. Tr. 853, 860–61; *see* Gov't Ex. 35 at 16.

This is again the type of hearsay evidence that, while not patently inadmissible, may not constitute substantial evidence and be afforded any weight, based upon an identical result yielded from a weighing of the *J.A.M. Builders* factors.[64] Mr. Laterza as an owner of NPPM had an obvious interest in protecting the integrity of the clinic and shielding it from liability, be it civil or criminal. Regarding possible bias, few situations would likely invoke a more heightened sense of self-preservation than when Mr. Laterza is speaking to law enforcement and reporting on potential criminal activity occurring within his own business, while specifically identifying and shifting blame to a former employee (the Respondent). Accordingly, the self-interest by which Mr. Laterza hoped law enforcement would rely and act upon his statements could not be greater, and his assertions were never put to the test of a meaningful cross-examination. Similarly, there is no corroborating information of record to test for consistency, and the information procured is clearly not of a nature that has been recognized by the courts as inherently reliable. The testimony regarding this interview can play no part in supporting a finding of substantial evidence in this case.

In an effort to generally establish the form and style in which the Respondent signed prescriptions, the Government elicited testimony from TFO Thomas that he spoke to Assistant State Attorney (ASA) Christy Rogers who spoke to Agent Bujnowski [65] who spoke to the Respondent who allegedly confirmed that he effected his signature upon a single prescription by employing a

[61] During this interview, Laterza's attorney, Myles Malman, Esq., was also present. Tr. 856.

[62] Theodore Degel, an employee at the clinic, was an additional participant to this interview. Tr. 851.

[63] TFO Thomas acknowledged that he had never seen any blank, pre-signed prescriptions with the Respondent's signature. Tr. 856.

[64] Timely, cogent, persuasive objections were interposed by the Respondent's counsel at the time this evidence was offered by the Government. Tr. 857.

[65] At another point in the proceedings, the Government signaled its intention to elicit information acquired by Bujnowski from DI McRae, who was apparently prepared to testify that she had obtained the information from Bujnowski through the means of a telephone call the day before the hearing. Tr. 565–69. That effort was abandoned upon the simultaneous representation that Bujnowski would be produced for the hearing. Tr. 569. Notwithstanding the Government's representation in this regard, Bujnowski was not produced. The Government indicated that a subpoena would be required to procure his testimony and was offered one on the spot, but declined and persevered in its efforts to present this information in this unfortunate manner. Tr. 828–33. During cross-examination, DI McRae even testified that Bujnowski located prescription scripts that were pre-signed by the Respondent. Tr. 587. Unfortunately, this testimony was not elicited from a witness with first-hand knowledge in a manner that could be relied upon in these proceedings.

single letter resembling a ''G'' or ''C'' that was obtained by law enforcement from a pharmacy and somehow suspected to have been pre-signed before it was issued. Tr. 861–64. In addition to speaking to ASA Rogers, TFO Thomas testified that he read a report drafted by Agent Bujnowski regarding this interaction with the Respondent. Tr. 863–64. The witness was not familiar with the details of the conversation purportedly conducted between Bujnowski and the Respondent, or even when it occurred. Tr. 862–63. The witness actually testified that he read a report (the details of which he could not remember) and spoke to someone who spoke to Bujnowski, who spoke to the Respondent. Tr. 864. This evidence was actually offered in this manner by the Government in support of its case. Even a highly-skilled cross-examiner, such as the Respondent's counsel in this case, would be at a loss to effectively engage such a vague, amorphous presentation of testimony. A timely, well-reasoned, continuing objection was interposed by the Respondent's counsel at the time this evidence was offered by the Government. Tr. 861. Like other evidence of similar ilk offered by the Government in this case, that the testimony was not patently inadmissible at administrative proceedings does not answer the question of whether it can be used to uphold an administrative enforcement action that must be supported by substantial evidence, a query that must ultimately be answered in the negative. Because of the obvious concerns regarding the reliability of this testimony and the needlessly tortured and obscure way that it was offered, even if the *J.A.M. Builders* factors weighed in favor of admission (which they most clearly do not), no weight whatsoever can be assigned to this testimony insofar as it pertains to the way the Respondent purportedly signed prescriptions at NPPM, or that the Respondent gave an admission about the manner in which he signed prescriptions while at NPPM. To consider such evidence against the Respondent on this record would violate the Administrative Procedure Act and result in a grievous miscarriage of justice. *See* 5 U.S.C. § 556(d) (''A party is entitled * * * to conduct such cross-examination as may be required for a full and true disclosure of the facts.'')

TFO Thomas also testified that a database maintained by DEA reflects that two phone calls were placed to DEA by the Respondent in September 2010, wherein he complained that although he was no longer working at NPPM, individuals associated with that clinic were still utilizing prescriptions in his name on forged scripts. Tr. 865–66, 920–22. Thomas testified that he placed two calls to the cellular phone number left by the caller, left detailed voicemails identifying himself as a DEA TFO, and received no call back. Tr. 867. In a peculiar irony, the same rationale that precludes consideration of unsubstantiated, unreliable hearsay offered against the Respondent precludes even negligible consideration of the DEA record of this phone call that purportedly emanated from the Respondent. That some DEA database contains a note entered a by an unknown DEA employee about a phone call that was purportedly lodged by the Respondent, offers little that can support or negate a finding of substantial evidence. In any event, as discussed in more detail, *infra,* the Respondent was present at the hearing and elected not to testify.

Subject to the parameters set forth above regarding weight and the permissible uses of his elicited testimony, TFO Thomas provided testimony that was sufficiently detailed, plausible, and internally consistent to be deemed credible.

DI McRae

Further testimony was elicited by the Government through DI Victoria McRae, who at the time of hearing worked at DEA as a Diversion Investigator for twenty-two years. Tr. 553. DI McRae is currently stationed at the Miami Field Division. *Id.* Although DI McRae provided some helpful foundational information regarding the admission of some DEA documentation,[66] that is where the utility of her testimony for these proceedings began and ended.

DI McRae testified that she was present when a search warrant was executed at NPPM and that she and TFO Thomas interviewed employees of the clinic as part of the investigation. Tr. 556–58. According to McRae, she and Thomas conducted an interview of former NPPM employee and pharmacy technician, Crystal Laster, on November 5, 2010 at the Palm Beach Gardens Police Department.[67] Tr. 556–58. According to DI McRae's testimony, Ms. Laster told her that she had worked at NPPM from April to July of 2010, had been fired,[68] and consequently sought in October 2010 to report illegal activity that she had observed during her employment. Tr. 558–60. McRae testified that Laster told her that she was directed by Palemire to deduct dosage units from filled prescriptions to make up for shortfalls, and that it was office practice to flush away overages. Tr. 560. Additionally, McRae testified that Laster said Palemire permitted early refills, that Laster saw the Respondent pre-sign prescriptions, and that the Respondent was not always present at the clinic when patients were being seen. Tr. 560–61, 578–79. McRae also testified that Laster told her that NPPM tolerated the practice of sponsoring.[69] Tr. 562, 585.

Notwithstanding the reality that the Respondent (like the Government)[70] could have sought process to compel Laster's appearance at the hearing, all other *J.A.M. Builders* factors weigh powerfully against admission of the testimony regarding this interview. That she was fired from her employment by NPPM and waited several months to report alleged misconduct raises the specter of bias, there was no admissible evidence upon which to test consistency, and the information was not of a type that has been recognized as inherently reliable by the courts. While the information that was purportedly obtained through Laster's interview was clearly relevant, it was not offered through a vehicle that could ever be considered to support a finding of substantial evidence and must be afforded no weight in these proceedings.

Subject to the parameters set forth above regarding weight and the permissible uses of her elicited testimony, DI McRae provided testimony that was sufficiently detailed, plausible, and internally consistent to be deemed credible.

GS Langston

The Government presented the testimony of Group Supervisor (GS) Susan Langston to support its allegation that the Respondent violated the Ryan

[66] Tr. 554–56; Gov't Exs. 1, 2.

[67] Although DI McCrae testified that the interview was recorded, for reasons not readily apparent, the Government did not seek admission of a recording or transcript of the interview. *See* Tr. 574.

[68] Ms. Laster told DI McRae that she was fired by Ms. Palemire due to a discovered shortage of twenty oxycodone tablets. Tr. 573–74.

[69] Sponsoring was explained as the process through which one person would pay the transportation, room and board, office visit, and/or medication costs for a group of patients traveling from out of state in exchange for a percentage of their controlled substance medication. Tr. 562–64.

[70] In view of the nature of the information purportedly held by Ms. Laster (pre-signed prescriptions, patients treated while the Respondent was not present, inventory regularities regarding controlled substances procured under the Respondent's COR), and the absence of any indication of her unavailability or unsuitability to process, the Government's tactical decision to present her information in this manner is striking.

Haight Act. GS Langston testified that she has been the Group Supervisor of Diversion at the DEA Fort Lauderdale Resident Office for the past two years and that she has been a DI since 1996. Tr. 509.

GS Langston testified that she came upon evidence related to this case while conducting an investigation into an unrelated matter. Specifically, Langston testified that on February 14, 2011, while conducting an on-site inspection of a retail pharmacy named American Pharmaceutical Group (American Pharmaceutical)[71] in connection with that entity's application for a second COR, she came upon prescription scripts for controlled substances that were authorized under the Respondent's name and COR number. Tr. 510–12, 539. During the course of her inspection, GS Langston spoke to Bruce Derby and Jay Olynck, who respectively served as company pharmacist/pharmacy department manager and company accountant. Tr. 513–17. According to Langston, these officials of American Pharmaceutical told her that their company had a business arrangement with three Internet companies: Key to Life Therapy, HMMG Medical, and Total Rejuvenation (contract Internet providers). Under the business arrangement, when authorized prescription orders were received by American Pharmaceutical via fax from the contract Internet providers, the prescriptions would be filled and shipped out directly to the patient/customer/ultimate consumer. The scripts authorized by the Respondent that Langston found bore the indicia of the three Internet companies involved in the arrangement.

According to Langston, the American Pharmaceutical employees told her that the contract Internet providers would match website-solicited patient/customers from various locations with physicians on contract with them. Tr. 513–14. The patient/customer would apparently request a specific controlled substance, and if, after blood work and consultation with one of their physicians on contract, the physician agreed to write the prescription, that script would be sent to American Pharmaceutical, which would then fill the prescription and ship it out. Tr. 514–15. Langston testified that during her inspection, she came upon scripts authorized under the Respondent's name and COR number that also bore the indicia of the contract Internet providers. Tr. 513–17.

Additionally, GS Langston testified that she was told that before American Pharmaceutical would fill prescriptions for a contract doctor, it required that he or she file a form certifying that a proper patient-doctor relationship was maintained with all patients for which prescriptions were transmitted. Tr. 541–44. While GS Langston looked through a file that American Pharmaceutical kept up containing these forms signed by many doctors, and based on what American Pharmaceutical told Langston there could/would/should have been one corresponding to the Respondent, Tr. 542–43, 546, GS Langston chose not to look for or take custody of a copy, and testified that she does not know whether such a form was ever executed by the Respondent, Tr. 542, 544.

The lion's share of GS Langston's testimony was devoted to detailing thirty-two prescriptions for anabolic steroids that were filled, over the Respondent's name and CORs issued to him, by American Pharmaceutical and a part of the document seizure performed by Langston.[72] *See generally* Tr. 519–33. The prescriptions were dispensed and shipped to patients located throughout the United States, over the Respondent's three registrations, for each of three contract Internet providers. *See* Tr. 519, 524, 532; Gov't Ex. 37. The documentation submitted into evidence demonstrates that between August 26, 2010 and February 11, 2011, controlled substance prescriptions were filled through American Pharmaceutical and shipped to twenty-eight clients in fourteen states outside Florida.[73]

During her testimony, GS Langston acknowledged that shipping controlled substances is not in itself a violation of the Ryan Haight Act, but urged that prescribing without establishing a valid doctor-patient relationship based upon at least one in-person examination is.[74] Tr. 544. GS Langston conceded that she did not actually know whether any of the patients who were prescribed anabolic steroids in documentation supplied by the Government were seen by the Respondent or by another physician who was in consult with the Respondent. Tr. 547–48. Furthermore, GS Langston testified that her assumption that the prescriptions were filled via the Internet process was based exclusively on her conversation with the American Pharmaceutical employees, Tr. 538, and that she neither took any steps to corroborate American Pharmaceutical's account of the business relationships involved in the Internet prescribing scheme, such as talking with personnel at the contract Internet providers, Tr. 517, nor did she verify with any of the patients the manner by which they were prescribed controlled substances, Tr. 548, as the focus of her investigation was solely on American Pharmaceutical, *id.*

The manner in which the Government's hearsay evidence on this issue was elicited presents a closer case regarding the appropriate weight to be accorded under the *J.A.M. Builders* factors. *See* 233 F.3d at 1354. While true that the Respondent arguably could have located and subpoenaed the American Pharmaceutical personnel interviewed by Langston, and that the information obtained is not the type traditionally deemed reliable by the courts, it is equally true that there is no obvious equation that suggests bias on the part of the interviewees towards the Respondent, and the scripts received into evidence that were obtained through a DEA inspection does add at least some level of corroboration to the account in view of the remote distances between the prescriber and patient/customer. However, it is not necessary to reach this issue, because, as discussed in more detail, *infra,* even if this evidence were deemed, *arguendo,* to be sufficiently reliable to support a substantial evidence finding, no evidence has been introduced from which it can properly be inferred that controlled substances were issued to the patient/customers without physical examinations. In fact, Langston conceded that American Pharmaceutical also had a walk-in aspect to its pharmacy, and that the admitted documents do not all even reflect that the controlled substances were shipped to the recipients. Tr. 536–37.

Regarding credibility, GS Langston's testimony was sufficiently detailed, plausible, and consistent to be deemed credible in these proceedings.

DI Milan

DI Marjorie Milan also testified on behalf of the Government. DI Milan testified that she is a Diversion Investigator at the Miami Field Division

[71] The notice of inspection (DEA Form 82) that was issued in connection with Langston's inspection indicates that American Pharmaceutical was located in Wilton Manors, Florida. Gov't Ex. 37 at 1.

[72] GS Langston admitted that while she seized all of American Pharmaceutical's prescription records, she did not go through all of them, and she had not gone through all of the prescriptions related to the Respondent. Tr. 511, 513, 518. GS Langston ended her investigation into American Pharmaceutical once it voluntarily surrendered its COR and ceased business, an event which was precipitated by the results of her inspection. Tr. 518.

[73] One page from the Government's exhibit does not list any controlled substances. Gov't Ex. 37 at 32.

[74] *See* 21 U.S.C. § 829(e) (2006 & Supp. III).

for just short of twelve years.[75] Tr. 435–36. DI Milan's participation of the investigation into the Respondent involved examining records seized on February 23, 2011 from NPPM by the West Palm Beach Sheriff's Office. Tr. 441. DI Milan's testimony was offered to identify records within the seized documents pertaining to the Respondent, Tr. 441–42, and to support the Government's allegation that the Respondent was noncompliant with his recordkeeping obligations as a DEA registrant.

DI Milan testified to her opinion that the controlled substance records were deficient in that they were not ''readily retrievable'' in violation of 21 C.F.R. § 1304.03–.04 (2011).[76] DI Milan explained (without benefit of specific guidance document or instruction)[77] that the term ''readily retrievable'' was the window of time that it takes DEA personnel to conduct an on-site inspection of a practitioner's premises, should DEA request at that time to review inventorying, dispensing, or any other applicable documents required to be maintained and so produced under the CSA. Tr. 442–43. To add generally to the confusion wrought by her testimony, Milan also informed that a registrant's required records may still be deemed ''readily retrievable'' if provided within a day or two of the request.[78] Tr. 443. Putting aside the relative merits of DI Milan's flexible definition of whether a registrant's records are ''readily retrievable,'' her testimony is clear on the point that the Respondent was never asked to retrieve anything. Tr. 444, 470–72. Milan's opinion that the Respondent defaulted in his responsibility to have ''readily retrievable'' records is based upon a sterile review of documents seized from NPPM at a time well after the Respondent's employment at that clinic was terminated. Tr. 473. The Respondent was terminated from his employment in September 2010, Tr. 473, but the seizure of records at NPPM did not take place until February 2011, Tr. 441. Milan testified that she was neither present during the seizure of records by the sheriff's office, nor was she aware of any inquiry made to the Respondent regarding the readily retrievable nature of what was recovered. Tr. 443–44. Indeed the records were taken pursuant to a criminal state search warrant, not an administrative inspection warrant, and the only time that DI Milan was in personal contact with the documents was while they were in custody of the sheriff's office. Tr. 443–45. No further testimony by DI Milan is on the record characterizing why or how the applicable information required to be kept was not retrievable in a ready fashion.

Aside from the merits of the celerity or accessibility of the files procured, DI Milan testified to required recordkeeping records that she noted were absent from the nine boxes of evidence held in custody by the sheriff's office. Tr. 475. DI Milan asserted that she specifically looked for inventory records or ordering records that would indicate amounts of controlled substances purchased. Tr. 475–76. This testimony (which was actually extracted from the witness on cross-examination) was insufficiently developed to ascertain anything concrete regarding whether recordkeeping was maintained in compliance with DEA regulation or whether those records, if they existed, would have been contained in the boxes seized. Moreover, while DI Milan explained why she did not need to look at every single page within the seizure to know the contents (a remarkable assertion in and of itself), she declared, ''I could pretty much distinguish what did not pertain to what I needed to look for. In other words, if it looked like it was financial records [sic], that was something that I wouldn't be looking at, because I was looking for any documentation that showed whether controlled substances had been ordered, and also what was being dispensed.'' Tr. 475–76. Even if the unreasonable proposition that records evaluated under the circumstances here could ever be assessed as ''readily retrievable'' or not was hypothetically indulged, from Milan's testimony it would be impossible to ascertain what, if any, documents were present or missing from the seized records; no one who testified has even reviewed all the seized records. Thus, the record is devoid of any evidence from which a finding of deficiency founded on lack of readily retrievable records could be based.

DI Milan also testified that she reviewed logbooks containing affixed controlled substance dispensing labels issued over the Respondent's COR, which she electronically scanned at the sheriff's office. Tr. 446–48. She then selected, without any particular process or method, one day in each month of February, March, April, May, and June in 2010 to concentrate her analysis.[79] Tr. 446–47, 481. She also scanned the executed scripts corresponding to the dispensing labels found within the records seized.[80] Tr. 451–53. The extent of the analysis conducted by DI Milan was limited to calculating the sums of dosage units dispensed by the Respondent for each of oxycodone 15 mg, oxycodone 30 mg, and alprazolam 2 mg on each of the five dates, Tr. 456–59, as well as providing less than assertive testimony coming up with a minimum and maximum prescribed dosage unit range for each of the three drug varieties cumulatively based upon the five dates.[81] Tr. 459–61. The documents providing the basis of DI Milan's testimony, included in the proposed exhibit by the Government (Government's Exhibit 43), were provisionally admitted into evidence subject to the witness providing a foundation sufficient to support why it was relevant. Tr. 448–49. While the exhibit remains in evidence, the Government provided no contextual evidence from which any relevant conclusion could rationally be based other than a statement of the tallies themselves. The total dosage units of a single type of substance prescribed on a particular day, or prescribed concurrently with other substances, without more, speaks nothing to the propriety or impropriety of the practitioner's prescribing behavior and

[75] Through DI Milan's testimony, the Government offered into evidence voluntary surrender forms signed by the Respondent for COR Numbers FG1242471 and FG2021804. While the Government noticed all three of the Respondent's CORs in its charging document, including the remaining registration of BG8251845, almost all of the misconduct alleged by the Government occurred over COR FG1242471, the registration associated with the NPPM address. Notwithstanding, misconduct, if proven, is relevant not only to the COR connected to the misconduct, but for all under the public interest factors.

[76] DI Milan was not able to testify as to which regulations required readily retrievable records, Tr. 442, and this issue likewise occupied no portion of the Government's brief.

[77] DI Milan could not identify any source for the ''readily retrievable'' records requirement. Tr. 442.

[78] On the issue of what temporal parameters define ''readily retrievable,'' Milan provided the following less-than-helpful guidance: ''Um, usually I think we give them like maybe a day or two for them to go ahead and provide the records to us so that we can review them. After that then we pretty much will, we figure if there's another avenue that we have to go through to be able to see the records.'' Tr. 443.

[79] The precise dates selected were February 19, March 5, April 1, May 28, and June 18, 2010. Tr. 450–51.

[80] DI Milan acknowledged that she had no idea who assembled the records or the significance of their organization scheme. Tr. 454.

[81] While it was proffered that DI Milan would testify as to how many patients were seen by the Respondent on each of the particular days examined by DI Milan based solely on the dispensing labels, Tr. 449, DI Milan eventually admitted that while this figure was ascertainable, she did not tally it, Tr. 460–63; *see* Tr. 487–88, 490–91. Later, DI Milan testified that her analysis did not suggest that the Respondent saw ''some exorbitant number'' of patients each day, all of to whom he prescribed controlled substances. Tr. 486, 492.

adds nothing (in the absence of contextual evidence) to the equation of whether it is in the public interest to continue the Respondent's privileges as a registrant. The same holds true for the range of tablets prescribed at any one time. In fact, DI Milan specifically testified that she was suggesting nothing proper or improper about what was prescribed or how many patients the Respondent prescribed to on any given day. Tr. 481, 492. For these reasons, Government's Exhibit 43 and the associated testimony by DI Milan sheds no appreciable light on the determination as to whether the Respondent's continued registration would be inconsistent with the public interest and has been given no weight in this recommended decision.

SDI Wright

The Government provided the testimony of Senior Diversion Investigator (SDI) Kyle Wright, Chief of DEA's Targeting and Analysis Section. Tr. 346. SDI Wright testified that he and his staff analyze data from the Automated Records and Controlled Ordering System (ARCOS), a database maintained by DEA pursuant to its obligations under the CSA. Tr. 346–47. Through ARCOS, DEA has the capacity to track the path of all Schedule II and Schedule III narcotic drugs [82] throughout their lifecycle events in the distribution chain, from the time their raw form elements are imported or created, through manufacturing, distribution, and the dispensing to the ultimate end user, i.e. typically the patient. Tr. 347. SDI Wright explained that the data loaded into ARCOS pertains to two broad groups, those DEA registrants who must report controlled substance transactions to ARCOS (e.g., manufacturer, distributor), and those registrants on whom transactions are reported to ARCOS (e.g., pharmacy, dispensing practitioner).[83] Tr. 348. The COR number of every party participating in an event is entered in connection with each transaction. Tr. 348, 358. According to SDI Wright, the information loaded into ARCOS is used both to monitor the legitimate flow of controlled substances within the closed regulatory system, as well as to highlight numerical anomalies that could reflect the potential for diversion. Tr. 349– 52.

Through SDI Wright's testimony, the Government presented some absolute and comparative statistical information based upon data culled from ARCOS. The data related to the Respondent's COR and was relevant to the extent that it showed purchasing trends of Schedule II and Schedule III narcotics associated with the Respondent's COR. However, the information, in the form it was offered, did not provide any insight into whether the Respondent committed any activity that was consistent or inconsistent with his responsibilities as a registrant.[84] This is not to say that statistical data could not support substantial evidence to revoke a registrant's COR in all cases. There was simply insufficient contextual evidence adduced at the hearing to utilize the statistics that were offered.[85] In the absence of testimony or other evidence that could provide some context to the data, and why the numbers Wright provided demonstrated whether or to what extent the Respondent was exercising due care regarding his responsibilities as a registrant, there is no use that the impressive array of statistical information he provided can be put to.[86] Beyond doubt, there are a host of factors that could account for why the Respondent's level of controlled substance prescribing should have been lower, higher, or was just right. A non-exhaustive list of such evidence might include (but not be limited to) the nature of his practice (pain specialist versus nephrologist),[87] the geographical location (and population) of his practice, the scarcity or abundance of other practitioners practicing the same medical field in similar proximity, the number of hours per week he practiced and number of patients he treated during that time period, and even the socioeconomic status of the region. All these factors, and certainly others, could likely shed light on why ARCOS figures related to the numbers of controlled substance prescriptions that were issued and/or dispensed reflected well or poorly on whether the Respondent was adequately discharging his duties under the CSA. To the extent that reasonable expectations regarding the Respondent's practice or similarly-situated registrants could be divined, it was not presented. The Respondent's level of dispensing was not compared with other registrants with a reliable metric that could establish anything relevant about the numbers. Here, the most SDI Wright could offer is that the numbers presented could support an investigatory red flag. Tr. 384. Beyond question, DI Wright presented as a forthright, credible witness with a superior command over the subject matter of his testimony. That said, the data was presented in something of a contextual vacuum, and as such, cannot be used to reach a determination as to whether the continuation of the Respondent's COR is in the public interest.[88]

The Respondent did not testify and presented no evidence at the hearing.

Other evidence required for a disposition of this issue is set forth in the analysis portion of this decision.

[82] SDI Wright explained that while all Schedule II substances are tracked, only a subset of Schedule III controlled substances considered to be narcotic drugs are tracked. Tr. 420; *but see* 21 C.F.R. § 1304.33 (2011) (also requiring reporting on all Schedule I controlled substances, gamma hydroxybutyric acid (Schedule III), and some activities involving selected psychotropic substances in Schedules III and IV).

[83] Registrants who are ''reported on'' are also referred to as the ''retail side'' in contrast to the ''reporter side.'' Tr. 348. Some of the types of transactions that trigger a reporting requirement are importation, loss, destruction, and purchases/sales. *Id.*

[84] The first set of data presented by SDI Wright consisted of raw numbers of dosage units purchased over the Respondent's COR in 2009 and 2010, Tr. 367–86, that, on SDI Wright's admission, did not suggest anything improper or illegal but that only raised an investigatory flag based primarily on a sharp increase from one quarter to a following quarter, Tr. 382–84; Gov't Ex. 41, at 1–6. SDI Wright's attention was also drawn to data indicating that variations of oxycodone 30 mg tablets were ordered much to the exclusion of other controlled substances. Tr. 382. Additionally, SDI Wright presented tables and graphs comparing the amount of oxycodone dosage units purchased by the Respondent to countywide, statewide, and nationwide practitioner ordering averages, Tr. 386–92, 395; Gov't Ex. 41 at 8 (calendar year 2009), 12 (calendar year 2010), and comparing the Respondent to two other practitioners constituting the top three purchasers in zip code 33404, Tr. 393–97; Gov't Ex. 41, at 9–11 (calendar year 2009), 13–15 (calendar year 2010).

[85] At the hearing, the Respondent's counsel interposed timely (ultimately well-founded) objections to various aspects of DI Wright's testimony. Tr. 353, 374, 376–77, 381, 391.

[86] When Wright was asked if he knew whether the Respondent authorized the prescriptions in question, he responded in this way: ''Okay, I'm going to answer your question precisely. I know nothing about his prescribing at all, because that's not what ARCOS tracks.'' Tr. 398.

[87] Tr. 406–07.

[88] The Government's argument that these raw numbers demonstrate the impact of the Respondent's poor prescribing practices, Gov't Br. at 26, is not persuasive on this record. The numbers here reflect only volume; not high volume or low volume. If the record revealed that controlled substances were being improperly dispensed through every (or even most) prescription issued or dispensed, the number of controlled substances being released without the benefit of adequate controls would arguably be relevant to show the impact of the Respondent's laxity. Here, beyond the instances demonstrated in the record where the Respondent's prescribing practices fell below the standard described by the Government's expert, there is no sensible way to extrapolate what percentage (if any) of the balance of the issued scripts or dispensed medications were disgorged from the closed regulatory system in an improper way. Put another way, volume of total prescriptions issued does not reveal anything meaningful (or even useable) about community impact.

The Analysis

Pursuant to 21 U.S.C. § 824(a)(4) (2006), the Administrator[89] is permitted to revoke a COR if persuaded that the registrant ''has committed such acts as would render * * * registration under section 823 * * * inconsistent with the public interest * * *.'' The following factors have been provided by Congress in determining ''the public interest'':

(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.

21 U.S.C. § 823(f) (2006 & Supp. III 2010).

''[T]hese factors are considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 Fed. Reg. 15227, 15230 (2003). Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Administrator may properly give each factor whatever weight she deems appropriate in determining whether an application for a registration should be denied. *Morall v. DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005); *JLB, Inc., d/b/a Boyd Drugs,* 53 Fed. Reg. 43945, 43947 (1988); *David E. Trawick, D.D.S.,* 53 Fed. Reg. 5326, 5327 (1988); *see also Joy's Ideas,* 70 Fed. Reg. 33195, 33197 (2005); *David H. Gillis, M.D.,* 58 Fed. Reg. 37507, 37508 (1993); *Henry J. Schwarz, Jr., M.D.,* 54 Fed. Reg. 16422, 16424 (1989). Moreover, the Administrator is ''not required to make findings as to all of the factors * * *.'' *Hoxie v. DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall,* 412 F.3d at 173–74. The Administrator is not required to discuss consideration of each factor in equal detail, or even every factor in any given level of detail. *Trawick v. DEA,* 861 F.2d 72, 76 (4th Cir. 1988) (the Administrator's obligation to explain the decision rationale may be satisfied even if only minimal consideration is given to the relevant factors and remand is required only when it is unclear whether the relevant factors were considered at all). The balancing of the public interest factors ''is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest * * *.'' *Jayam Krishna-Iyer, M.D.,* 74 Fed. Reg. 459, 462 (2009).

In an action to revoke a registrant's DEA COR, the DEA has the burden of proving that the requirements for revocation are satisfied. 21 C.F.R. § 1301.44(e) (2011). Once DEA has made its *prima facie* case for revocation of the registrant's DEA Certificate of Registration, the burden of production then shifts to the Respondent to show that, given the totality of the facts and circumstances in the record, revoking the registrant's registration would not be appropriate. *Morall,* 412 F.3d at 174; *Humphreys v. DEA,* 96 F.3d 658, 661 (3d Cir. 1996); *Shatz v. U.S. Dept. of Justice,* 873 F.2d 1089, 1091 (8th Cir. 1989); *Thomas E. Johnston,* 45 Fed. Reg. 72311, 72312 (1980). Further, ''to rebut the Government's *prima facie* case, [the Respondent] is required not only to accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the reoccurrence of similar acts.'' *Jeri Hassman, M.D.,* 75 Fed. Reg. 8194, 8236 (2010).

Where the Government has sustained its burden and established that a registrant has committed acts inconsistent with the public interest, that registrant must present sufficient mitigating evidence to assure the Administrator that he or she can be entrusted with the responsibility commensurate with such a registration. *Steven M. Abbadessa, D.O.,* 74 Fed. Reg. 10077, 10078, 10081 (2009); *Medicine Shoppe-Jonesborough,* 73 Fed. Reg. 364, 387 (2008); *Samuel S. Jackson, D.D.S.,* 72 Fed. Reg. 23848, 23853 (2007). Normal hardships to the practitioner and even to the surrounding community that are attendant upon the lack of registration are not relevant considerations. *Abbadessa,* 74 Fed. Reg. at 10078; *see also Gregory D. Owens, D.D.S.,* 74 Fed. Reg. 36751, 36757 (2009).

The Agency's conclusion that past performance is the best predictor of future performance has been sustained on review in the courts, *Alra Labs. v. DEA,* 54 F.3d 450, 452 (7th Cir. 1995), as has the Agency's consistent policy of strongly weighing whether a registrant who has committed acts inconsistent with the public interest has accepted responsibility and demonstrated that he or she will not engage in future misconduct. *Hoxie,* 419 F.3d at 483; *Ronald Lynch, M.D.,* 75 Fed. Reg. 78745, 78749 (2010) (Respondent's attempts to minimize misconduct held to undermine acceptance of responsibility); *George Mathew, M.D.,* 75 Fed. Reg. 66138, 66140, 66145, 66148 (2010); *East Main Street Pharmacy,* 75 Fed. Reg. 66149, 66165 (2010); *George C. Aycock, M.D.,* 74 Fed. Reg. 17529, 17543 (2009); *Abbadessa,* 74 Fed. Reg. at 10078; *Krishna-Iyer,* 74 Fed. Reg. at 463; *Medicine Shoppe,* 73 Fed. Reg. at 387.

While the burden of proof at this administrative hearing is a preponderance-of-the-evidence standard, *see Steadman v. SEC,* 450 U.S. 91, 100–01 (1981), the Administrator's factual findings will be sustained on review to the extent they are supported by ''substantial evidence.'' *Hoxie,* 419 F.3d at 481. And while ''the possibility of drawing two inconsistent conclusions from the evidence'' does not limit the Administrator's ability to find facts on either side of the contested issues in the case, *Shatz,* 873 F.2d at 1092; *Trawick,* 861 F.2d at 77, all ''important aspect[s] of the problem,'' such as a Respondent's defense or explanation that runs counter to the Government's evidence, must be considered. *Wedgewood Vill. Pharmacy v. DEA,* 509 F.3d 541, 549 (D.C. Cir. 2007); *Humphreys,* 96 F.3d at 663. The ultimate disposition of the case must be in accordance with the weight of the evidence, not simply supported by enough evidence to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn from it is one of fact for the jury. *Steadman,* 450 U.S. at 99 (internal quotation marks omitted).

Regarding the exercise of discretionary authority, the courts have recognized that gross deviations from past agency precedent must be adequately supported, *Morall,* 412 F.3d at 183, but mere unevenness in application does not, standing alone, render a particular discretionary action unwarranted. *Chein v. DEA,* 533 F.3d 828, 835 (D.C. Cir. 2008) (citing *Butz v. Glover Livestock Comm. Co.,* 411 U.S. 182, 188 (1973)), *cert. denied,* __ U.S. __, 129 S. Ct. 1033, 1033 (2009). It is well-settled that since the Administrative Law Judge has had the opportunity to observe the demeanor and conduct of hearing witnesses, the factual findings set forth in this recommended decision are entitled to significant deference, *Universal Camera Corp. v. NLRB,* 340 U.S. 474, 496 (1951), and that this recommended decision constitutes an important part of the record that must be considered in the Administrator's decision, *Morall,* 412 F.3d at 179. However, any recommendations set forth herein

[89] This authority has been delegated pursuant to 28 C.F.R. §§ 0.100(b) and 0.104 (2010).

regarding the exercise of discretion are by no means binding on the Administrator and do not limit the exercise of that discretion. 5 U.S.C. § 557(b) (2006); *River Forest Pharmacy, Inc. v. DEA,* 501 F.2d 1202, 1206 (7th Cir. 1974); *Attorney General's Manual on the Administrative Procedure Act* 8 (1947).

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, it is undisputed that the Respondent holds a valid and current state license to practice medicine in Florida. The record contains no evidence of a recommendation regarding the Respondent's medical privileges by any cognizant state licensing board or professional disciplinary authority. However, that a state has not acted against a registrant's medical license is not dispositive in this administrative determination as to whether continuation of a registration is consistent with the public interest. *Patrick W. Stodola, M.D.,* 74 Fed. Reg. 20727, 20730 (2009); *Jayam Krishna-Iyer,* 74 Fed. Reg. at 461. It is well-established Agency precedent that a ''state license is a necessary, but not a sufficient condition for registration.'' *Leslie,* 68 Fed. Reg. at 15230; *John H. Kennedy, M.D.,* 71 Fed. Reg. 35705, 35708 (2006). Even the reinstatement of a state medical license does not affect the DEA's independent responsibility to determine whether a registration is in the public interest. *Mortimer B. Levin, D.O.,* 55 Fed. Reg. 9209, 8210 (1990). The ultimate responsibility to determine whether a registration is consistent with the public interest has been delegated exclusively to the DEA, not to entities within state government. *Edmund Chein, M.D.,* 72 Fed. Reg. 6580, 6590 (2007), *aff'd, Chein v. DEA,* 533 F.3d 828 (D.C. Cir. 2008), *cert. denied,* __ U.S. __, 129 S. Ct. 1033 (2009). Congress vested authority to enforce the CSA in the Attorney General, not state officials. *Stodola,* 74 Fed. Reg. at 20375. Here, there is no evidence of record that the state licensing board has even considered the issue of a formal action against the Respondent's licensure. Thus, on these facts, that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of the Respondent's DEA certification is consistent with the public interest.

Regarding the third factor (convictions relating to the manufacture, distribution, or dispensing of controlled substances), the record in this case does not contain evidence that the Respondent has been convicted of a crime related to the manufacture, distribution, or dispensing of controlled substances. DEA administrative proceedings are non-punitive and ''a remedial measure, based upon the public interest and the necessity to protect the public from those individuals who have misused controlled substances or their DEA COR, and who have not presented sufficient mitigating evidence to assure the [Administrator] that they can be trusted with the responsibility carried by such a registration.'' *Jackson,* 72 Fed. Reg. at 23853; *Leo R. Miller, M.D.,* 53 Fed. Reg. 21931, 21932 (1988). Where evidence in a particular case reflects that the Respondent has acquired convictions relating to the manufacture, distribution, or dispensing of controlled substances, those convictions must be carefully examined and weighed in the adjudication of whether the issuance of a registration is in the public interest. 21 U.S.C. § 823(f).

Although the standard of proof in a criminal case is more stringent than the standard required at an administrative proceeding, and the elements of both federal and state crimes relating to controlled substances are not always co-extensive with conduct that is relevant to a determination of whether registration is within the public interest, evidence that a registrant has been convicted of crimes related to controlled substances is a factor to be evaluated in reaching a determination as to whether he or she should be entrusted with a DEA certificate. The probative value of an absence of any evidence of criminal prosecution is somewhat diminished by the myriad of considerations that are factored into a decision to initiate, pursue, and dispose of criminal proceedings by federal, state, and local prosecution authorities. *See Robert L. Dougherty, M.D.,* 76 Fed. Reg. 16823, 16833 n.13 (2011); *Dewey C. Mackay, M.D.,* 75 Fed. Reg. 49956, 49973 (2010) (''[W]hile a history of criminal convictions for offenses involving the distribution or dispensing of controlled substances is a highly relevant consideration, there are any number of reasons why a registrant may not have been convicted of such an offense, and thus, the absence of such a conviction is of considerably less consequence in the public interest inquiry.'' (citing *Jayam Krishna-Iyer, M.D.,* 74 Fed. Reg. 459, 461 (2009); *Edmund Chein, M.D.,* 72 Fed. Reg. 6580, 6593 n.22 (2007), *aff'd, Chein v. DEA,* 533 F.3d 828 (D.C. Cir. 2008), *cert. denied,* __ U.S. __, 129 S. Ct. 1033 (2009))); *Ladapo O. Shyngle, M.D.,* 74 Fed. Reg. 6056, 6057 n.2 (2009). Although there is information in the record implying that the Respondent was arrested for conduct connected to that which was alleged in this case,[90] no evidence was offered or received which indicates whether law enforcement authorities are still engaged in a prosecution (or even a criminal investigation) of the Respondent, the current status of the charges that supported the arrest, or (beyond being ''drug-related'') even what the Respondent was arrested for or charged with. More to the point, an arrest is merely an untested accusation, not a conviction.

Accordingly, consideration of the evidence of record under the first and third factors neither supports the Government's argument for revocation nor militates against it.

Factors 2, 4, and 5: The Respondent's Experience in Dispensing Controlled Substances; Compliance with Applicable State, Federal, or Local Laws Relating to Controlled Substances; and Such Other Conduct Which May Threaten the Public Health and Safety

In this case, the gravamen of the allegations in the OSC/ISO, as well as the factual concentration of much of the evidence presented, share as a principal focus the manner in which the Respondent has either prescribed and dispensed controlled substances under the authority of his COR, and/or permitted/authorized others to do so. Thus, it is analytically logical to consider public interest factors two, four, and five together. That being said, factors two, four, and five involve analysis of common and distinct considerations.

Regarding Factor 2, in requiring an examination of a registrant's experience in handling controlled substances, Congress, in mandating a consideration of this element, manifested an acknowledgement that the qualitative manner and the quantitative volume in which a registrant has engaged in the dispensing of controlled substances, and how long he has been in the business of doing so, are significant factors to be evaluated in reaching a determination as to whether he should be entrusted with a DEA certificate. In some cases, viewing a registrant's actions against a backdrop of how he has performed activity within the scope of the

[90] Stipulation B; Tr. 468–69.

certificate can provide a contextual lens to assist in a fair adjudication of whether continued registration is in the public interest.

Evidence that a practitioner may have conducted a significant level of sustained activity within the scope of the registration for a sustained period is a relevant and correct consideration which must be accorded due weight. However, the Agency has taken the reasonable position that this factor can be readily outweighed by acts held to be inconsistent with the public interest. *Jayam Krishna-Iyer,* 74 Fed. Reg. at 463. Experience which occurred prior and subsequent to proven allegations of malfeasance may be relevant. Evidence that precedes proven misconduct may add support to the contention that, even acknowledging the gravity of a registrant's transgressions, they are sufficiently isolated and/or attenuated that adverse action against his registration is not compelled by public interest concerns. Likewise, evidence presented by the Government that the proven allegations are congruous with a consistent past pattern of poor behavior can enhance the Government's case.

In a similar vein, conduct which occurs after proven allegations can shed light on whether a registrant has taken steps to reform and/or conform his or her conduct to appropriate standards. Contrariwise, a registrant who has persisted in incorrect behavior, or made attempts to circumvent Agency directives, even after being put on notice, can enhance the Government's case for revocation. *Novelty, Inc.,* 73 Fed. Reg. 52689, 52703 (2008), *aff'd,* 571 F.3d 1176 (D.C. Cir. 2009); *Southwood Pharm., Inc.,* 72 Fed. Reg. 36487, 36503 (2007); *John J. Fotinopoulous,* 72 Fed. Reg. 24602, 24606 (2007).

In *Jayam Krishna-Iyer,* 74 Fed. Reg. at 463, DEA policy regarding this aspect of the public interest determination was clarified to some extent. The decision in that case acknowledged the reality that even a significant and sustained history of uneventful practice under a DEA certificate can be offset by proof that a registrant has committed acts inconsistent with the public interest. *Id.; see also Jeri Hassman, M.D.,* 75 Fed. Reg. 8194, 8235 (2010) (acknowledging Agency precedential rejection of the concept that conduct which is inconsistent with the public interest is rendered less so by comparing it with a Respondent's legitimate activities which occurred in substantially higher numbers); *Paul J. Cargine, Jr.,* 36 Fed. Reg. 51592, 515600 (1998) (''even though the patients at issue are only a small portion of Respondent's patient population, his prescribing of controlled substances to these individuals raises serious concerns regarding [his] ability to responsibly handle controlled substances in the future.''). In the context of a pharmacy registrant, Agency precedent has consistently held that even a significant level of legitimate dispensing cannot offset flagrant violations. *See, e.g., Medicine Shoppe-Jonesborough,* 73 Fed. Reg. 364, 386 & n.56 (2008).

The Agency, in its administrative precedent (notwithstanding what might be perceived as an arguable lack of at least readily-apparent ambiguity employed by Congress in the language of the statute) [91] has further curtailed the scope of Factor 2. The Agency's current view regarding Factor 2 is that while evidence of a registrant's experience handling controlled substances may be entitled to some weight in assessing whether errant practices have been reformed, it is entitled to no weight in cases where the Government has met its *prima facie* burden and a practitioner has failed to acknowledge wrongdoing. *Cynthia M. Cadet, M.D.,* 76 Fed. Reg. 19450 n.3 (2011); *Roni Dreszer, M.D.,* 76 Fed. Reg. 19434 n.3 (2011); *Michael J. Aruta, M.D.,* 76 Fed. Reg. 19420 n.3 (2011); *Jacobo Dreszer, M.D.,* 76 Fed. Reg. 19386–87 n.3 (2011). In this case, it is undisputed that the Respondent was issued a license to practice medicine in Florida. Since neither party to the litigation introduced any evidence regarding how the Respondent conducted himself as a registrant prior to the conduct alleged in the OSC/ISO, the quality and history of the Respondent's prior experience as a DEA registrant was simply not an issue in this case. However, as discussed, *infra,* other features of Factor 2 clearly do bear on a disposition of this case.

Regarding Factor 4, to effectuate the dual goals of conquering drug abuse and controlling both legitimate and illegitimate traffic in controlled substances, ''Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.'' *Gonzales v. Raich,* 545 U.S. 1, 13 (2005). Consistent with the maintenance of that closed regulatory system, subject to limited exceptions not relevant here, a controlled substance may only be dispensed upon a prescription issued by a practitioner, and such a prescription is unlawful unless it is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 C.F.R. § 1306.04(a). Furthermore, ''an order purporting to be a prescription issued not in the usual course of professional treatment * * * is not a prescription within the meaning and intent of [21 U.S.C. § 829] and the person knowingly * * * issuing it, shall be subject to the penalties provided for violations of the provisions of law related to controlled substances.'' *Id.*

A registered practitioner is authorized to dispense,[92] which the CSA defines as ''to deliver a controlled substance to an ultimate user [93] * * * by, or pursuant to the lawful order of a practitioner.'' 21 U.S.C. 802(10) (2006 & Supp. III 2010); *see also Rose Mary Jacinta Lewis,* 72 Fed. Reg. 4035, 4040 (2007). The prescription requirement is designed to ensure that controlled substances are used under the supervision of a doctor as a bulwark against the risk of addiction and recreational abuse. *Aycock,* 74 Fed. Reg. at 17541 (citing *Gonzales v. Oregon,* 546 U.S. 243, 274 (2006); *United States v. Moore,* 423 U.S. 122, 135, 142–43 (1975) (noting that evidence established that a physician exceeded the bounds of professional practice when he gave inadequate examinations or none at all, ignored the results of the tests he did make, and took no precautions against misuse and diversion)). The prescription requirement likewise stands as a proscription against doctors ''peddling to patients who crave the drugs for those prohibited uses.'' *Id.* The courts have sustained criminal convictions based on the issuing of illegitimate prescriptions where physicians conducted no physical examinations or sham physical examinations. *United States v. Alerre,* 430 F.3d 681, 690–91 (4th Cir. 2005), *cert. denied,* 574 U.S. 1113 (2006); *United States v. Norris,* 780 F.2d 1207, 1209 (5th Cir. 1986).

[91] See *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.,* 467 U.S. 837 (1984) for the two-step process constructed by the United States Supreme Court regarding the deference afforded to an agency in interpreting a statute it is charged to administer.

First * * * [i]f the intent of Congress is clear, that is the end of the matter; for the * * * agency[ ] must give effect to the unambiguously expressed intent of Congress. * * * [I]f the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.''

467 U.S. at 842–43.

[92] 21 U.S.C. § 823(f).

[93] ''Ultimate user'' is defined as ''a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.'' 21 U.S.C. § 802(27).

Prescribing Under the Respondent's Registration

Beyond doubt, the Government's evidence establishes that employees at NPPM, utilizing the authority of the Respondent's COR, were playing fast and loose with controlled substance prescriptions, which were preceded by physical examinations that could be only generously described as cursory, and which were conducted in a slovenly manner by non-physicians. The activities were unquestionably the crudest form of a mass-production operation aimed at making money by providing controlled substances without regard to medical need or legal requirement. That said, the evidence also establishes that the Respondent was not the owner of NPPM, but an employee from early 2009 to September 2010. Tr. 588, 865, 892. The focus of a correct determination in this case hinges on the appropriate level of responsibility to be required of a DEA registrant under these facts.

The Agency has consistently held that a DEA registrant is strictly liable for the misconduct of any person or entity he authorizes to act under his registration. *Scott C. Bickman, M.D.,* 76 Fed. Reg. 17694, 17703 (2011); *Paul Volkman,* 73 Fed. Reg. 30630, 30644 n.42 (2008), *aff'd, Volkman v. DEA,* 567 F.3d 215, 224 (6th Cir. 2009); *Rose Mary Jacinta Lewis, M.D.,* 72 Fed. Reg. 4035, 4041 (2007). While complete omniscience on the part of a registrant is not the standard, the Agency has made it clear that it will not countenance deliberate indifference on the part of those who enjoy the privileges of a DEA COR. *See Holloway Distrib.,* 72 Fed. Reg. 42118, 42124 (2007) (a policy of ''see no evil, hear no evil'' in a List I distributor context is held to be fundamentally inconsistent with the obligations of a DEA registrant). Even in a criminal context regarding prescriptions illegitimately issued, the courts have held that a factfinder ''may consider willful blindness as a basis for knowledge.'' *United States v. Katz,* 445 F.3d 1023, 1031 (8th Cir. 2006).

TFO Schwartz made ten visits to NPPM as UC Patient Rix, received controlled substances for his efforts during five, and obtained an unfilled prescription for controlled substances during one. Controlled pain medications and testosterone were provided to him under the Respondent's COR although he did not meet the Respondent until his fifth (November 21st) visit. *See* Tr. 646, 807. As UC Patient Rix, Schwartz had met with Laterza about obtaining testosterone and HRT, and with Nurse Sanchez about pain management, during clinic UC visits which occurred on October 21st and 23rd. Tr. 600–01, 608–12, 618–19. During the fifth (November 21st) UC visit, where he met with the Respondent for the first time, Patient Rix informed the Respondent (who had picked up the Patient Rix medical chart from the reception desk and was punching keys at a computer terminal during their entire interaction in the examination room) that he had previously met with Ms. Sanchez at this practice and received controlled substance pain medication, and that he had previously met with Laterza and received controlled substance testosterone from him. Tr. 647–49; Gov't Ex. 19 at 18. To emphasize the point, Patient Rix highlighted Ms. Sanchez's decision to provide a level of pain medication that was below the amount Rix had sought from her. Tr. 647; Gov't Ex. 19 at 18. Similarly, Rix explained to the Respondent that he was consulting with Laterza about HRT and sought advice from the Respondent about possible medication interactions, which the Respondent answered with assurances. Tr. 648; Gov't Ex. 19 at 18. Thus, there is no doubt, that based on Schwartz's credible testimony in this regard, that the Respondent knew or should have known that his COR was being used for the prescribing of controlled substances in the past, at times when he was or was not present. The Respondent's decision to blithely press on and issue prescriptions for controlled substances at an increased level to UC Patient Rix, based upon the conversation that he had with the patient and the chart he held in his hand, stands unexplained and unexplainable. Whether the Respondent knew of (or even designed) the controlled-substance shenanigans perpetrated by Laterza and Sanchez before that moment, or prescribed in spite of them and thereby ratified it thereafter, his actions fell markedly below the level of care required by one entrusted with a DEA COR. If he was so inclined, he could have, at a minimum, evaluated UC Patient Rix himself with a full and adequate physical examination. Instead, the Respondent, unfazed, increased UC Patient Rix's prescriptions for powerful and addictive controlled narcotics and endorsed their use by the patient with controlled steroids. Even a brief examination of the patient chart that the Respondent held in his hand would have allowed him to evaluate the discrepancies between the neck complaints expressed at the visit with the back complaints addressed in the MRI report provided. Further, the chart notes are replete with examinations and observations that can accurately be described as based in fantasy. It is clear that the Respondent prescribed dangerous and controlled substances to UC Patient Rix for reasons that lacked a legitimate medical purpose and were outside the course of professional practice in violation of 21 C.F.R. § 1306.04(a).

The Respondent's decision to prescribe controlled substances under the circumstances present at the (5th) November 21st UC visit without corrective action or even cursory inquiry, standing alone, is conduct sufficient to sustain the Government's burden to establish that the Respondent has committed acts inconsistent with the public interest. However, the Respondent's demeanor and inaction upon the direct communication by UC Patient Rix about how prescribing was being handled at NPPM under his COR stands as powerful and unrebutted evidence that the Respondent knew what was going on and ignored it—or worse. Thus, the evidence demonstrates that the Respondent either intentionally violated 21 C.F.R. § 1306.04(a) through the agency of NPPM functionaries when controlled drug prescriptions were issued over his COR to UC Patient Rix, UC Patient Hays, and UC Patient Barbaro, or shirked his responsibility as a COR registrant by taking no action to correct the illegality. Furthermore, the evidence fully supports the Government's theory that the Respondent issued controlled substance prescriptions in a manner that fell substantially below the standards required of a practitioner in Florida based upon the Government's expert's review of the patient charts maintained on Patients SL, CH, CC, and PL.

The Respondent, acting on the advice of counsel, invoked his Fifth Amendment right to remain silent. Tr. 334–35, 833–34. At a DEA administrative hearing, it is permissible to draw an adverse inference from silence, even in the face of a Fifth Amendment invocation. *See Hoxie v. DEA,* 419 F.3d 477, 483 (6th Cir. 2005) (citing *United States v. Hale,* 422 U.S. 171, 176 (1975) (''Silence gains more probative weight where it persists in the face of accusation, since it is assumed in such circumstances that the accused would be more likely than not to dispute an untrue accusation.'')); *Joseph Baumstarck, M.D.,* 74 Fed. Reg. 17525, 17528, n.3 (2009) (citing *Ohio Adult Parole Auth. v. Woodward,* 523 U.S. 272, 286 (1998)). The Government's case presented credible evidence that the Respondent had evidence that UC Patient Rix had received controlled substance prescriptions under the

Respondent's COR before he even met him, and ratified that decision when Schwartz (as Patient Rix) directly told him so. His response to this information was to prescribe even more controlled substances at a higher dosage level. UC Patients Hays and Barbaro received controlled substances under the Respondent's COR without meeting him at all. This evidence was presented at the hearing, yet the Respondent presented no evidence in contradiction or diminishment. No competent evidence was received that could sustain a finding that the Respondent did not know of the misconduct accomplished with his COR. On the facts of this case, where the supported allegations are of a nature that a registrant would be more likely than not to dispute them if untrue, an adverse inference based on the Respondent's silence is appropriate. Accordingly, as an evidentiary matter, it should be, and will be assumed that if the Respondent had contrary testimony to offer, he would have presented it, and that the Government has established, by a preponderance of the evidence, that controlled substances were prescribed and dispensed under the Respondent's COR under circumstances where he knew it was done, *and* where he should have known it was done.

Readily Retrievable Records

Accurate and reliable records are an obvious bedrock safeguard that is essential to ensure the integrity of the closed regulatory system. Because controlled substance activity is tracked through records, it can only be regulated by insisting on adequate documentation. Paperwork anomalies that could be viewed as minor infractions in other contexts rarely can be considered as such in this environment. In fact, it is no overstatement that adequate recordkeeping is a vital component to regulating activity related to controlled substances. A truly closed system requires not only that certain records and inventories be kept by all those registrants who either generate or take custody of controlled substances in any phase of the distribution chain until they reach the ultimate user, but that those documents be subject to periodic inspection and ready retrieval for that purpose. Registrants, such as the Respondent, who are authorized to dispense controlled substances are required to keep such records and to maintain them in a manner that is ''readily retrievable'' upon demand of those DEA officials charged with conducting inspections. *See* 21 C.F.R. § 1304.04(g) & (f)(2) (2011); *see* 21 C.F.R. § 1304.03 (requiring recordkeeping set forth in § 1304.04 for dispensing physicians). Readily retrievable is defined in the regulations as ''records kept * * * in such a manner that they can be separated out from all other records in a reasonable time * * *.'' 21 C.F.R. § 1300.01(b)(38).

At the hearing, DI Milan testified that the West Palm Beach Sheriff's Office seized records on February 23, 2011 pertaining to the Respondent, and that she was tasked with reviewing controlled substance transaction records associated with the Respondent's COR. Tr. 441–42. DI Milan further testified that, in her view, the Respondent's records were not readily retrievable, in contravention to applicable federal regulations. Tr. 442. However, DI Milan did not specify which records were not readily retrievable (or what regulation required them to be so). Furthermore, and more fundamentally, Milan acknowledged that no one ever asked the Respondent to produce any records. Tr. 444. It is not necessary, in this case, to reach a conclusion as to the reasonable parameters of when records can be accessed to meet the regulatory requirement of being ''readily retrievable,'' because the Respondent was never asked to retrieve any records. On these facts, where Milan testified that she had not reviewed all documents seized by the West Palm Beach Sherriff's Office from NPPM, and never made a demand of any kind for the production of any records from the Respondent, and was not present during the execution of the state criminal search warrant seizing the records that she reviewed, it would be illogical to find that the Respondent violated the requirement to have any records, much less that his records were unsatisfactory because they were not readily retrievable. Furthermore, the records were seized from NPPM five months after the Respondent was separated from his employment there. Tr. 441, 473, 865, 892. There is no evidence as to who had access to the records during the five months that they were out of the Respondent's control. Under the circumstances present in this record, it would border upon the surreal to sustain a finding that records that were out of the Respondent's control for five months, never fully inventoried by the Government before, during, or after seizure, or ever even requested of the registrant, were absent or delinquent in that they were not maintained in a readily retrievable manner. *See, e.g., Edmund Chein, M.D.,* 72 Fed. Reg. 6580, 6598 (2007) (recognizing that readily retrievable does not mean ''instantaneously produced'' and finding no basis to conclude that records and inventory records were not ''readily retrievable'' during inspection where evidence reflected neither how long DEA personnel waited for records nor total time present at clinic).

The Respondent's Prescribing and Dispensing

While true that the CSA authorizes the ''regulat[ion] of medical practice so far as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood,'' *Gonzales,* 546 U.S. at 266–67, an evaluation of cognizant state standards is essential, *Joseph Gaudio, M.D.,* 74 Fed. Reg. 10083, 10090 (2009); *Kamir Garces-Mejias, M.D.,* 72 Fed. Reg. 54931, 54935 (2007); *United Prescription Servs., Inc.,* 72 Fed. Reg. 50397, 50407 (2007). In this adjudication, the evaluation of the Respondent's prescribing practices must be consistent with the CSA's recognition of state regulation of the medical profession and its bar on physicians from peddling to patients who crave drugs for prohibited uses. The analysis must be ''tethered securely'' to state law and federal regulations in application of the public interest factors, and may not be based on a mere disagreement between experts as to the most efficacious way to prescribe controlled substances to treat chronic pain sufferers. *Volkman v. DEA,* 567 F.3d 215, 223 (6th Cir. 2009) (citing *Gonzales,* 546 U.S. at 272, 274).

Under the CSA, it is fundamental that a practitioner must establish and maintain a bona fide doctor-patient relationship in order to act ''in the usual course of * * * professional practice'' and to issue a prescription for a legitimate medical purpose.'' *Dewey C. Mackay, M.D.,* 75 Fed. Reg. 49956, 49973 (2010); *Stodola,* 74 Fed. Reg. at 20731; *Shyngle,* 74 Fed. Reg. at 6057–58 (citing *Moore,* 423 U.S. at 141–43). The CSA generally looks to state law to determine whether a bona fide doctor-patient relationship was established and maintained. *Stodola,* 74 Fed. Reg. at 20731; *Shyngle,* 74 Fed. Reg. at 6058; *Garces-Mejias,* 72 Fed. Reg. at 54935; *United Prescription Servs.,* 72 Fed. Reg. at 50407.

Under Florida law, grounds for disciplinary action or denial of state licensure include ''prescribing * * * any controlled substance, other than in the course of the physician's professional practice,'' and prescribing such substances ''inappropriately or in excessive or inappropriate quantities [as it] is [presumed to] not [be] in the best interest of the patient and is not in the

course of the physician's professional practice, without regard to his or her intent.'' Fla. Stat. § 458.331(1)(q) (2010). Florida law further provides that grounds for such disciplinary action also include:

> Failing to keep legible, as defined by department rule in consultation with the board, medical records that identify the licensed physician * * * and that justify the course of treatment of the patient, including, but not limited to, patient histories; examination results; test results; records of drugs prescribed, dispensed, or administered; and reports of consultations and hospitalizations.

Id. § 458.331(1)(m).[94]

In exercising its rulemaking function,[95] the Florida Board of Medicine (Florida Board) promulgated a regulation addressing ''Standards for Adequacy of Medical Records'' applicable to all physicians. Fla. Admin. Code Ann. r. 64B8–9.003 (2010). That regulation provides, in pertinent part:

> (2) A licensed physician shall maintain patient medical records in English, in a legible manner and with sufficient detail to clearly demonstrate why the course of treatment was undertaken.
> (3) The medical record shall contain sufficient information to identify the patient, support the diagnosis, justify the treatment and document the course and results of treatment accurately, by including, at a minimum, patient histories; examination results; test results; records of drugs prescribed, dispensed or administered; reports of consultations and hospitalizations; and copies of records or reports or other documentation obtained from other health care practitioners at the request of the physician and relied upon by the physician in determining the appropriate treatment of the patient.
> (4) All entries made into the medical records shall be accurately dated and timed. Late entries are permitted, but must be clearly and accurately noted as late entries and dated and timed accurately when they are entered in to the record * * *.

Id.

With respect to defining the parameters of what constitutes ''professional practice'' in the context of pain management prescribing, Florida state law provides:

> Notwithstanding any other provision of law, a physician may prescribe or administer any controlled substance under Schedules II–V * * * to a person for the treatment of intractable pain,[96] provided the physician does so in accordance with that level of care, skill, and treatment recognized by a reasonably prudent physician under similar conditions and circumstances.

Fla. Stat. § 458.326. Moreover, the Florida Board has adopted,[97] albeit in modified version, the *Model Policy for the Use of Controlled Substances for the Treatment of Pain* (*Model Policy*), a document drafted by the Federation of State Medical Boards (FSMB) to provide professional guidelines for the treatment of pain with controlled substances. The standards adopted by Florida share the key tenants of the *Model Policy's* standards for pain management prescribing, including the emphasis on diligent efforts by physicians to prevent drug diversion, prescribing based on clear documentation of unrelieved pain and thorough medical records, and compliance with applicable federal and state law.

Like the *Model Policy,* which was promulgated ''to encourage the legitimate medical uses of controlled substances for the treatment of pain while stressing the need to safeguard against abuse and diversion,'' Florida's regulation providing ''Standards for the Use of Controlled Substances for the Treatment of Pain'' (Florida Standards), Fla. Admin. Code Ann. r. 64B8–9.013, recognizes that ''inappropriate prescribing of controlled substances * * * may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use,'' *id.* at 9.013(d). The language employed by the regulation under the preamble section titled ''Pain [M]anagement [P]rinciples'' makes clear that the standards ''are not intended to define *complete or best practice,* but rather to communicate what the [Florida Board] considers to be *within the boundaries of professional practice''* (emphasis supplied), *id.* at 9.013(1)(g); thus, the plain text supports an inference that the standards provide the *minimum* requirements for establishing conduct that comports with the professional practice of controlled substance-based pain management within the state. Likewise, the level of integral range of acceptable practice that is built into the regulation underscores the importance of seeking an expert professional opinion in reaching a correct adjudication of whether a registrant has met the applicable Florida standard. It is clear that in assessing whether the controlled substance prescribing practices of a Florida practitioner fall within the acceptable range of what constitutes within the bounds of being ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice,'' [98] on the facts presented here,[99] input from an expert witness was helpful in some respects.

The Florida Standards direct that ''[p]hysicians should be diligent in preventing the diversion of drugs for illegitimate purposes,'' *id.* at 9.013(1)(d), and provide that the prescribing of controlled substances for pain will be considered

> To be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on *clear documentation* of unrelieved pain and in compliance with applicable state or federal law.

Id. at 9.013(1)(e) (emphasis supplied).

The Florida Standards further provide that the validity of prescribing will be judged ''based on the physician's treatment of the patient and *on available documentation,* rather than on the quantity and chronicity of prescribing'' (emphasis supplied). *Id.* at 9.013(1)(g). Furthermore, the Standards advise that physicians should not fear disciplinary action for ''prescribing * * * controlled substances * * * for a legitimate medical purpose and that is supported by *appropriate documentation* establishing a valid medical need and treatment plan'' (emphasis supplied), or ''for failing to adhere strictly to the provisions of these standards, *if good cause is shown for such deviation.'' Id.* at 9.013(1)(b), (f) (emphasis supplied).

Although, as discussed above, the Florida Board instituted general guidance applicable to all physicians regarding medical records, it also promulgated a separate set of documentation requirements in the Florida Standards applicable

[94] An additional ground recently amended to the statute is failing to comply with the requirements of 21 U.S.C. § 821 *et seq.* (Drug Abuse Prevention and Control Act). Fla. Stat. § 458.331(1)(oo)(2010). However, the alleged conduct in this matter precedes the effective date of the amendment, October 1, 2010.

[95] Rulemaking authority regarding the practice of medicine within the state of Florida has been delegated to the Florida Board of Medicine (Florida Board). Fla. Stat. § 458.309(1) (2010).

[96] Florida defines ''intractable pain'' to mean ''pain for which, in the generally accepted course of medical practice, the cause cannot be removed and otherwise treated.'' *Id.* § 458.326(1).

[97] Pursuant to authority vested in the Florida Board by the Florida legislature specifically to promulgate rules regarding state standards for pain management clinical practice. *Id.* § 458.309(5).

[98] 21 C.F.R. § 1306.04(a).

[99] Although the Agency has acknowledged the directive from the federal courts that a mere disagreement between experts cannot, standing alone, ordinarily form the basis of an adverse action against a practitioner's privilege to handle control substances, *Volkman v. DEA,* 567 F.3d 215, 223 (6th Cir. 2009) (citing *Gonzales,* 546 U.S. at 272, 274), it has also stated that expert testimony is not mandated ''[w]here, for example, the Government produces evidence of undercover visits showing that a physician knowingly engaged in outright drug deals * * *.'' *Cadet,* 76 Fed. Reg. at 19450 n.3; *R. Dreszer,* 76 Fed. Reg. at 19434 n.3; *Aruta,* 76 Fed. Reg. at 19420 n.3; *J. Dreszer,* 76 Fed. Reg. at 19386–87 n.3.

specifically to those physicians who prescribe controlled substances in the pain-management context. The Florida Standards, under the subheading ''Medical Records,'' state that ''[t]he physician is required to keep *accurate and complete records''* (emphasis supplied) including, though not limited to:

1. The medical history and physical examination, including history of drug abuse or dependence, as appropriate;
2. Diagnostic, therapeutic, and laboratory results;
3. Evaluations and consultations;
4. Treatment objectives;
5. Discussion of risks and benefits;
6. Treatments;
7. Medications (including date, type, dosage, and quantity prescribed);
8. Instructions and agreements; and
9. Periodic reviews.

Id. at 9.013(3)(f). The same section directs that ''[r]ecords must remain current and be maintained in an acceptable manner and readily available for review.'' *Id.*

The Florida Standards similarly emphasize the need for proper documentation in the patient evaluation context by specifying:

A complete[100] medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Id. at 9.013(3)(a).

Furthermore, the Florida Standards require a written treatment plan that ''should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned.'' *Id.* at 9.013(3)(b). Subsequent to the initiation of treatment, ''the physician should *adjust* drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.'' *Id.* (emphasis supplied).

Another standard adopted by the Florida Board, under the subheading ''Informed Consent and Agreement for Treatment,'' is the directive that

[T]he physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician should employ the use of a written agreement between physician and patient outlining patient responsibilities, including, but not limited to:
1. Urine/serum medication levels screening when requested;
2. Number and frequency of all prescription refills; and
3. Reasons for which drug therapy may be discontinued (i.e., violation of agreement).

Id. at 9.003(3)(c).

The Florida Standards contain a further requirement to periodically review ''the course of pain treatment and any new information about the etiology of the pain.'' *Id.* at 9.013(3)(d). The Florida Standards explain the importance of periodic review in the following manner:

Continuation or modification of therapy should depend on the physician's evaluation of the patient's progress. If treatment goals are not being achieved, despite medication *adjustments,* the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

Id. (emphasis supplied).

_____Under the subheading ''Consultation,'' the Florida Board promulgated the instruction that

[t]he physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation, and may require consultation with or referral to an expert in the management of such patients.

Id. at 9.013(3)(e).

It is abundantly clear from the plain language of the Florida Standards that the Florida Board places critical emphasis on physician implementation of adequate safeguards in their practice to minimize diversion and the need to document the objective signs and rationale employed in the course of pain treatment utilizing the prescription of controlled substances, as well as documentation regarding risks, benefits, and side effects of prescribed medications. Conscientious, legible documentation is repeatedly emphasized as not just a ministerial act, but a key treatment tool and a vital indicator to evaluate whether the physician's prescribing practices are ''within the usual course of professional practice.''

In *Sergio Rodriguez, M.D.,* Fla. Bd. of Med., No. 2008–20504 (Jan. 7, 2011), the Florida Board considered a case with many striking similarities to the case presented here. In *Rodriguez,* the respondent-practitioner had repeatedly seen an undercover agent, and without the benefit of a physical examination, medical history, tests, or treatment plan, and with incomplete and incorrect documentation, prescribed controlled substances. The Board adopted the state Administrative Law Judge's conclusion that the doctor's ''relationship with [the undercover patient] consisted solely of his writing prescriptions for controlled substances [and found that the doctor] was not prescribing these medications in the course of his professional practice.'' *Id.,* ALJ Dec. at 14.

The Government's evidence establishes that the Respondent issued controlled substance prescriptions to undercover law enforcement personnel posing as patients and other patients at his Florida office beginning in October 2009 and continuing until August 2010. As discussed at length elsewhere in this decision, in addition to the fact that controlled substances were prescribed and dispensed to patients without the Respondent even meeting them, the physical examinations were either cursory or non-existent, and the histories and documentation were inconsistent, incomplete, for the most part abjectly illegible, woefully inadequate, and frequently outright false. Much like the evidence that sustained the criminal conviction in *Moore,*[101] the examinations were inadequate and the patient records are devoid of any indication that steps were taken to safeguard against misuse and diversion. The uncontroverted and persuasive testimony of the Government's expert, Dr. Rubenstein, established, by a preponderance of the evidence, that the Respondent's prescribing practices fell well below the applicable standard in Florida regarding the controlled substances prescribed and dispensed to the undercover agents,

[100] The original *Model Policy* version of the guidelines does not contain a reference to the need for a *complete* medical history, instead only requiring a medical history generally. Thus, the Florida Board has adopted a higher standard than the measure that has been set in the *Model Policy* by the FSMB.

[101] 423 U.S. at 142–43.

as well as to the patients whose charts he reviewed.

On this record, the Government has established that the Respondent employed his COR and/or allowed/enabled others to do so in a manner where controlled substances were prescribed and dispensed for other than a legitimate medical purpose or outside the usual course of professional practice, based on the absence of acceptable physician-patient relationships and even minimal due care in documentation as those concepts are dealt with under federal and Florida state law.

Ryan Haight Act

Under the Ryan Haight Act, it is a violation of federal law to ''deliver[], distribute[], or dispense[][102] a controlled substance by means of the Internet without a valid prescription.'' 21 U.S.C. § 829(e). For a prescription to be valid under the meaning of this provision, it must have been ''issued for a legitimate medical purpose in the usual course of professional practice by * * * a practitioner who has conducted at least one in-person medical evaluation of the patient.[103] *Id.* An in-person medical evaluation is defined as ''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.* at § (2)(B)(i).

The Government alleged that the Respondent issued ''controlled substance prescriptions to patents in states other than Florida and that the controlled substances were being shipped into the resident state of these patients and that this was being accomplished in violation of the Ryan Haight Act and [sic] in 21 U.S.C. § 829(e).'' ALJ Ex. 6 at 6. As it unfolded at the hearing, the Government's evidence sought to establish that the Respondent issued controlled substance prescriptions to twenty-eight out-of-state individuals in fourteen states without providing an in-person physical examination to a single one. Gov't Ex. 37. Without question, to the extent that these prescriptions were issued without the benefit of an in-person physical examination, their issuance would constitute violations of the CSA as amended by the Ryan Haight Act, as well as the laws of many of the states where they were received by the end users. Without physical examinations, the Respondent may well have violated state prescribing proscriptions in several states, including (but not limited to) Alabama,[104] California,[105] Illinois,[106] Louisiana,[107] Mississippi,[108] and others. It is also unquestionably true that these controlled substance prescriptions were issued by the Respondent in a sufficiently high number and in a relatively brief period such that the evidence would be more than ample to support the adverse COR action sought by the Government in this matter. However, the Government's allegation that the Respondent prescribed controlled substances contrary to the Ryan Haight Act was dependent upon it establishing that the Respondent prescribed anabolic steroids without providing a physical examination and without a legitimate doctor-patient relationship. The only evidence tending to support that possibility was the shipping information of the steroids to arguably remote destinations outside Florida. However, evidence which may provide ample underpinnings to sustain a reasonable suspicion is not the same quantum required to support a finding of substantial evidence. Under the substantial evidence test, the evidence, such as the circumstantial evidence here, must ''do more than create a suspicion of the existence of the fact to be established.'' *Alvin Darby, M.D.,* 75 Fed. Reg. 26993, 26999 n.31 (2010) (quoting *NLRB v. Columbian Enameling & Stamping Co.,* 306 U.S. 292, 300 (1939)). Here, there is a missing link. There is no evidence that a single patient that received a controlled substance under the Respondent's COR outside the state of Florida was not examined by him. It is not that evidence was presented and found lacking; it is that no evidence was presented on the issue at all. A Ryan Haight violation sustained under the evidence presented would allow the Government to establish that no in-person physical examination occurred based on shipping label addresses and double hearsay business practice testimony from a diversion investigator who interviewed an individual who was an employee of a now-defunct company who did business with the Internet providers. In short, on the present record, it would be tantamount to sustaining a Ryan Haight violation based upon the mere fact that controlled substances were shipped to locations outside the registrant's home state. Unlike other similar cases, no documentary or reliable testimonial evidence was introduced regarding the nature of the Respondent's relationship with the Internet providers. While an adverse inference based on the Respondent's failure to testify is admittedly a possible evidentiary mechanism available to the Government on these facts, such an inference should not, on the present record, be utilized to establish an element upon which the Government presented no evidence.[109] Thus, the record compels a finding that the Government did not establish a violation of the Ryan Haight Act.

Factors 2, 4, and 5 Considered

The Government's evidence under these factors, as discussed above, present something of a mixed bag. On the one hand, there is insufficient evidence to support its allegations that the Respondent failed to maintain required records in a readily retrievable manner, in violation of regulatory requirements to do so, or its allegations that the Respondent prescribed in violation of the Ryan Haight Act. Thus, the evidence introduced on these issues, like the statistical data elicited through the head of its ARCOS Unit, does not impact a consideration of Factors 2, 4, or 5 (or any other relevant consideration in these proceedings) in any way.

On the other hand, the Government's evidence does establish that the Respondent was profoundly delinquent

[102] The statutory definition of the term ''dispense'' includes the prescribing and administering of controlled substances. 21 U.S.C. § 802(10).

[103] Provisions of the law dealing with the authorization of a ''covering practitioner'' and ''telemedicine'' practice have no applicability to the facts developed at this hearing. *See id.* at §§ 2(A)(ii), (C), 3(A).

[104] Ala. Code §§ 34–24–50(1), -51, -53, -343, -501, -502(a) (2010); Ala. Admin. Code r. 540-x-9-.11 (2010).

[105] Cal. Bus. & Prof. Code §§ 2052, 2060, 2242, 2242.1 (West 2010); Carlos Gustavo Levy (Med. Bd. of Cal. Jan. 28, 2003) (citation order); Carlos Gustavo Levy (Med. Bd. of Cal. Nov. 30, 2001) (citation order); Joan Jerzak, *Drugs on the Information Highway,* 88 Med. Bd. of Cal. Action Rep., Feb. 2004, at 4, available at *http://www.medbd.ca.gov/licensee/internet_prescribing.html.*

[106] 225 Ill. Comp. Stat. 60/49, 49.5 (2010).

[107] La. Rev. Stat. Ann. §§ 37:1262, 37:1271, 37:1290, 40:1238.4 (2010); La. Bd. of Med. Exam'rs, Statement of Position on Internet/Telephonic Prescribing (2000), *http://www.lsbme.louisiana.gov/Statements%20of%20Position/InternetTelephonicPrescribing.pdf.*

[108] Miss. Code Ann. §§ 73–25–1, -25–34, -43–11 (West 2010); 30–17 Miss. Code R. § 1:21(100), (102) (LexisNexis 2010).

[109] Inasmuch as the Ryan Haight Act became effective on April 13, 2009, the interpretive precedent regarding the law is predictably still in its nascent stages. It would not be unreasonable for the Agency to interpret the statute in such a way that a clear and convincing demonstration on the part of the Government that a practitioner has caused controlled substances prescribed and/or dispensed under his or her COR to be shipped to a remote, out-of-state location from the COR registered address would result in a burden of production on the part of the registrant to demonstrate that an in-person physical examination had been conducted. However, as of the date of this recommended decision, the Agency has not yet had the opportunity to evaluate the issue in this context.

in his responsibilities as a DEA registrant. He prescribed and dispensed controlled substances in the face of direct proof that others at NPPM were utilizing his COR to prescribe and dispense controlled pain medications and steroids. The evidence supports a finding that he knew that NPPM functionaries were busily prescribing and dispensing controlled substances under his COR while the enterprise compensated him as an employee. Under these conditions, the Respondent's salary appears, in many ways, to have been tantamount to the price of his complicity or willful ignorance. Patients were receiving dangerous and potentially addictive controlled substances while the Respondent was not present. The patient charts reviewed by the Government's expert demonstrated that the Respondent has been unwilling to take his responsibilities as a registrant regarding documented analysis related to the professional utilization and control of controlled substances in any way seriously. The patient charts maintained on the UCs contained out-and-out falsehoods. Most of the chart notes were illegible. The prescribing done by and allowed by the Respondent in the absence of valid physician-patient relationships, like the poor documentation in his charts, was done in violation of federal and state law, fell below the standard expected of a practitioner in the Florida, and resulted in the prescribing and dispensing of controlled substances outside the course of a professional practice and for illegitimate purposes. 21 C.F.R. § 1306.04(a). Consideration of the evidence of record under Factors 2 and 4 militate powerfully in favor of revocation.

The Fifth statutory factor, which plays a critical role in a disposition of this case given the facts presented, permits the Administrator to consider ''other conduct which may threaten the public health and safety.'' 21 U.S.C. § 823(f)(5). Under current Agency precedent, this factor has been held to be sufficiently broad as to encompass ''conduct which creates a probable or possible threat * * * to public health and safety. *Cadet,* 76 Fed. Reg. at 19450 n.3; *R. Dreszer,* 76 Fed. Reg. at 19434 n.3; *Aruta,* 76 Fed. Reg. at 19420 n.3; *J. Dreszer,* 76 Fed. Reg. at 19386–87 n.3.

The Respondent has used his COR, and allowed it to be used, in a manner where controlled substances were provided to individuals he never met, and where he has failed to provide even the most basic documentation to support his prescribing and dispensing. He has acted in a manner that was contrary to the most bedrock obligations attendant upon a registrant to guard against diversion, and has committed and endured conduct that allowed and facilitated powerful, addictive controlled substances to be prescribed and distributed without the benefits of the basic safeguards required to ensure a closed regulatory system. His actions created an environment where individuals were receiving potentially dangerous controlled substances without regard to whether such substances were medically required or in the best interests of the patients. Simply put, the Respondent has endangered the public and this factor militates strongly in favor or revocation.

Recommendation

Based on the foregoing, the evidence supports a finding that the Government has established that the Respondent has committed acts that are inconsistent with the public interest. In cases, such as the present case, where the Government has made out a *prima facie* case that the Respondent has committed acts that render his continued registration inconsistent with the public interest, Agency precedent has firmly placed acknowledgement of guilt and acceptance of responsibility as conditions precedent to merit the continued status as a registrant and avoid revocation. *Hoxie v. DEA,* 419 F.3d 477, 483 (6th Cir. 2005); *Ronald Lynch, M.D.,* 75 Fed. Reg. 78745, 78749 (2010) (Respondent's attempts to minimize misconduct held to undermine acceptance of responsibility); *George Mathew, M.D.,* 75 Fed. Reg. 66138, 66140, 66145, 66148 (2010); *George C. Aycock, M.D.,* 74 Fed. Reg. 17529, 17543 (2009); *Steven M. Abbadessa, D.O.,* 74 Fed. Reg. 10077, 10078 (2009); *Jayam Krishna-Iyer, M.D.,* 74 Fed. Reg. 459, 463 (2009); *Medicine Shoppe-Jonesborough,* 73 Fed. Reg. 364, 387 (2008). Here, the Respondent has not accepted responsibility for his actions, expressed remorse for his conduct at any level, or presented a shred of evidence that could reasonably support a finding that the Administrator should continue to entrust him with a Certificate of Registration. Under current Agency precedent, the evidence of record compels a recommendation that the Government's petition to revoke the Respondent's registration be sustained.

Accordingly, the Respondent's Certificate of Registration should be **REVOKED**, and any pending renewal applications should be **DENIED**.

Dated: July 18, 2011.

JOHN J. MULROONEY, II

Chief Administrative Law Judge

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