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9 a.m.-12:30 p.m.

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Conference Room, Suite 700
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Washington, DC 20002

RESERVATIONS: (202) 741-6008



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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.

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC-2011-0002]

RIN 3150-A189

List of Approved Spent Fuel Storage Casks: NUHOMS® HD System Revision 1

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC or the Commission) is amending its spent fuel storage regulations by revising the Transnuclear, Inc. (TN) NUHOMS® HD System listing within the “List of Approved Spent Fuel Storage Casks” to include Amendment No. 1 to Certificate of Compliance (CoC) Number 1030. Amendment No. 1 will revise the definitions for Damaged Fuel Assembly and Transfer Operations; add definitions for Fuel Class and Reconstituted Fuel Assembly; add Combustion Engineering 16x16 class fuel assemblies as authorized contents; reduce the minimum off-normal ambient temperature from -20°F to -21°F ; expand the authorized contents of the NUHOMS® HD System to include pressurized water reactor fuel assemblies with control components; reduce the minimum initial enrichment of fuel assemblies from 1.5 weight percent uranium-235 to 0.2 weight percent uranium-235; clarify the requirements of reconstituted fuel assemblies; add requirements to qualify metal matrix composite neutron absorbers with integral aluminum cladding; clarify the requirements for neutron absorber tests; delete use of nitrogen for draining the water from the dry shielded canister (DSC), and allow only helium as a cover gas during DSC

cavity water removal operations; and make corresponding changes to the technical specifications (TS).

DATES: The final rule is effective March 29, 2011, unless significant adverse comments are received by February 14, 2011. A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule’s underlying premise or approach, or would be ineffective or unacceptable without a change. If the rule is withdrawn, timely notice will be published in the **Federal Register**.

ADDRESSES: You can access publicly available documents related to this document using the following methods:

Federal e-Rulemaking Portal: Go to <http://www.regulations.gov> and search for documents filed under Docket ID [NRC-2011-0002]. Address questions about NRC dockets to Carol Gallagher 301-492-3668; e-mail Carol.Gallagher@nrc.gov.

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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. An electronic copy of the proposed CoC, Technical Specifications (TS), and preliminary safety evaluation report (SER) can be found under ADAMS Package Accession Number ML102500570. The ADAMS Accession Number for the Transnuclear, Inc application, dated November 1, 2007, is ML073110525.

CoC No. 1030, the TS, the preliminary SER, and the environmental assessment are available for inspection at the NRC’s PDR, Room O-1F21, One White Flint North, 11555 Rockville Pike, Rockville, MD. Single copies of these documents may be obtained from Gregory Trussell,

Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone 301-415-6445, e-mail Gregory.Trussell@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Gregory Trussell, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone 301-415-6445, e-mail Gregory.Trussell@nrc.gov.

SUPPLEMENTARY INFORMATION:

Background

Section 218(a) of the Nuclear Waste Policy Act (NWPA) of 1982, as amended, requires that “the Secretary [of the Department of Energy] shall establish a demonstration program, in cooperation with the private sector, for the dry storage of spent nuclear fuel at civilian nuclear power reactor sites, with the objective of establishing one or more technologies that the [Nuclear Regulatory] Commission may, by rule, approve for use at the sites of civilian nuclear power reactors without, to the maximum extent practicable, the need for additional site-specific approvals by the Commission.” Section 133 of the NWPA states, in part, that “the Commission shall, by rule, establish procedures for the licensing of any technology approved by the Commission under Section 218(a) for use at the site of any civilian nuclear power reactor.”

To implement this mandate, the NRC approved dry storage of spent nuclear fuel in NRC-approved casks under a general license by publishing a final rule in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 72, which added a new Subpart K within 10 CFR Part 72, entitled “General License for Storage of Spent Fuel at Power Reactor Sites” (55 FR 29181; July 18, 1990). This rule also established a new Subpart L within 10 CFR Part 72, entitled “Approval of Spent Fuel Storage Casks,” which contains procedures and criteria for obtaining NRC approval of spent fuel storage cask designs. The NRC subsequently issued a final rule on December 11, 2006 (71 FR 71463), that approved the NUHOMS® HD System cask design and added it to the list of NRC-approved cask designs in 10 CFR 72.214 as CoC No. 1030.

Discussion

On November 1, 2007, and as supplemented on December 15, 2008, February 19, April 30, May 26, June 10, September 17, 2009, June 17 (proprietary information not publicly available), July 9, July 26, and August 24, 2010, TN, the holder of CoC No. 1030, submitted an application to the NRC that requested an amendment to CoC No. 1030. Specifically, TN requested changes to revise definitions for Damaged Fuel Assembly and Transfer Operations; add definitions for Fuel Class and Reconstituted Fuel Assembly; add Combustion Engineering 16x16 class fuel assemblies as authorized contents; reduce the minimum off-normal ambient temperature from -20°F to -21°F ; expand the authorized contents of the NUHOMS[®] HD System to include pressurized water reactor fuel assemblies with control components; reduce the minimum initial enrichment of fuel assemblies from 1.5 weight percent uranium-235 to 0.2 weight percent uranium-235; clarify the requirements of reconstituted fuel assemblies; add requirements to qualify metal matrix composite neutron absorbers with integral aluminum cladding; clarify the requirements for neutron absorber tests; and delete use of nitrogen for draining the water from the DSC, and allow only helium as a cover gas during DSC cavity water removal operations; and make corresponding changes to TS 1.1, 2.1, 2.2.3, 3.1, 3.2, 4.3.1, 4.6.3(5), 5.2.5, 5.3.2, and 5.6. Tables 1 and 5 will be deleted and replaced with TS 2.1, and Tables 2, 3, 4, and 7 will be revised to incorporate TS changes.

As documented in the SER, the NRC staff performed a detailed safety evaluation of the proposed CoC amendment request and found that an acceptable safety margin is maintained. In addition, the NRC staff has determined that there continues to be reasonable assurance that public health and safety will be adequately protected.

This direct final rule revises the NUHOMS[®] HD System listing in 10 CFR 72.214 by adding Amendment No. 1 to CoC No. 1030. The amendment consists of the changes described above, as set forth in the revised CoC and TS. The revised TS are identified in the SER.

The amended NUHOMS[®] HD System cask design, when used under the conditions specified in the CoC, the TS, and NRC regulations, will meet the requirements of Part 72; thus, adequate protection of public health and safety will continue to be ensured. When this

direct final rule becomes effective, persons who hold a general license under 10 CFR 72.210 may load spent nuclear fuel into NUHOMS[®] HD System casks that meet the criteria of Amendment No. 1 to CoC No. 1030 under 10 CFR 72.212.

Discussion of Amendments by Section

§ 72.214 List of approved spent fuel storage casks.

Certificate No. 1030 is revised by adding the effective date of Amendment Number 1.

Procedural Background

On May 6 and 7, 2010, respectively, a direct final rule (75 FR 24786) and companion proposed rule (75 FR 25120) were published in the **Federal Register** to revise the cask system listing for the TN NUHOMS[®] HD System by adding Amendment No. 1 to the list of approved spent fuel storage casks in 10 CFR 72.214. After the rules were published, the applicant identified that a certain TS for Boral characterization (TS 4.3.1, "Neutron Absorber Tests") was not written precisely and in a manner that could be readily and demonstrably implemented.

On July 16, 2010, the NRC withdrew the direct final rule (75 FR 41369) and the companion proposed rule (75 FR 41404). The applicant submitted revised language for TS 4.3.1 (and Final Safety Analysis Report (FSAR) sections incorporated into the TS by reference) on July 26 and August 24, 2010, which NRC staff reviewed and found to be acceptable. This direct final rule includes the original Amendment No. 1 changes and the revised TS 4.3.1 and FSAR sections incorporated into the TS by reference.

This rule is limited to the changes contained in Amendment No. 1 to CoC No. 1030 and does not include other aspects of the NUHOMS[®] HD System. The NRC is using the "direct final rule procedure" to issue this amendment because it represents a limited and routine change to an existing CoC that is expected to be noncontroversial. Adequate protection of public health and safety continues to be ensured. The amendment to the rule will become effective on March 29, 2011. However, if the NRC receives significant adverse comments on this direct final rule by February 14, 2011, then the NRC will publish a document that withdraws this action and will subsequently address the comments received in a final rule as a response to the companion proposed rule published elsewhere in this issue of the **Federal Register**. Absent significant modifications to the proposed revisions requiring republication, the NRC will

not initiate a second comment period on this action.

A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when:

(a) The comment causes the NRC staff to reevaluate (or reconsider) its position or conduct additional analysis;

(b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(c) The comment raises a relevant issue that was not previously addressed or considered by the NRC staff.

(2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the NRC staff to make a change (other than editorial) to the rule, CoC, or TS.

For detailed instructions on filling comments, please see the companion proposed rule published elsewhere in this issue of the **Federal Register**.

Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this direct final rule, the NRC will revise the NUHOMS[®] HD System cask design listed in § 72.214 (List of approved spent fuel storage casks). This action does not constitute the establishment of a standard that contains generally applicable requirements.

Agreement State Compatibility

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997, and published in the **Federal Register** on September 3, 1997 (62 FR 46517), this rule is classified as Compatibility Category "NRC." Compatibility is not required for Category "NRC" regulations. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC

by the Atomic Energy Act of 1954, as amended, or the provisions of 10 CFR. Although an Agreement State may not adopt program elements reserved to NRC, it may wish to inform its licensees of certain requirements via a mechanism that is consistent with the particular State's administrative procedure laws but does not confer regulatory authority on the State.

Plain Language

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

Finding of No Significant Environmental Impact: Availability

Under the National Environmental Policy Act of 1969, as amended, and the NRC regulations in Subpart A of 10 CFR Part 51, the NRC has determined that this rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. The NRC has prepared an environmental assessment and, on the basis of this environmental assessment, has made a finding of no significant impact. This rule will amend the CoC for the NUHOMS® HD System cask design within the list of approved spent fuel storage casks that power reactor licensees can use to store spent fuel at reactor sites under a general license. The amendment will revise the definitions for Damaged Fuel Assembly and Transfer Operations; add definitions for Fuel Class and Reconstituted Fuel Assembly; add Combustion Engineering 16x16 class fuel assemblies as authorized contents; reduce the minimum off-normal ambient temperature from -20 °F to -21 °F; expand the authorized contents of the NUHOMS® HD System to include pressurized water reactor fuel assemblies with control components; reduce the minimum initial enrichment of fuel assemblies from 1.5 weight percent uranium-235 to 0.2 weight percent uranium-235; clarify the requirements of reconstituted fuel assemblies; add requirements to qualify metal matrix composite neutron absorbers with integral aluminum cladding; clarify the requirements for neutron absorber tests; delete use of

nitrogen for draining the water from the DSC, and allow only helium as a cover gas during DSC cavity water removal operation; and make corresponding changes to the TS that are revised to include TS 1.1, 2.1, 2.2.3, 3.1, 3.2, 4.3.1, 4.6.3(5), 5.2.5, 5.3.2, and 5.6. Tables 1 and 5 are deleted and replaced with TS 2.1, and Tables 2, 3, 4, and 7 are revised to incorporate TS changes.

The environmental assessment and finding of no significant impact on which this determination is based are available for inspection at the NRC Public Document Room, Room O-1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. Single copies of the environmental assessment and finding of no significant impact are available from Gregory Trussell, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: 301-415-6445, e-mail: Gregory.Trussell@nrc.gov.

Paperwork Reduction Act Statement

This rule does not contain any information collection requirements and, therefore, is not subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing requirements were approved by the Office of Management and Budget (OMB), Approval Number 3150-0132.

Public Protection Notification

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

Regulatory Analysis

On July 18, 1990 (55 FR 29181), the NRC issued an amendment to 10 CFR Part 72 to provide for the storage of spent nuclear fuel under a general license in cask designs approved by the NRC. Any nuclear power reactor licensee can use NRC-approved cask designs to store spent nuclear fuel if it notifies the NRC in advance, the spent fuel is stored under the conditions specified in the cask's CoC, and the conditions of the general license are met. A list of NRC-approved cask designs is contained in 10 CFR 72.214. On December 11, 2006 (71 FR 71463), the NRC issued an amendment to Part 72 that approved the NUHOMS® HD System cask design by adding it to the list of NRC-approved cask designs in 10 CFR 72.214. On November 1, 2007, as supplemented on December 15, 2008, February 19, April 30, May 26, June 10,

September 17, 2009, June 17 (proprietary information not publicly available), July 9, July 26, and August 24, 2010, the certificate holder (TN) submitted an application to the NRC to amend CoC No. 1030 to revise the definitions for Damaged Fuel Assembly and Transfer Operations; add definitions for Fuel Class and Reconstituted Fuel Assembly; add Combustion Engineering 16x16 class fuel assemblies as authorized contents; reduce the minimum off-normal ambient temperature from -20 °F to -21 °F; expand the authorized contents of the NUHOMS® HD System to include pressurized water reactor fuel assemblies with control components; reduce the minimum initial enrichment of fuel assemblies from 1.5 weight percent uranium-235 to 0.2 weight percent uranium-235; clarify the requirements of reconstituted fuel assemblies; add requirements to qualify metal matrix composite neutron absorbers with integral aluminum cladding; clarify the requirements for neutron absorber tests; delete use of nitrogen for draining the water from the DSC, and allow only helium as a cover gas during DSC cavity water removal operations; and make corresponding changes to TS 1.1, 2.1, 2.2.3, 3.1, 3.2, 4.3.1, 4.6.3(5), 5.2.5, 5.3.2, and 5.6. Tables 1 and 5 are deleted and replaced with TS 2.1, and Tables 2, 3, 4, and 7 are revised to incorporate TS changes.

The alternative to this action is to withhold approval of Amendment No. 1 and to require any Part 72 general licensee, seeking to load spent nuclear fuel into NUHOMS® HD System casks under the changes described in Amendment No. 1, to request an exemption from the requirements of 10 CFR 72.212 and 72.214. Under this alternative, each interested Part 72 licensee would have to prepare, and the NRC would have to review, a separate exemption request, thereby increasing the administrative burden upon the NRC and the costs to each licensee.

Approval of the direct final rule is consistent with previous NRC actions. Further, as documented in the SER and the environmental assessment, the direct final rule will have no adverse effect on public health and safety. This direct final rule has no significant identifiable impact or benefit on other Government agencies. Based on this regulatory analysis, the NRC concludes that the requirements of the direct final rule are commensurate with the NRC's responsibilities for public health and safety and the common defense and security. No other available alternative is believed to be as satisfactory, and thus, this action is recommended.

Regulatory Flexibility Certification

Under the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the NRC certifies that this rule will not, if issued, have a significant economic impact on a substantial number of small entities. This direct final rule affects only nuclear power plant licensees and TN. These entities do not fall within the scope of the definition of “small entities” set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810).

Backfit Analysis

The NRC has determined that the backfit rule (10 CFR 72.62) does not apply to this direct final rule because this amendment does not involve any provisions that would impose backfits as defined in 10 CFR Chapter 1. Therefore, a backfit analysis is not required.

Congressional Review Act

Under the Congressional Review Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs, OMB.

List of Subjects in 10 CFR Part 72

Administrative practice and procedure, Hazardous waste, Nuclear materials, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements, Security measures, Spent fuel, Whistleblowing.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; the Nuclear Waste Policy Act of 1982, as amended; and 5 U.S.C. 552 and 553; the NRC is adopting the following amendments to 10 CFR Part 72.

PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL, HIGH-LEVEL RADIOACTIVE WASTE, AND REACTOR-RELATED GREATER THAN CLASS C WASTE

■ 1. The authority citation for Part 72 continues to read as follows:

Authority: Secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2232, 2233, 2234, 2236, 2237, 2238, 2282); sec. 274, Pub. L. 86–373, 73 Stat. 688, as amended (42 U.S.C. 2021); sec. 201, as amended, 202, 206,

88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); Pub. L. 95–601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102–486, sec. 7902, 106 Stat. 3123 (42 U.S.C. 5851); sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332); secs. 131, 132, 133, 135, 137, 141, Pub. L. 97–425, 96 Stat. 2229, 2230, 2232, 2241, sec. 148, Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10151, 10152, 10153, 10155, 10157, 10161, 10168); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–10 (42 U.S.C. 2014, 2021, 2021b, 2111).

Section 72.44(g) also issued under secs. 142(b) and 148(c), (d), Pub. L. 100–203, 101 Stat. 1330–232, 1330–236 (42 U.S.C. 10162(b), 10168(c), (d)). Section 72.46 also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97–425, 96 Stat. 2230 (42 U.S.C. 10154). Section 72.96(d) also issued under sec. 145(g), Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10165(g)). Subpart J also issued under secs. 2(2), 2(15), 2(19), 117(a), 141(h), Pub. L. 97–425, 96 Stat. 2202, 2203, 2204, 2222, 2244 (42 U.S.C. 10101, 10137(a), 10161(h)). Subparts K and L are also issued under sec. 133, 98 Stat. 2230 (42 U.S.C. 10153) and sec. 218(a), 96 Stat. 2252 (42 U.S.C. 10198).

■ 2. In § 72.214, Certificate of Compliance 1030 is revised to read as follows:

§ 72.214 List of approved spent fuel storage casks.

* * * * *

Certificate Number: 1030.
Initial Certificate Effective Date: January 10, 2007.
Amendment Number 1 Effective Date: March 29, 2011.
SAR Submitted by: Transnuclear, Inc.
SAR Title: Final Safety Analysis Report for the NUHOMS® HD Horizontal Modular Storage System for Irradiated Nuclear Fuel.
Docket Number: 72–1030.
Certificate Expiration Date: January 10, 2027.
Model Number: NUHOMS® HD–32PTH.

* * * * *

Dated at Rockville, Maryland, this 13th day of December 2010.

For the Nuclear Regulatory Commission.

R.W. Borchardt,

Executive Director for Operations.

[FR Doc. 2011–642 Filed 1–12–11; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 185

[DoD–2008–OS–0085; RIN 0790–AI34]

Defense Support of Civil Authorities (DSCA)

AGENCY: Department of Defense.

ACTION: Final rule.

SUMMARY: This final rule establishes policy and assigns responsibilities for DSCA, supplements regulations regarding military support for civilian law enforcement, and sets forth policy guidance for the execution and oversight of DSCA when requested by civil authorities and approved by the appropriate Department of Defense (DoD) authority, or as directed by the President, within the United States, including the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and any territory or possession of the United States or any political subdivision thereof. Legislative changes over the years have made the existing guidance outdated and inconsistent with current law and the current organizational structure of the Department of Defense. This final rule will facilitate civil authorities’ access to the support they are seeking from the Department by establishing updated policy guidance and assigning the correct responsibilities within the Department for Defense Support of Civil Authorities in response to requests for assistance for domestic emergencies, designated law enforcement support, special events, and other domestic activities.

DATES: *Effective Date:* This rule is effective February 14, 2011.

FOR FURTHER INFORMATION CONTACT: Colonel Brent Feick, 703–697–5415.

SUPPLEMENTARY INFORMATION: The Department of Defense published a proposed rule on December 4, 2008 (73 FR 73896–73900). Eighty-four comments were received and are addressed below:

Comment: Thirty-nine of the 84 public comments question the Constitutionality of the Department of Defense supporting civil authorities domestically. Example: DOD–2008–0085–006 “The U.S. Constitution outlines the use of military force within our borders. We don’t need this. We need leaders who have respect for our Constitution and our Liberty.”

Response: The rule has been thoroughly reviewed by attorneys at several levels of the Departments of Defense, Justice, and Homeland Security and found not to violate any provisions of the Constitution. The Department of Defense (DoD) has historically been requested by civil authorities to provide support or assistance during various types of man-made or natural disasters, support for special events such as the National Political Conventions, the

Group of Eight Summit, the Inauguration, the Olympics, the Special Olympics, the United Nations General Assembly, and even support to law enforcement to help quell civil disobedience and restore public order, such as the Los Angeles Riots in 1992. Each of these support missions is conducted consistent with the Constitution, applicable law, and National policy. This rule sets forth DoD policy guidance for the execution and oversight of Defense Support of Civil Authorities when support or assistance is requested by civil authorities. The rule, by itself, provides no new, separate, or independent authority to the President, the Secretary of Defense, or anyone else in the Department of Defense.

Comment: Sixteen of the 84 public comments asserted that the rule was in violation of the Posse Comitatus Act (Title 18, United States Code, Section 1385). Example: DOD-2008-0085-010 "The Defense Support of Civil Authorities Plan is a violation of Posse Comitatus and will sink this once great country to the level of a third world dictatorship. The DOD should be fighting for individual freedom in the US, not helping to extinguish it."

Response: The rule has been thoroughly reviewed by attorneys at several levels of the Departments of Defense, Justice, and Homeland Security and found not to violate any current law, including the Posse Comitatus Act.

Comment: Eight of the 84 public comments asserted that the rule was inconsistent with the Second Amendment to the Constitution. Example: DOD-2008-0085-054 "This proposed regulation is an unconstitutional infringement on Second Amendment rights. It also gives excessive power to the U.S. Military to serve as an internal police force."

Response: The rule has been thoroughly reviewed by attorneys at several levels of the Departments of Defense, Justice, and Homeland Security and found not to violate any provisions of the Constitution, including the Second Amendment. There is no attempt to usurp civilian authority or use the military as an internal police force. The rule sets forth policy guidance for the execution and oversight of defense support of civilian authorities when requested by civil authorities.

Comment: Seven of the 84 public comments asserted that National Guard forces were sufficient to fill this support or assistance role under the direction of respective Governors. Example: DOD-2008-0085-002 "There is no reason to involve the forces of the United States

military when each state already has National Guard units which can fill this role and are under the direction of the Governor. I'm a big supporter of a strong US military for the protection of our country from outside threats. This redundancy is not only unwarranted, it runs against the principles of our founding fathers."

Response: The National Guard, when in Federal service or funded by the Department of Defense and in coordination with the Governors, is a vital component of Defense Support of Civil Authorities. In the Department of Defense's Strategy for Homeland Defense and Civil Support, there is a focused reliance on the Reserve Components to support and assist civil authorities. Individual state National Guard units are more capable and better equipped and resourced than during any time in their history. But each state National Guard cannot be manned, equipped, trained, and resourced to meet the needs of every conceivable contingency operation. Most states are part of Regional or National Emergency Management Assistance Compacts, which permit the Governor of one state to commit that state's resources to support another state. This process works very well during localized emergencies or disasters, but mutual aid support between states is not as efficient during special events or incidents other than localized major disasters and emergencies. In the event of multiple, near simultaneous, geographically dispersed terrorist attacks in the United States, or the rapid spread of a pandemic, it is unknown if Governors would release their National Guard capabilities to support another state or a Federal Agency if there is a chance that resources would be needed in their home states. Many emergencies, disasters, or events affect more than one state. It is not realistic to expect Federal Departments or Agencies to coordinate requests for assistance or support with multiple States, Commonwealths, and Territories. Finally, there are some capabilities that are available only in the Active Duty military force or in DoD.

Comment: Five of the 84 public comments asserted that it was the military's role to protect against foreign threats only. Example: DOD-2008-0085-020 "This proposal is ridiculous and in violation of the Constitution. If this is a need that must be met, use the funding it would require and invest it in civil law enforcement and emergency services. The military is for defending us from foreign aggressors."

Response: The rule has been thoroughly reviewed by attorneys at several levels of the Departments of

Defense, Justice, and Homeland Security and found not to violate any provisions of the Constitution. Additionally, a number of statutes provide specific authority for DSCA. This rule sets forth DoD policy guidance for the execution and oversight of defense support of civil authorities. There are no provisions for the DoD components to take over what is inherently a civilian responsibility, but rather provisions for providing support or assistance when requested.

Comment: Five of the 84 public comments asserted that the proposed rule was too broad and gave the military or the President too much power. Example: DOD-2008-OS-0085-0036 "I am opposed to this government regulation 'Defense Support of Civil Authorities'. It gives power to the military to assume civilian law enforcement at the behest of the president with no restriction on this power. This is unconstitutional! This document is too broad and clearly states that the military can intervene at the request of civil authorities OR by presidential executive order. This is a very dangerous rule to individual freedom!"

Response: This rule sets forth DoD policy guidance for the execution and oversight of Defense Support of Civil Authorities when support or assistance is requested by civil authorities. The rule, by itself, provides no new, separate, or independent authority to the President, the Secretary of Defense, or anyone else in the Department of Defense.

Comment: Four of the 84 public comments asserted that the rule violated or erodes the 10th Amendment to the Constitution. Example: DOD-2008-OS-0085-17 "There is no Constitutional basis for any portion of this proposed regulation. Leaving the deployment of our military within our own borders to assist with undefined domestic issues to the whims of the President is dangerous, adds undue stress on the office, and severely erodes the rights afforded to the states under the 10th Amendment."

Response: This rule sets forth DoD policy guidance for the execution and oversight of Defense Support of Civil Authorities when support or assistance is requested by civil authorities. The rule, by itself, provides no new, separate, or independent authority, nor does it violate, restrict, or erode the rights afforded to the states under the 10th Amendment. This rule enables civil authorities (See Joint Publication 1-02)¹ to request and receive support or

¹ Available by downloading at http://www.dtic.mil/doctrine/new_pubs/jp1_02.pdf.

assistance from the Department of Defense.

Comment: Three of the 84 public comments expressed concern over the inclusion of “special events” in the rule. Example: DOD–2008–OS–0085–0019 “The role of the US military is to protect us from foreign threats. This regulation is overbroad in that it would allow the use of the US military to suppress any kind of gathering. As an example, consider the Rainbow gatherings, 50–60,000 people exercising their right to gather on public lands. Under this regulation, the military could be called in to quash this. This regulation essentially guts the constitution. Because of clauses like ‘special events’ and ‘other domestic activities’ are broad, they could be interpreted to allow military intervention in any special event, such as concerts, parades, demonstrations, religious conventions, gun shows, political events, etc. This regulation establishes de facto marshal (military) law. Narrowing this regulation to state ‘in response to insurrections only’ would be constitutional. I am adamantly opposed to this rule.”

Response: The rule sets forth policy guidance for the execution and oversight of defense support of civilian authorities when requested by civil authorities. In addition to providing capabilities to assist and support civilian authorities during emergencies or in response to major disasters, DoD is often asked by civilian authorities to provide support and assistance for planned special events. As noted in the Glossary, a special event is an international or domestic event, contest, activity, or meeting, which by its very nature, or by specific statutory or regulatory authority, may require security, safety, and/or other logistical support or assistance from the Department of Defense. Congress has granted to the Secretary of Defense the authority to approve DoD support and assistance for certain specific events such as the Presidential inaugural, the Boy Scout Jamboree, and certain sporting competitions. Each specific authorization establishes necessary oversight and controls. DoD support during other special events, such as the Presidential nominating conventions, such as the United Nations General Assembly, Super Bowls, and the Group of Eight Economic Summit, are in reality, DoD supporting other civil authorities like the United States Secret Service, which is authorized under 18 U.S.C. 3056, when directed by the President, to plan, coordinate, and implement security operations at special events. DoD support at such events is generally in support of other federal

agencies, such as the Federal Bureau of Investigation, as well as state and local entities such as the Colorado Office of Homeland Security, or the San Diego Police Department. DoD has very limited authority to deploy DoD resources in support of event organizers.

In addition to the comments received above, the following has been included in the final rule based on internal comments received on the corresponding DoD instruction: Provisions regarding the “emergency authority” of responsible DoD officials and commanders to use military forces if necessary to prevent loss of life or wanton destruction of property or to restore governmental functions and public order under specified conditions. These provisions were included to bring this rule into consistency with the authorities in DoD Directives 3025.12 and 5525.5, as well as 32 CFR part 215.4.

Regulatory Procedures

Executive Order 12866, “Regulatory Planning and Review”

It has been certified that 32 CFR part 185 does not:

- (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy; a section of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribunal governments or communities;
- (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency;
- (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or
- (4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive Order.

Sec. 202, Public Law 104–4, “Unfunded Mandates Reform Act”

It has been certified that 32 CFR part 185 does not contain a Federal mandate that may result in the expenditure by State, local, and tribunal governments, in aggregate, or by the private sector, of \$100 million or more in any one year.

Public Law 96–354, “Regulatory Flexibility Act” (5 U.S.C. 601)

It has been certified that 32 CFR part 185 is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. This rule establishes policy and assigns

responsibilities within DoD for DSCA, supplements regulations regarding military support for civilian law enforcement, and sets forth policy guidance for the execution and oversight of DSCA when requested by civil authorities and approved by the appropriate DoD authority, or as directed by the President. Therefore, it is not expected that small entities will be affected because there will be no economically significant regulatory requirements placed upon them.

Public Law 96–511, “Paperwork Reduction Act” (44 U.S.C. Chapter 35)

It has been certified that 32 CFR part 185 does not impose reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995.

Executive Order 13132, “Federalism”

It has been certified that 32 CFR part 185 does not have federalism implications, as set forth in Executive Order 13132. This rule does not have substantial direct effects on:

- (1) The States;
- (2) The relationship between the National Government and the States; or
- (3) The distribution of power and responsibilities among the various levels of Government.

List of Subjects in 32 CFR Part 185

Armed forces, Civil defense.
Accordingly, the Department of Defense revises 32 CFR part 185 to read as follows:

PART 185—DEFENSE SUPPORT OF CIVIL AUTHORITIES (DSCA)

Sec.

- 185.1 Purpose.
- 185.2 Applicability and scope.
- 185.3 Definitions.
- 185.4 Policy.
- 185.5 Responsibilities.

Authority: Legal authority includes, 10 U.S.C. sections 113, 331–335, 371–382, 2553, 2554, 2555, and 2564; 31 U.S.C. 1535–1536 (Economy Act); 42 U.S.C. section 5121 et seq. (Robert T. Stafford Disaster Relief and Emergency Assistance Act, as amended (Stafford Act)); and Public Law 94–524, as amended (Presidential Protection Assistance Act of 1976).

§ 185.1. Purpose.

This part:

(a) Establishes policy and assigns responsibilities for DSCA, also referred to as civil support.

(b) Supplements the regulations (in DoD Directive 5525.5)¹ required by section 375 of title 10, United States

¹ Available for downloading at <http://www.dtic.mil/whs/directives/corres/pdf/552505p.pdf>

Code (U.S.C.), regarding military support for civilian law enforcement.

(c) Sets forth policy guidance for the execution and oversight of DSCA when requested by civil authorities or by qualifying entities and approved by the appropriate DoD official, or as directed by the President, within the United States, including the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and any territory or possession of the United States or any political subdivision thereof.

(d) Authorizes immediate response authority for providing DSCA, when requested.

(e) Authorizes emergency authority for the use of military force, under dire situations, as described in § 185.4(i) of this part.

§ 185.2. Applicability and scope.

This part:

(a) Applies to the Office of the Secretary of Defense, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the Department of Defense (hereafter referred to collectively as the “DoD Components”).

(b) Applies to the Army National Guard and the Air National Guard (hereafter referred to collectively as the “National Guard”) personnel when under Federal command and control. Also applies to National Guard personnel when the Secretary of Defense determines that it is appropriate to employ National Guard personnel in title 32, U.S.C., status to fulfill a request for DSCA, the Secretary of Defense requests the concurrence of the Governors of the affected States, and those Governors concur in the employment of National Guard personnel in such a status.

(c) Applies to all DSCA (except the specific forms of DSCA listed in paragraph (d) of this section), including but not limited to:

(1) Mutual or automatic aid, also known as reciprocal fire protection agreements (see chapter 15A of title 42 U.S.C.).

(2) DoD fire and emergency services programs (see DoD Instruction 6055.06)².

(3) Support of special events in accordance with applicable laws and DoD policy (see DoD Directive 2000.15)³.

(4) United States Army Corps of Engineers (USACE) activities as the DoD Coordinating and Primary Agency for Emergency Support Function #3, Public Works and Engineering, of the National Response Framework.

(5) Defense support to civilian law enforcement agencies (see DoDD 3025.12⁴ and DoD Directive 5525.5).

(d) Does not apply to the following:

(1) Support in response to foreign disasters provided in accordance with DoD Directive 5100.46⁵.

(2) Joint investigations conducted by the Inspector General of the Department of Defense, the Defense Criminal Investigative Service, and the military criminal investigative organizations with civil law enforcement agencies on matters within their respective jurisdictions using their own forces and equipment.

(3) Detail of DoD personnel to duty outside the Department of Defense in accordance with DoD Instruction 1000.17⁶.

(4) Counternarcotics operations conducted under the authority of section 1004 of Public Law 101–510 (1991).

(5) Support provided by the USACE when accomplishing missions and responsibilities under the authority of section 701n of title 33, U.S.C. and Executive Order 12656.

(6) Assistance provided by DoD intelligence and counterintelligence components in accordance with DoD Directive 5240.01⁷, Executive Orders 12333 and 13388, DoD 5240.1–R⁸, and other applicable laws and regulations.

(7) Military community relations programs and activities administered by the Assistant Secretary of Defense for Public Affairs (see DoD Directive

5410.18⁹ and DoD Instruction 5410.19¹⁰).

(8) Sensitive support in accordance with DoD Directive S–5210.36¹¹.

(9) Activities performed by the Civil Air Patrol in support of civil authorities or qualifying entities when approved by the Air Force as auxiliary missions in accordance with section 9442 of title 10, U.S.C. and DoD 3025.1–M¹² except as restricted by § 185.4(j) of this part.

(10) Innovative readiness training (formerly called “civil-military cooperative action programs”) (see DoD Directive 1100.20)¹³.

§ 185.3. Definitions.

Civil Authorities. See Joint Publication 1–02¹⁴.

Civil Disturbances. See Joint Publication 1–02.

Defense Domestic Crisis Manager. The lead DoD official responsible for DoD’s domestic crisis management response, ensuring the information needs and other requirements of the Secretary of Defense are met, and developing, coordinating, and overseeing the implementation of DoD policy for crisis management to ensure DoD capability to develop and execute options to prevent, mitigate, or respond to a potential or actual domestic crisis. The Assistant Secretary of Defense for Homeland Defense and Americas’ Security Affairs (ASD(HD&ASA)) serves as the Defense Domestic Crisis Manager.

Defense Support of Civil Authorities (DSCA). Support provided by U.S. Federal military forces, DoD civilians, DoD contract personnel, DoD Component assets, and National Guard forces (when the Secretary of Defense, in coordination with the Governors of the affected States, elects and requests to use those forces in title 32, U.S.C., status) in response to requests for assistance from civil authorities for domestic emergencies, law enforcement support, and other domestic activities, or from qualifying entities for special events. Also known as civil support.

Direct Liaison. An authority for Federal military forces to consult with,

⁹ Available by downloading at <http://www.dtic.mil/whs/directives/corres/pdf/541018p.pdf>.

¹⁰ Available by downloading at <http://www.dtic.mil/whs/directives/corres/pdf/541019p.pdf>.

¹¹ Document is classified and copies maybe requested by contacting USD(I), USDI.pubs@osd.mil

¹² Available by downloading at <http://www.dtic.mil/whs/directives/corres/pdf/302501m.pdf>.

¹³ Available by downloading at <http://www.dtic.mil/whs/directives/corres/pdf/110020p.pdf>.

¹⁴ Available by downloading at http://www.dtic.mil/doctrine/new_pubs/jp1_02.pdf.

² Available by downloading at <http://www.dtic.mil/whs/directives/corres/pdf/605506p.pdf>.

³ Available by downloading at <http://www.dtic.mil/whs/directives/corres/pdf/200015p.pdf>.

⁴ Available by downloading at <http://www.dtic.mil/whs/directives/corres/pdf/302512p.pdf>.

⁵ Available by downloading at <http://www.dtic.mil/whs/directives/corres/pdf/510046p.pdf>.

⁶ Available by downloading at <http://www.dtic.mil/whs/directives/corres/pdf/100017p.pdf>.

⁷ Available by downloading at <http://www.dtic.mil/whs/directives/corres/pdf/524001p.pdf>.

⁸ Available by downloading at <http://www.dtic.mil/whs/directives/corres/pdf/524001r.pdf>.

coordinate with, and respond to State authorities (including National Guard units and personnel operating in Title 32 status or in State Active Duty status) or Federal civilian authorities in the tactical-level execution of assigned tasks, pursuant to an order by the Secretary of Defense or the President to provide support to those authorities.

Emergency Authority. A Federal military commander's authority, in extraordinary emergency circumstances where prior authorization by the President is impossible and duly constituted local authorities are unable to control the situation, to engage temporarily in activities that are necessary to quell large-scale, unexpected civil disturbances because (1) such activities are necessary to prevent significant loss of life or wanton destruction of property and are necessary to restore governmental function and public order or (2) duly constituted Federal, State, or local authorities are unable or decline to provide adequate protection for Federal property or Federal governmental functions.

Federal Military Forces. Army, Navy, Marine Corps and Air Force personnel (including Reserve Component personnel) on Federal active duty and National Guard personnel when under Federal command and control.

Immediate Response Authority. A Federal military commander's, DoD Component Head's, and/or responsible DoD civilian official's authority temporarily to employ resources under their control, subject to any supplemental direction provided by higher headquarters, and provide those resources to save lives, prevent human suffering, or mitigate great property damage in response to a request for assistance from a civil authority, under imminently serious conditions when time does not permit approval from a higher authority within the United States. Immediate response authority does not permit actions that would subject civilians to the use of military power that is regulatory, prescriptive, proscriptive, or compulsory. State immediate response is addressed in § 185.4(h) of this part.

Qualifying Entity. A non-Governmental organization to which the Department of Defense may provide assistance for special events by virtue of statute, regulation, policy, or other approval by the Secretary of Defense or his or her authorized designee.

Responsible DoD Civilian. For purposes of DSCA, the Head of a DoD Component or other DoD civilian official who has authority over DoD

assets that may be used for a DSCA response.

Special Event. An international or domestic event, contest, activity, or meeting, which by its very nature, or by specific statutory or regulatory authority, may warrant security, safety, and/or other logistical support or assistance from the Department of Defense.

Total Force. See DoD Directive 1200.17¹⁵.

§ 185.4. Policy.

It is DoD policy that:

(a) This part shall be implemented consistent with national security objectives and military readiness.

(b) Unless expressly stated otherwise, the provisions of this part should not be construed to rescind any existing authorities of the Heads of DoD Components, commanders, and/or responsible DoD civilians to provide DSCA in accordance with existing laws, DoD issuances, and Secretary of Defense-approved orders.

(c) DSCA is initiated by a request for DoD assistance from civil authorities or qualifying entities or is authorized by the President or Secretary of Defense.

(d) All requests for DSCA shall be written, and shall include a commitment to reimburse the Department of Defense in accordance with the Stafford Act, Economy Act, or other authorities except requests for support for immediate response, and mutual or automatic aid, in accordance with § 185.4(g) and (m) of this part. Unless approval authority is otherwise delegated by the Secretary of Defense, all DSCA requests shall be submitted to the office of the Executive Secretary of the Department of Defense. For assistance provided according to § 185.4(g) of this part, civil authorities shall be informed that oral requests for assistance in an emergency must be followed by a written request that includes an offer to reimburse the Department of Defense at the earliest available opportunity. States also must reimburse the United States Treasury in accordance with section 9701 of title 31, U.S.C. Support may be provided on a non-reimbursable basis only if required by law or if both authorized by law and approved by the appropriate DoD official.

(e) All requests from civil authorities and qualifying entities for assistance shall be evaluated for:

- (1) Legality (compliance with laws).
- (2) Lethality (potential use of lethal force by or against DoD Forces).

(3) Risk (safety of DoD Forces).

(4) Cost (including the source of funding and the effect on the DoD budget).

(5) Appropriateness (whether providing the requested support is in the interest of the Department).

(6) Readiness (impact on the Department of Defense's ability to perform its primary mission).

(f) DSCA plans shall be compatible with the National Response Framework; the National Incident Management System; all contingency plans for operations in the locations listed in § 185.1(c) of this part; and any other national plans (approved by the President or Secretary of Defense) or DoD issuances governing DSCA operations. DSCA planning will consider command and control options that will emphasize unity of effort, and authorize direct liaison if authorized by the Secretary of Defense.

(g) Federal military commanders, Heads of DoD Components, and/or responsible DoD civilian officials (hereafter referred to collectively as "DoD officials") have immediate response authority as described in this part. In response to a request for assistance from a civil authority, under imminently serious conditions and if time does not permit approval from higher authority, DoD officials may provide an immediate response by temporarily employing the resources under their control, subject to any supplemental direction provided by higher headquarters, to save lives, prevent human suffering, or mitigate great property damage within the United States. Immediate response authority does not permit actions that would subject civilians to the use of military power that is regulatory, prescriptive, proscriptive, or compulsory.

(1) The DoD official directing a response under immediate response authority shall immediately notify the National Joint Operations and Intelligence Center (NJOIC), through the chain of command, of the details of the response. The NJOIC will inform appropriate DoD Components to including the geographic Combatant Command.

(2) An immediate response shall end when the necessity giving rise to the response is no longer present (e.g., when there are sufficient resources available from State, local, and other Federal agencies to respond adequately and that agency or department has initiated response activities) or when the initiating DoD official or a higher authority directs an end to the response. The DoD official directing a response

¹⁵ Available by downloading at <http://www.dtic.mil/whs/directives/corres/pdf/120017p.pdf>.

under immediate response authority shall reassess whether there remains a necessity for the Department of Defense to respond under this authority as soon as practicable but, if immediate response activities have not yet ended, not later than 72 hours after the request of assistance was received.

(3) Support provided under immediate response authority should be provided on a cost-reimbursable basis, where appropriate or legally required, but will not be delayed or denied based on the inability or unwillingness of the requester to make a commitment to reimburse the Department of Defense.

(h) The authority of State officials is recognized to direct a State immediate response using National Guard personnel under State command and control (including personnel in a title 32, U.S.C. (hereafter referred to as "Title 32") status) in accordance with State law, but National Guard personnel will not be placed in or extended in Title 32 status to conduct State immediate response activities.

(i) Federal military commanders are provided emergency authority under this part. Federal military forces shall not be used to quell civil disturbances unless specifically authorized by the President in accordance with applicable law (e.g., chapter 15 of title 10, U.S.C.) or permitted under emergency authority, as described below (See DoD Directive 3025.12¹⁶ and DoD Directive 5525.5¹⁷.) In these circumstances, those Federal military commanders have the authority, in extraordinary emergency circumstances where prior authorization by the President is impossible and duly constituted local authorities are unable to control the situation, to engage temporarily in activities that are necessary to quell large-scale, unexpected civil disturbances because:

(1) Such activities are necessary to prevent significant loss of life or wanton destruction of property and are necessary to restore governmental function and public order, or,

(2) When duly constituted Federal, State, or local authorities are unable or decline to provide adequate protection for Federal property or Federal governmental functions. Federal action, including the use of Federal military forces, is authorized when necessary to protect the Federal property or functions.

(j) Except for immediate response and emergency authority as described in

§ 185.4(g) and § 185.4(i) of this part, only the Secretary of Defense may approve requests from civil authorities or qualifying entities for Federal military support for:

(1) Defense assistance in responding to civil disturbances (requires Presidential authorization) in accordance with DoD Directive 3025.12.

(2) Defense response to CBRNE events (see DoD Instruction 2000.18)¹⁸.

(3) Defense assistance to civilian law enforcement organizations, except as authorized in DoD Directive 5525.5.

(4) Assistance in responding with assets with potential for lethality. This support includes loans of arms; vessels or aircraft; or ammunition. It also includes assistance under section 382 of title 10, U.S.C., and section 831 of title 18, U.S.C.; all support to counterterrorism operations; and all support to civilian law enforcement authorities in situations where a confrontation between civilian law enforcement and civilian individuals or groups is reasonably anticipated.

(k) Federal military forces employed for DSCA activities shall remain under Federal military command and control at all times.

(l) Special event support to a qualifying entity shall be treated as DSCA.

(m) All requests for DSCA mutual and automatic aid via the DoD Fire & Emergency Services programs shall be in accordance with DoD Instruction 6055.06.

(n) DSCA is a total force mission (see DoD Directive 1200.17).

(o) No DoD unmanned aircraft systems (UAS) will be used for DSCA operations, including support to Federal, State, local, and tribal government organizations, unless expressly approved by the Secretary of Defense. Use of armed UAS for DSCA operations is not authorized. (See DoD Directive 5240.01, Executive Orders 12333 and 13388, and DoD 5240.1–R.)

(p) Direct liaison between DoD Components and the States should occur only when time does not permit compliance with § 185.5(m)(1) of this part. In each such instance, the Chief, National Guard Bureau, will be informed of the direct liaison.

§ 185.5 Responsibilities.

(a) The Under Secretary of Defense for Policy (USD(P)) shall:

(1) Coordinate DSCA policy with other Federal departments and agencies, State agencies, and the DoD Components, as appropriate.

(2) Establish DoD policy governing DSCA.

(b) The Assistant Secretary of Defense for Homeland Defense and Americas' Security Affairs (ASD(HD&ASA)), under the authority, direction, and control of the USD(P) shall:

(1) Serve as the principal civilian advisor to the Secretary of Defense and the USD(P) for DSCA.

(2) Serve as the Defense Domestic Crisis Manager.

(3) As delegated by the Secretary of Defense in accordance with DoD Directive 5111.13¹⁹, serve as approval authority for requests for assistance from civil authorities or qualifying entities sent to the Secretary of Defense, except for those items retained in § 185.4(j) and (o) of this part, or delegated to other officials. This authority may not be delegated further than the Principal Deputy Assistant Secretary of Defense for Homeland Defense and Americas' Security Affairs. When carrying out this authority, the ASD(HD&ASA) shall:

(i) Coordinate requests with the Chairman of the Joint Chiefs of Staff, the Commanders of the Combatant Commands with DSCA responsibilities in the matter, and Military Department Secretaries and other DoD officials as appropriate.

(ii) Immediately notify the Secretary of Defense of the use of this authority.

(4) Develop, coordinate, and oversee the implementation of DoD policy for DSCA plans and activities, including:

(i) Requests for assistance during domestic crises, emergencies, or civil disturbances.

(ii) Domestic consequence management.

(iii) Coordination or consultation, as appropriate, with the Department of Homeland Security and other Federal agencies on the development and validation of DSCA requirements.

(iv) DoD support for national special security events.

(v) DoD support for national and international sporting events, in accordance with section 2564 of title 10, U.S.C.

(vi) Direct the fullest appropriate dissemination of information relating to all aspects of DSCA, using all approved media and in accordance with DoD Directive 8320.02²⁰.

(5) Exercise staff cognizance over DoD Directive 5525.5.

(c) The Assistant Secretary of Defense for Special Operations and Low

¹⁶ Available by downloading at <http://www.dtic.mil/whs/directives/corres/pdf/302512p.pdf>.

¹⁷ Available by downloading at <http://www.dtic.mil/whs/directives/corres/pdf/552505p.pdf>.

¹⁸ Available by downloading at <http://www.dtic.mil/whs/directives/corres/pdf/200018p.pdf>.

¹⁹ Available by downloading at <http://www.dtic.mil/whs/directives/corres/pdf/511113p.pdf>.

²⁰ Available by downloading at <http://www.dtic.mil/whs/directives/corres/pdf/832002p.pdf>.

Intensity Conflict and Interdependent Capabilities, under the authority, direction, and control of the USD(P), shall support planning by the Defense Domestic Crisis Manager during DSCA operations, as required.

(d) The Under Secretary of Defense (Comptroller)/Chief Financial Officer shall:

(1) Establish policies and procedures to ensure timely reimbursement to the Department of Defense for reimbursable DSCA activities.

(2) Assist in management of statutory resources for DSCA in support of appropriate international and domestic sporting events.

(e) The Under Secretary of Defense for Personnel and Readiness (USD(P&R)) shall identify, monitor, and oversee the development of integrated DSCA training capabilities and the integration of these training capabilities into exercises and training to build, sustain, and assess DSCA readiness in accordance with DoD Directive 1322.18²¹.

(f) The Assistant Secretary of Defense for Health Affairs (ASD(HA)), under the authority, direction, and control of the USD(P&R), as the principal advisor to the Secretary of Defense for all DoD health policy shall:

(1) Provide guidance and support for all domestic crisis situations or emergencies that require health or medical-related DSCA to ASD(HD&ASA).

(2) Exercise authority in accordance with section 300hh-11 of title 42, U.S.C., and according to DoD Directive 6010.22²², for participation in the National Disaster Medical System.

(g) The Assistant Secretary of Defense for Reserve Affairs, under the authority, direction, and control of USD(P&R), shall provide recommendations, guidance, and support on the use of the Reserve Components to perform DSCA missions to ASD(HD&ASA).

(h) The Under Secretary of Defense for Acquisition, Technology, and Logistics (USD(AT&L)) shall establish policies and procedures, in coordination with ASD(HD&ASA), to implement DSCA requirements for DoD Fire and Emergency Services programs and mutual or automatic aid that may be part of that program.

(i) The Heads of the DoD Components shall:

(1) Direct that any DSCA-related DoD issuances, concept plans, interagency

agreements, and memorandums of understanding or agreement with external agencies are in full compliance with this part.

(2) Direct Component compliance with financial management guidance related to support provided for DSCA operations, including guidance related to tracking costs and seeking reimbursement.

(3) When approved by the Secretary of Defense, plan, program, and budget for DSCA capabilities in accordance with law, policy, and assigned missions.

(j) The Secretaries of the Military Departments in addition to the responsibilities in § 185.5(i) of this part, shall:

(1) Establish the necessary policies and procedures to ensure the appropriate personnel are trained to execute DSCA plans as directed by the Secretary of Defense.

(2) Direct that requests for reimbursement of actual DSCA expenditures (performance of work or services, payments to contractors, or delivery from inventory) begin within 30 calendar days after the month in which performance occurred. Final billing invoices shall be submitted to supported departments and agencies within 90 calendar days of the termination of the supported event.

(k) The Chairman of the Joint Chiefs of Staff in addition to the responsibilities in § 185.5(i) of this part, shall:

(1) Advise the Secretary of Defense on the effects of requests for DSCA on national security and military readiness.

(2) Identify available resources for support in response to DSCA requests and release related orders when approved by the Secretary of Defense.

(3) Incorporate DSCA into joint training and exercise programs in consultation with the USD(P&R), the Chief, National Guard Bureau (NGB), and appropriate officials from the Department of Homeland Security and other appropriate Federal departments and agencies.

(4) Advocate for needed DSCA capabilities.

(l) The Commanders of Combatant Commands with DSCA responsibilities, in addition to the responsibilities in § 185.5(i) of this part and in accordance with the Unified Command Plan shall:

(1) In coordination with the Chairman of the Joint Chiefs of Staff, plan and execute DSCA operations in their areas of responsibility in accordance with this part, the Unified Command Plan and the Global Force Management Implementation Guidance.

(2) In coordination with the Chairman of the Joint Chiefs of Staff, incorporate

DSCA into joint training and exercise programs in consultation with the Department of Homeland Security, other appropriate Federal departments and agencies, and the NGB.

(3) Advocate for needed DSCA capabilities and requirements through the Joint Requirements Oversight Council, subject to § 185.5(i) of this part, and the planning, programming, budgeting, and execution process.

(4) Work closely with subordinate commands to ensure that they are appropriately reimbursed for DSCA in accordance with § 185.5(j) of this part.

(5) Exercise Training Readiness Oversight (TRO) over assigned Reserve Component forces when not on active duty or when on active duty for training in accordance with DoD Instruction 1215.06²³.

(m) The Chief, NGB, under the authority, direction, and control of the Secretary of Defense, normally through the Secretary of the Army and the Secretary of the Air Force, shall:

(1) Serve as the channel of communications for all matters pertaining to the National Guard between DoD Components and the States in accordance with DoD Directive 5105.77²⁴.

(2) Annually assess the readiness of the National Guard of the States to conduct DSCA activities and report on this assessment to the Secretaries of the Army and the Air Force; the USD(P&R), ASD(HD&ASA), and ASD(RA); and, through the Chairman of the Joint Chiefs of Staff, to the Secretary of Defense and appropriate Combatant Commanders.

(3) Report National Guard support of civil authorities or qualifying entities when using Federal resources, equipment, and/or funding to the NJOIC.

(4) Serve as an advisor to the Combatant Commanders on National Guard matters pertaining to the combatant command missions, and support planning and coordination for DSCA activities as requested by the Chairman of the Joint Chiefs of Staff or the Combatant Commanders.

(5) Ensure that National Guard appropriations are appropriately reimbursed for DSCA activities.

(6) Advocate for needed DSCA capabilities.

(7) Develop and promulgate, in accordance with DoD Directive 5105.77 and in coordination with the Secretaries of the Army and Air Force and the

²¹ Available by downloading at <http://www.dtic.mil/whs/directives/corres/pdf/132218p.pdf>.

²² Available by downloading at <http://www.dtic.mil/whs/directives/corres/pdf/601022p.pdf>.

²³ Available by downloading at <http://www.dtic.mil/whs/directives/corres/pdf/121506p.pdf>.

²⁴ Available by downloading at <http://www.dtic.mil/whs/directives/corres/pdf/510577p.pdf>.

ASD(HD&ASA), guidance regarding this part as it relates to National Guard matters.

Dated: December 22, 2010.

Patricia L. Toppings,
OSD Federal Register Liaison Officer,
Department of Defense.

[FR Doc. 2011-620 Filed 1-12-11; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DoD-2009-HA-0051]

RIN 0720-AB31

TRICARE; Coverage of National Cancer Institute (NCI) Sponsored Phase I Studies

AGENCY: Office of the Secretary, DoD.

ACTION: Final rule.

SUMMARY: This final rule adds coverage of National Cancer Institute (NCI) sponsored Phase I studies for certain beneficiaries. The NCI sponsored clinical treatment trials are conducted in a series of steps called phases. Phase I trials are the first studies conducted in people. They evaluate how a new drug should be given (by mouth, injected into the blood, or injected into the muscle), how often, and what dose is safe.

DATES: *Effective Date:* This rule is effective February 14, 2011.

FOR FURTHER INFORMATION CONTACT: Commander James Ellzy, TRICARE Management Activity, Office of the Chief Medical Officer, telephone (703) 681-0064.

SUPPLEMENTARY INFORMATION:

A. Background

This final rule adds the coverage of a subset of National Cancer Institute (NCI) sponsored Phase I trials for certain TRICARE patients. The NCI sponsored clinical treatment trials are conducted in a series of steps called phases. Phase I trials are the first studies conducted in people. They evaluate how a new drug should be given (by mouth, injected into the blood, or injected into the muscle), how often, and what dose is safe. A Phase I trial usually enrolls only a small number of patients, sometimes as few as a dozen. A Phase II trial continues to test the safety of the drug, and begins to evaluate how well the new drug works. Phase II studies usually focus on a particular type of cancer. A Phase III trial tests a new drug, a new combination of drugs, or a new surgical

procedure in comparison to the current standard. A participant will usually be assigned to the standard group or the new group at random. Phase III trials often enroll large numbers of people and may be conducted at many doctors' offices, clinics, and cancer centers nationwide.

This final rule adds coverage only of NCI sponsored Phase I trials with clinical or pre-clinical data providing a reasonable expectation that the treatment will be at least as effective as the non-investigational alternative. Additionally, only those TRICARE patients for whom standard treatment has been or would be ineffective, does not exist, or there is no superior non-investigational treatment alternative, would be eligible for these additional trials. TRICARE has covered NCI sponsored Phase II and III trials since 1996. The NCI estimates that Phase I trial participants represent about 3.4 percent of overall Phase II and III participants combined. Based on the history of Department of Defense participation in these studies, it is estimated that there would be a maximum of 1,000 new patients annually enrolling in Phase I trials. It is estimated that the net cost to TRICARE of adding Phase I treatment trials will increase costs by 12.8 percent of the total gross costs (approximately \$150,000 in FY09). Currently, ten States mandate coverage of at least some Phase I trials.

B. Public Comments

The DoD published a proposed rule on June 22, 2009 (74 FR 29435-29436). One set of comments was received on the proposed rule. The sole commenter strongly supported the proposed rule and urged the DoD to make it final. We agree with this recommendation and have not made any modifications to the proposed rule.

C. Regulatory Procedures

Executive Order 12866, "Regulatory Planning and Review"

Section 801 of Title 5, United States Code (U.S.C.), and Executive Order (E.O.) 12866 requires certain regulatory assessments and procedures for any major rule or significant regulatory action, defined as one that would result in an annual effect of \$100 million or more on the national economy, or which would have other substantial impacts. It has been certified that this rule is not an economically significant rule; however, it is a regulatory action which has been reviewed by the Office of Management and Budget as required under the provisions of E.O. 12866.

Sec. 202, Public Law 104-4, "Unfunded Mandates Reform Act"

It has been certified that this rule does not contain a Federal mandate that may result in the expenditure by State, local and Tribal governments, in aggregate, or by the private sector, of \$100 million or more in any one year.

Public Law 96-354, "Regulatory Flexibility Act" (5 U.S.C. 601)

The Regulatory Flexibility Act (RFA) requires each Federal agency prepare, and make available for public comment, a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities. This final rule will not significantly affect a substantial number of small entities for purposes of the RFA.

Public Law 96-511, "Paperwork Reduction Act" (44 U.S.C. Chapter 35)

This rule will not impose additional information collection requirements on the public under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3511).

Executive Order 13132, "Federalism"

This final rule has been examined for its impact under E.O. 13132 and it does not contain policies that have federalism implications that would have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government; therefore, consultation with State and local officials is not required.

List of Subjects in 32 CFR Part 199

Claims, Dental Health, Health Care, Health Insurance, Individuals with Disabilities, Military Personnel.

■ Accordingly, 32 CFR, Part 199 is amended as follows:

PART 199—[AMENDED]

■ 1. The authority citation for Part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. Chapter 55.

■ 2. Section 199.4 is amended by:

■ A. Redesignating paragraphs (e)(26)(ii)(B)(2), (3) and (4) as paragraphs (e)(26)(ii)(B)(3), (4) and (5);

■ B. Adding a sentence to the introductory text in paragraph (e)(26)(ii)(B);

■ C. Revising paragraph (e)(26)(ii)(B)(1)(i);

■ D. Revising paragraph (e)(26)(ii)(B)(1)(iv);

■ E. Adding paragraph (e)(26)(ii)(B)(1)(v); and

■ F. Adding a new paragraph (e)(26)(ii)(B)(2) to read as follows:

§ 199.4 Basic program benefits.

* * * * *

(e) * * *

(26) * * *

(ii) * * *

(B) * * * Additionally, Phase I studies may be approved on a case by case basis when the requirements below are met.

(1) * * *

(i) Such treatments are NCI sponsored Phase I, Phase II or Phase III protocols; and

* * * * *

(iv) The institutional and individual providers are CHAMPUS authorized providers; and,

(v) The requirements for Phase I protocols in paragraph (e)(26)(ii)(B)(2) of this section are met:

(2) Requirements for Phase I protocols are:

(i) Standard treatment has been or would be ineffective, does not exist, or there is no superior non-investigational treatment alternative; and,

(ii) The available clinical or preclinical data provide a reasonable expectation that the treatment will be at least as effective as the non-investigational alternative; and,

(iii) The facility and personnel providing the treatment are capable of doing so by virtue of their experience, training, and volume of patients treated to maintain expertise; and,

(iv) The referring physician has concluded that the enrollee's participation in such a trial would be appropriate based upon the satisfaction of paragraphs (e)(26)(ii)(B)(2)(i) through (iii) of this section.

* * * * *

Dated: January 4, 2011.

Patricia L. Toppings,

*OSD Federal Register, Liaison Officer,
Department of Defense.*

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 146

[Docket No. USCG-2008-1088]

RIN 1625-AB28

Notice of Arrival on the Outer Continental Shelf

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard revises its regulations on Outer Continental Shelf (OCS) Activities to enhance maritime domain safety and security awareness on the OCS by issuing regulations which will require notice of arrival for floating facilities, mobile offshore drilling units (MODUs), and vessels planning to engage in OCS activities. This final rule implements provisions of the Security and Accountability for Every Port Act of 2006 and increases overall maritime domain awareness by requiring owners or operators of United States and foreign flag floating facilities, MODUs, and vessels to submit notice of arrival information to the National Vessel Movement Center prior to engaging in OCS activities.

DATES: This final rule is effective February 14, 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-2008-1088 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-2008-1088 in the "Keyword" box, and then clicking "Search."

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail Mr. Kevin Pekarek, Vessel and Facility Operating Standards Division (CG-5222), Coast Guard; telephone 202-372-1386, e-mail Kevin.Y.Pekarek2@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

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I. Abbreviations

BOEMRE Bureau of Ocean Energy Management, Regulation and Enforcement.
CFR Code of Federal Regulations.
DHS Department of Homeland Security.
FR **FEDERAL REGISTER.**
ISM International Safety Management.
ISSC International Ship Security Certificate.
MMS Minerals Management Service.
MODU Mobile Offshore Drilling Unit.
NAICS North American Industry Classification System.
NOA Notice of Arrival.
NOA OCS Notice of Arrival on the Outer Continental Shelf.
NPRM Notice of Proposed Rulemaking.
NTTAA National Technology Transfer and Advancement Act, 15 U.S.C. 272 note.
NVMC National Vessel Movement Center.
OCS Outer Continental Shelf.
OCSLA Outer Continental Shelf Lands Act.
OIRA Office of Information and Regulatory Affairs.
OMB Office of Management and Budget.
RFA Regulatory Flexibility Act, 5 U.S.C. 601-612.
SAFE Port Act Security and Accountability for Every Port Act of 2006, Pub. L. 109-347, 120 Stat. 1884 (2006).
U.S.C. United States Code.
U.S.C.A. United States Code Annotated.

II. Regulatory History

On June 22, 2009, we published a notice of proposed rulemaking (NPRM) entitled Notice of Arrival (NOA) on the Outer Continental Shelf in the **Federal Register** (74 FR 29439). We received two sets of comments on the proposed rule prior to the close of the comment period. One additional set of comments was received after the close of the

comment period, responding to comments submitted earlier. No public meeting was requested and none was held.

III. Basis and Purpose

Congress and the President enacted the Security and Accountability for Every Port Act of 2006 (SAFE Port Act), Public Law 109–347, 120 Stat. 1884, on October 13, 2006. This rule is in response to Section 109 of the SAFE Port Act,¹ which requires publication, within 180 days of enactment, of regulations that “update and finalize” NOA procedures for foreign vessels² on the OCS. As required by the SAFE Port Act, this final rule makes our regulations “consistent with information required under the Notice of Arrival § 160.206 of title 33, Code of Federal Regulations as in effect on the date of enactment of the Act.” It adds NOA requirements for foreign vessels on the OCS. It also extends those requirements to U.S. floating facilities, MODUs, and vessels arriving on, and engaging in, OCS activities from foreign ports or places, and moving from one OCS block area to another. In addition to implementing the SAFE Port Act and expanding NOA requirements, this rule enhances security by requiring U.S. and foreign vessels, floating facilities, and MODUs arriving on and engaging in OCS activities to report their arrival times and locations and information regarding the vessels, voyage, cargo, and crew. Such information is critical to maritime domain safety and security awareness and will enable the Coast Guard to more effectively prevent or respond to a safety or security concern on the OCS.

IV. Background

The legislative history for the SAFE Port Act relating to the “update and finalize” language found in section 109 provides no specific direction for implementing that section. The Senate version of the bill contains the section 109 provisions, and the House of Representatives bill does not. The Congressional record does not otherwise elucidate the requirement. The House of Representatives Conference Report reveals only that both houses of Congress adopted section 109 without additional discussion.³

Other Coast Guard NOA OCS Regulations, 33 CFR 146.202

The Coast Guard does, however, have existing OCS NOA regulations, which cover only MODUs. These were established on March 4, 1982, as part of a final rule entitled, Outer Continental Shelf Activities (47 FR 9366). The Outer Continental Shelf Activities rule was in response to enactment of the Outer Continental Shelf Lands Act Amendments of 1978 and impacted requirements for design, equipment, operations, manning, inspections, and investigations for facilities, vessels, and other units (domestic and foreign) engaged in OCS activities.

However, the rule also had provisions specifically regarding MODUs. Those provisions ensured that foreign MODUs operating on the OCS meet the manning and safety standards comparable to those met by U.S. MODUs. A provision of that rule, 33 CFR 146.202, specifically addresses NOA and relocation of any MODU on the OCS. That section provides that an owner of any MODU engaged in OCS activities must, 14 days before arrival of the MODU on the OCS or as soon thereafter as practicable, notify the District Commander for the area in which the MODU will operate of: (1) The MODU’s name, nationality, and designation assigned for identification under 30 CFR 250.37; (2) the location and year that the MODU was built; (3) the name and address of the owner, and the owner’s local representative, if any; (4) classification or inspection certificates currently held by the MODU; (5) the location and date that operations are expected to commence, and their anticipated duration; and (6) the location and date that the MODU will be available and ready for inspection by the Coast Guard. In addition, once a MODU is located on the OCS, the owner must notify the District Commander before relocating the MODU. The purpose of 33 CFR 146.202 is to assist District Commanders in gathering information on MODUs prior to inspection of those units.

Consistency With 33 CFR 160.206

The Coast Guard also has recently updated NOA rules. In response to the terrorist attacks of September 11, 2001, the Coast Guard published, on February 28, 2003, the final rule entitled Notification of Arrival in U.S. Ports (68 FR 9537). The rule enhanced notification of arrival and departure requirements for U.S. and foreign vessels bound for, or departing from, ports or places in the United States. The rule also increased, from 24 hours to 96 hours, the advance notice a vessel must

submit to the National Vessel Movement Center (NVMC); described the timeframes for updating an NOA; and added more information to the list of items that must be submitted, as part of the NOA, to the NVMC. Pursuant to that rule, specifically 33 CFR 160.206, the information items submitted to the NVMC include: Vessel information; voyage information; cargo information; information for each crewmember onboard; information for each person onboard in addition to the crew; operational condition of equipment; International Safety Management (ISM) code notice; Cargo Declaration; and International Ship and Port Facility code (ISPS) notice. The Coast Guard collects this information to ensure, to the extent practicable, public safety, security, and the uninterrupted flow of commerce.

Coast Guard Action

After considering section 109 of the SAFE Port Act and current NOA rules, the Coast Guard has determined that section 109 of the SAFE Port Act requires finalizing NOA OCS rules by adding to those requirements found at § 146.202 for MODUs. This new final rule is designed to be consistent with the NOA requirements of § 160.206 for vessels bound for, or departing from, ports, or places in the United States.

This rulemaking is intended to comply with the section 109 mandate. It also extends those NOA OCS requirements to U.S. floating facilities, MODUs, and vessels (arriving on, and engaging in, OCS activities from foreign ports or places) under the authority of the Outer Continental Shelf Lands Act, 43 U.S.C. 1356 (2007), and the Ports and Waterways Safety Act, 33 U.S.C. 1226 (2007). Extending the NOA OCS requirements is essential for overall maritime domain safety and security awareness. Moreover, obtaining knowledge of all individuals, floating facilities, MODUs, and vessels engaging in OCS activities will better equip the Coast Guard to prevent and respond to a safety or security incident on the OCS. If the Coast Guard receives specific threat information for an area, the knowledge obtained from these requirements will enable it to know who is in the area, what they are doing, and how to contact them. In addition, if a floating facility, MODU, or vessel has an incident, the Coast Guard will be able to use this knowledge to better assess the potential impacts of the event, respond to it, and seek additional assistance in that or a nearby area when needed.

¹ 33 U.S.C. 1223 note (West 2009).

² As defined in 1 U.S.C. 3 (and reiterated in part 140 of this subchapter) a vessel is “every description of watercraft or other artificial contrivance used, or capable of being used, as a means of transportation on water.” This definition includes those units we propose to regulate with this rulemaking (i.e., floating facilities, MODUs, and vessels engaging in OCS activities).

³ H.R. 4954, 152nd Cong. (2006).

V. Discussion of Comments and Changes

The Coast Guard received two sets of comments from trade associations in response to the NPRM. The Coast Guard considered all comments filed. Below, we discuss in detail the public comments addressing issues raised in the NPRM and our responses to those comments.

1. Definition of "OCS Activity" and the Energy Policy Act

Two separate commenters suggested that the definition of "OCS activity," as used in the rule, be revised in light of amendments to the Outer Continental Shelf Lands Act (OCSLA), particularly those amendments created by Section 388 of the Energy Policy Act of 2005.

Coast Guard Response. The definition of "OCS activity" is found in the regulations at 33 CFR 140.10. Section 140.10 defines "OCS activity" as "any offshore activity associated with exploration for, or development or production of, the minerals of the Outer Continental Shelf." 33 CFR 140.10. This rulemaking was intended to implement the SAFE Port Act and not the Energy Policy Act of 2005, which permits leases, easements, or rights-of-way on the OCS for activities not otherwise authorized under other laws, including: (1) Exploration, development, production, or storage of oil or natural gas except in areas prohibited by a moratorium; (2) transportation of oil or natural gas, excluding shipping activities; (3) production, transportation, or transmission of energy from sources other than oil or gas; and (3) use of facilities for activities authorized under the Act. Energy Policy Act of 2005 section 388, Public Law 109-58, 119 Stat. 744. Because the goal of this rule was directed by the SAFE Port Act and was not to alter the definition of "OCS activity," as established in Title 33 of the CFR, doing so would be beyond the scope of this rule.

2. NOAs for Moves Between OCS Locations

One commenter asks that we either modify the rule to eliminate the need for NOAs for units moving between locations on the OCS or coordinate the processing of the NOA requirements with those regarding navigation safety (33 CFR 143.15) to reduce reporting burdens. A separate commenter asserts the opposite, stating that vessels must report their movements between OCS locations and ports and that this requirement should also include vessels that do not moor offshore.

Coast Guard Response. Current regulations state that the owner must

notify the District Commander when a unit is relocated. The goal of the SAFE Port Act is to improve maritime and cargo security through enhanced layered defenses. Requiring revised NOAs each time there is a change in position furthers that goal. However, the Coast Guard believes it would be sufficient for an NOA to be required only when MODUs, floating facilities, and vessels arrive from a foreign port or place, or move a few miles from one OCS block area to another. OCS block areas are used by the Bureau of Ocean Energy Management, Regulation and Enforcement (BOE)—formerly the Minerals Management Service—to facilitate management and leasing on the OCS. They vary in size depending on the OCS blocks the block areas contain. The OCSLA permits a maximum size for an OCS block of 5,760 acres (9 square miles).

For example, a MODU, floating facility, or vessel moving within the Green Canyon block area would not have to submit a revised NOA; but if moving from Green Canyon to the Walker Ridge block area, a revised NOA would be required. Therefore, §§ 146.103(a), 146.104(a), 146.215(a), and 146.405(a)(1) have been revised to reflect this change. Definitions for "arrives on the OCS" and "OCS block areas" have been added as new §§ 146.102, 146.200, and 146.402.

For the alternative suggestion of coordinating processing of the NOA requirements with those regarding navigation safety, this is not possible because the reports are for different functions and are sent to different offices. Coast Guard navigation safety requirements used for lights and warning devices to prevent collisions at sea are sent to the office of the District Commander. NOA requirements for maritime security are submitted to the National Vessel Movement Center office (NVMC).

3. Authorities

One commenter questions the use of the Ports and Waterways Safety Act as an authority for this rule. That commenter notes that at the time the Coast Guard proposed the existing NOA rules in 33 CFR 160.206, this same commenter questioned the applicability of those rules to OCS facilities as a "port or place in the United States." The commenter argues that our response to that comment indicates that we do not interpret OCS locations to be a "port or place in the United States" for purposes of the Ports and Waterways Safety Act. As such, the commenter says 33 U.S.C. 1223 and 1226 should not be listed as authorities. If they are included, they

ask the Coast Guard to clarify its understanding of OCS facilities under the Act.

Coast Guard Response. 33 U.S.C. 1223 refers to "a port or place subject to the jurisdiction of the United States" (rather than a "port or place in the United States"). Also, 33 U.S.C. 1226 provides authority to take actions to prevent or respond to acts of terrorism against individuals, vessels, or structures "subject to the jurisdiction of the United States." 33 CFR 101.105 defines "waters subject to the jurisdiction of the U.S." as including the following: "in respect to facilities located on the Outer Continental Shelf of the U.S., the waters superjacent thereto." These provisions underscore the authority of the Ports and Waterways Safety Act in driving this rule, which establishes regulations requiring notice of arrival for United States and foreign flag floating facilities, MODUs, and vessels prior to engaging in OCS activities.

4. Use of Information Reported

One commenter states that the information the Coast Guard requests with this rule, particularly in § 146.103(a)(6)(v), which requires reporting positions or duties for individuals on board floating facilities, will be used for other purposes, such as enforcement of cabotage (coastal trade and/or navigation) or OCS employment restrictions. This commenter requests that we remove this requirement.

Coast Guard Response. The Coast Guard disagrees that this information is being requested for cabotage, OCS employment restrictions, or other non-NOA purposes. The information is being requested for security purposes and reflects existing NOA requirements in 33 CFR 160.206, as required by the SAFE Port Act. As noted, maintaining situational awareness is the foundation of a comprehensive security regime. This information will enable the Coast Guard to respond to emerging threats on the OCS through such mechanisms as critical notices to operators in the area that may be threatened. It will also improve maritime safety by enabling the Coast Guard to better protect mariners operating on the OCS.

5. Estimated Costs

One commenter states that costs should be modified to eliminate the need for vessels moving between OCS locations to comply with NOA requirements.

Coast Guard Response. As indicated above, we have clarified the need for NOAs when moving between OCS locations. Vessels moving between OCS block areas will still need to comply

with the NOA requirements. However, vessels moving from one location to another within the same OCS block area do not have to submit NOAs.

6. Information Collection

One commenter suggests that the Coast Guard eliminate the need to report certain information regarding persons onboard the arriving vessels.

Coast Guard Response. The Coast Guard disagrees with this recommendation. We request this information to comply with the SAFE Port Act (Table 160.206 item (4)(v)).

7. Coordinating With Other Rulemakings

One commenter states that the rulemakings on OCS Notice of Arrival and the current development of notice of arrival and departure requirements should be coordinated.

Coast Guard Response. The Coast Guard agrees and we have worked to ensure uniformity between this and other relevant rulemakings.

8. Making NOA Information Accessible

One commenter states that some of the information reported under the NOA, though not information relating to crew personnel, should be publicly accessible and made available in real-time. In addition, the commenter states that all information submitted under this regulation should be accessible to Customs and Border Protection (CBP) and other Federal agencies.

Coast Guard Response. General information about a vessel's arrival or departure is normally made available by port authorities. Local harbor masters have access to this data and are good sources of information. In addition, such information is available to the public through such sources as <http://www.vesseltracker.com>. More detailed information in an NOA will be released in accordance with the Freedom of Information Act, 5 U.S.C. 552. The Coast Guard already routinely shares this information with other Federal, State, and local agencies and coordinates with CBP.

9. Section 146.103—Vessels Under Tow

One commenter believes any vessels, facilities, or MODUs under tow should provide separate NOAs from the towing vessel or offer an option for the "lead" towing vessel to submit a single NOA for the combined "tow."

Coast Guard Response. The Coast Guard agrees that the "lead" towing vessel could submit a single NOA for the entire "tow." It is the responsibility of the owner or operator of the unit being towed to designate which towing

vessel, if there is more than one, is the "lead" towing vessel and is responsible for submitting the overall NOA. Section 146.103(f) has been revised to clarify that the "lead" towing vessel is responsible for submitting the overall NOA. Sections 146.104(f), 146.215(f), and 146.405(f) have also been revised to reflect this change.

10. Section 146.103—Reference to "Flag Administration"

One commenter recommends that the Coast Guard remove § 146.103(a)(7) and (a)(8), which reference "flag administration" because that section is specific to U.S. floating facilities.

Coast Guard Response. The Coast Guard agrees with this comment. Therefore, § 146.103(a)(7) and (a)(8) have been removed.

11. Section 146.103—Change in Delay for Updated NOA

One commenter suggests the change in arrival time not requiring an updated NOA in this section be changed from 6 hours to 24 hours (§ 146.103(c)(1)). This commenter believes that there is no substantive difference in the risk posed by a delay of 24 hours versus a delay of 6 hours, given the remote locations and minimal direct threat.

Coast Guard Response. The Coast Guard disagrees because the SAFE Port Act requires us to issue regulations consistent with the existing NOA regulations found in Title 33 of the CFR. Existing regulations in 33 CFR 160.208(b)(1) require vessels to submit revised NOAs if changes in arrival or departure times are more than 6 hours.

12. Section 146.103(c)(2)

One commenter finds the wording in § 146.103(c)(2) confusing since the location of the floating facility would be known at the time the report is made.

Coast Guard Response. The Coast Guard agrees and has revised § 146.103(c)(2) to read: "Changes in the location, latitude and longitude, of the floating facility from the location at the time the NOA was reported; or". The Coast Guard also made similar changes in § 146.104(c)(2), § 146.215(c)(2), and § 146.405(c)(2).

13. Section 146.103(d)(1)

One commenter finds that § 146.103(d)(1) and (d)(2) provides an exception to the 96-hour reporting requirement created in § 146.103(a) and that paragraph (d)(1) is redundant with paragraph (a).

Coast Guard Response. The Coast Guard agrees that paragraph (d)(1) is redundant, but it provides additional clarity by repeating this requirement

and then breaking out the differing requirements when the voyage is more than 96 hours, as opposed to when the voyage is less than 96 hours.

14. Section 146.103(f)—Towing of a Facility/Vessel

One commenter states that § 146.103(f) should be removed because it implies that the towing of a facility or vessel to an OCS location is an "OCS activity" as defined in 33 CFR 140.10. The same commenter asks that as an alternative to removing paragraph (f), we address the possibility that multiple towing vessels may be involved in the tow of a single facility/vessel and discuss how NOA requirements would be met for a facility/vessel arriving on the OCS via a heavy lift transport.

Coast Guard Response. The Coast Guard does not believe that paragraph (f) should be removed. In 33 CFR 140.10, "OCS activity" is defined as "any offshore activity associated with exploration for, or development or production of, the minerals of the Outer Continental Shelf." This is a broad definition that encompasses a towing vessel on the OCS towing a facility/vessel on the OCS. The Coast Guard has exempted vessels, floating facilities, and MODUs that are merely transiting across the OCS and not engaging in OCS activities.

However, as noted above, the Coast Guard agrees it is possible to have multiple towing vessels involved in the tow of a single facility/vessel. We believe it is the responsibility of the owner or operator of the unit being towed to designate which towing vessel will be the lead towing vessel, if there is more than one, and therefore responsible for submitting the overall NOA.

15. Section 146.103(g)—"Superjacent" vs. "Superadjacent"

One commenter recommends that the word "superjacent" be changed to "superadjacent" in § 146.103(g) for consistency within Title 33 and points to the definition of "waters subject to the jurisdiction of the U.S." at 33 CFR 101.105.

Coast Guard Response. The Coast Guard disagrees that "superjacent" should be changed to "superadjacent." Title 33 of the U.S. Code uses "superjacent" and not "superadjacent." We are using the word "superjacent" in order to be consistent with its use in both Title 33 and 33 CFR 101.105.

16. Section 146.215(a)(3)—Reporting the IMO Number

One commenter states that the Coast Guard should also require MODUs to

report the IMO number in addition to the facility's name.

Coast Guard Response. The Coast Guard agrees and has modified § 146.215(a)(3) as requested.

17. Section 146.215—Reporting “Position or Duties”

One commenter states that the requirement for the description of “position or duties” of personnel on a facility or vessel (as required in § 146.215(a)(6)(v)) is irrelevant because the job descriptions of industrial personnel would be difficult for the Coast Guard to interpret.

Coast Guard Response. The Coast Guard does not agree because the SAFE Port Act requires us to issue regulations consistent with the existing NOA regulations found in Title 33 of the CFR. Existing regulations in 33 CFR Subpart C Table 160.206 item (4)(v) require descriptions of positions or duties to be provided as part of an NOA.

18. Section 146.215—MODU NOA

One commenter states that MODUs should not be required to submit anything other than a simple notice of arrival because they do not present the risk of being weaponized or of smuggling merchandise or individuals into the United States.

Coast Guard Response. The Coast Guard does not agree. We believe that MODUs arriving on the OCS from abroad present the same security risk as OCS facilities and vessels.

19. Section 146.405—Interpreting “Arrives on the OCS”

One commenter states that the phrase “arrives on the OCS” could be interpreted in more than one way and that the interpretation affects how the rule is applied.

Coast Guard Response. The Coast Guard partially agrees that the phrase could be interpreted in more than one way. We have added § 146.102 to define “arrives on the OCS” to offer clarity to the issue. New §§ 146.200 and 146.402 have also been added to similarly clarify the use of the phrase in these subparts.

20. Section 146.405(b)(1)—Exceptions to NOA Information

One commenter states that in § 146.405(b)(1), it was unclear why only item (2)(iii) of Table 160.206 was exempted and not items (2)(iv) through (2)(vi).

Coast Guard Response. The Coast Guard agrees that items (2)(iv) through (2)(vi) should also be exempted and has revised § 146.405(b)(1) accordingly. The information in items (2)(iv) through (2)(vi) is not applicable and is not

required for MODUs and floating facilities and will not be required for vessels.

21. Section 146.405(b)(1)—Cargo Declaration

One commenter asserts that it is inappropriate to require a cargo declaration for NOAs as stated in § 146.405 since most vessels subject to this subpart would not require customs clearance. A separate commenter states the opposite, insisting that a cargo declaration form should be necessary whenever a foreign vessel transports cargo to and from a port and an OCS location.

Coast Guard Response. In those instances where foreign flag vessels are transporting cargo to and from a U.S. port and a mineral extraction facility pursuant to OCSLA, the owners/operators of those vessels are, in fact, required to submit cargo declaration forms pursuant to CBP regulations on vessel entry (as established under 19 U.S.C. 1434) and clearance (as established under 46 U.S.C. 60105). However, the Coast Guard agrees that it would be inappropriate for those vessels not otherwise required to submit a cargo declaration form to have to submit one for NOA purposes. Accordingly, we have revised § 146.405 to exempt item (8) from the information required in Table 160.206 for all vessels except those foreign flag vessels subject to the CBP regulations noted above.

22. Section 146.103

One commenter notes the language in new § 146.103 (a)(2): “The area designation and block number or lease number, assigned under 30 CFR 250.154 for identification, where the floating facility plans to perform OCS activities.” The commenter points out that facilities are not sentient and, therefore, cannot plan activities on the OCS.

Coast Guard Response. The Coast Guard agrees and has made the necessary changes in the regulatory text to clarify (in sections 146.103, 146.104 and 146.405).

VI. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

A. Regulatory Planning and Review

This rule is a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review. The Office of Management and Budget has reviewed it under that

Order. It requires an assessment of potential costs and benefits under section 6(a)(3) of that Order.

Public comments on the NPRM are summarized in Part V of this publication. We received no public comments that would alter our assessment of the impacts discussed in the NPRM. We have adopted the assessment in the NPRM as final. See the “Regulatory Analyses” section of the NPRM for more details. A summary of the assessment follows.

This rulemaking requires certain U.S. and foreign owners or operators of floating facilities, MODUs, and vessels to submit NOA information to the NVMC prior to engaging in OCS activities.

Based on industry information from the National Offshore Advisory Committee (NOSAC), we estimate that there are 7 to 12 arrivals on the OCS each month for a total of 84 to 144 annual arrivals on the OCS each year. We also estimate that approximately 95 percent of the floating facilities, vessels, and MODUs operating on the OCS affected under this rulemaking would be foreign flag.

The additional costs of this rulemaking to industry are the proposed NOA reporting requirements. We estimate that one NOA requires 30 minutes to complete plus a transmittal fee of \$2 per submission.⁴ Similar to other NOA reporting analyses, we use an average loaded wage rate of approximately \$31 per hour to estimate the labor costs for NOA reporting activities.

Based on the arrival data and the reporting time and cost information, we estimate the annual cost of this rulemaking to industry to be \$1,470 to \$2,520 (non-discounted). We estimate the present value 10-year cost of this rulemaking to industry to be \$10,300 to \$17,700 at a 7 percent discount rate (rounded).

We expect the primary benefit of this rulemaking would be enhanced situational awareness of activities on the OCS. This enhanced situational awareness would assist the Coast Guard in evaluating potential safety and security risks associated with these activities and assist the Coast Guard in managing resources used to regulate these activities and respond to incidents on the OCS.

⁴ Sources: (1) Collection of Information, OMB Control Number 1625-0100, “Advance Notice of Arrival and Electronic Transmission of Vessel Transit Data”; and (2) Notice of Proposed Rulemaking, “Vessel Requirements for Notices of Arrival and Departure, and Automatic Identification System” [USCG-2005-21869].

B. Small Entities

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601–612), we have considered whether this 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.

In the NPRM, we certified under 5 U.S.C. 605(b) that the proposed rule would not have a significant economic impact on a substantial number of small entities. We received no public comments that would alter our certification in the NPRM. We have found no additional data or information that would change our findings in the NPRM. We have adopted the certification in the NPRM for this final rule. See the “Small Entity” section of the NPRM for additional details.

We expect the rule would not have a significant economic impact on any entities since the costs of this rulemaking are small and the cost burden per NOA submission is only about \$18.

Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this rule would 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), we want 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 would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please consult Mr. Kevin Pekarek, Vessel and Facility Operating Standards Division (CG–5222); telephone 202–372–1386. 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 calls for a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). It would require a revision to an existing collection. The following is a summary of the burden associated with the revision.

As defined in 5 CFR 1320.3(c), “collection of information” comprises reporting, recordkeeping, monitoring, posting, labeling, and other similar actions. The title and description of the information collection, a description of those who must collect the information, and an estimate of the total annual burden follow. The estimate covers the time for reviewing instructions, searching existing sources of data, gathering and maintaining the data needed, and completing and reviewing the collection.

This rule amends the collection of information requirements for owners and operators. The rule requires modifying the burden in the previously approved collection under OMB Control Number 1625–0100.

Title: Advance Notice of Vessel Arrival.

OMB Control Number: 1625–0100.

Summary of the Collection of Information: The rule requires owners and operators of vessels, MODUs, and floating facilities to submit an advance notice of arrival electronically to the NVMC. This requires a change in the previously approved OMB Collection 1625–0100 because it expands the NOA requirement to include vessels, MODUs, and floating facilities engaging in OCS activities.

This rule will not change the information collected in OMB Collection 1625–0100. This rule will expand the number of respondents to include owners and operators of vessels, MODUs, and floating facilities that engage in OCS activities.

Proposed Use of Information: The Coast Guard would use the information to enhance maritime domain awareness.

Description of the Respondents: The respondents are owners and operators of vessels, MODUs, and floating facilities which arrive on the OCS from foreign ports and engage in OCS activities.

Number of Respondents: The rule increases the number of respondents in this OMB-approved collection by no more than 144 respondents. See the “Regulatory Planning and Review” section for more details on the respondents affected by this rule.

Frequency of Response: The rule increases the annual number of responses in this OMB-approved collection by no more than 144 responses. OCS units such as MODUs and floating production facilities may stay on the OCS for long periods, such as a year or more, so we do not expect these units to have more than one NOA submittal per year.

Burden of Response: We estimate the burden of this rule to be the preparation and submission of the NOA. Based on discussion in the “Regulatory Analysis” section of this final rule, we estimate that it would take 30 minutes to prepare and submit an NOA to the NVMC.

Estimate of Total Annual Burden: The annual total burden of this rule would be no more than 72 hours.

As required by 44 U.S.C. 3507(d), we submitted a copy of the rule to the Office of Management and Budget (OMB) for its review of the collection of information. On December 9, 2010, OMB approved the revision (ICR Ref. No. 201012–1625–002) to OMB Control Number 1625–0100, which expires on December 31, 2013. The section numbers associated with the collection of information are: §§ 146.103, 146.104, 146.215 and 146.405. Our estimate of the total annual burden is unchanged from the proposed rule to this final rule.

You are not required to respond to a collection of information unless it displays a currently valid OMB control number.

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. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

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 or more in any one year. Though this rule would not result in such an expenditure, we do 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

We have 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 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

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order. Though it is a "significant regulatory action" under Executive Order 12866, it 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 the Office of Management and Budget, 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 rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

M. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023-01 and Commandant Instruction M16475.ID, 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 which do not individually or cumulatively have a significant effect on the human environment. Therefore, this rule is categorically excluded, under section 2.B.2. Figure 2-1, paragraphs 34(a) and (d), of the Instruction, and neither an environmental assessment nor an environmental impact statement is required. This rule outlines the procedures that owners or operators of floating facilities, mobile offshore drilling units, and vessels will follow in submitting notice of arrival information to the Coast Guard's National Vessel Movement Center. This rule is procedural and concerns the documentation of vessels, falling under paragraphs 34(a) and (d) of the Instruction. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under **ADDRESSES**.

List of Subjects for 33 CFR Part 146

Continental shelf, Marine safety, Occupational safety and health, Reporting and recordkeeping requirements, Vessels.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 146, as follows:

PART 146—OPERATIONS

- 1. The authority citation for part 146 is revised to read as follows:

Authority: 33 U.S.C. 1223, 1226; 43 U.S.C. 1333, 1348, 1350, 1356; Sec. 109, Pub. L. No. 109-347, 120 Stat. 1884; Department of Homeland Security Delegation No. 0170.1.

- 2. Add § 146.102 to read as follows:

§ 146.102 Definitions.

For the purpose of this subpart:
Arrives on the OCS means when a floating facility enters any OCS block area for the purpose of engaging in operations subject to the jurisdiction of the OCS Lands Act.

OCS block area means the names given by the Bureau of Ocean Energy Management, Regulation and

Enforcement (BOE) to define the OCS areas used to facilitate management or leasing on the OCS.

U.S., as used in the term, "U.S. floating facility," means a "floating facility," that is registered, documented, or certificated under the laws of the United States or that is not registered, documented, or certificated under the laws of the United States or any other nation.

- 3. Add § 146.103 to read as follows:

§ 146.103 Safety and Security notice of arrival for U.S. floating facilities.

(a) *General*. At least 96 hours before a U.S. floating facility arrives on the OCS from a foreign port or place or from a different OCS block area, excluding those U.S. floating facilities arriving directly from a U.S. port or place, to engage in OCS activities, the owner or operator of the floating facility, except as provided in paragraph (f) of this section, must submit the following information to the National Vessel Movement Center (NVMC):

(1) The location, latitude and longitude, of the floating facility at the time the notice of arrival (NOA) is reported;

(2) The area designation, block number or lease number, assigned under 30 CFR 250.154 for identification, where the owner or operator of the floating facility plans to perform OCS activities;

(3) The floating facility's name, if any;

(4) The date when OCS operations of the floating facility are expected to begin and end;

(5) Names of the last two ports or places visited and the associated dates of arrival and departure;

(6) The following information for each individual onboard:

(i) Full name;

(ii) Date of birth;

(iii) Nationality;

(iv) Passport number or marine documentation number (type of identification and number);

(v) Position or duties on the floating facility; and

(vi) Name of the port, or place, and country where the individual embarked.

(b) *Methods of submission*. The notice must be submitted to the NVMC by electronic Notice of Arrival and Departure format using methods specified in the NVMC's Web site at <http://www.nvmc.uscg.gov/>.

(c) *Updates to a submitted NOA*. Unless otherwise specified in this section, whenever the most recently submitted NOA information becomes inaccurate, the owner or operator of a U.S. floating facility must revise and re-submit the NOA within the times required in paragraph (e) of this section.

An owner or operator does not need to revise or re-submit an NOA for the following:

(1) A change in submitted arrival time that is less than 6 hours;

(2) Changes in the location, latitude and longitude, of the floating facility from the location at the time the NOA was reported; or

(3) Changes to personnel positions or duties on the floating facility.

(d) *Required reporting time of an initial NOA.* The owner or operator of a U.S. floating facility subject to this section must submit an initial NOA:

(1) If the voyage time is more than 96 hours, owners or operators of a floating facility must submit an initial NOA at least 96 hours before the U.S. floating facility arrives at the OCS location where the owner or operator plans to perform OCS activities; or

(2) If the voyage time is less than 96 hours, owners and operators of a floating facility must submit an initial NOA at least 24 hours before the U.S. floating facility arrives at the OCS location where the owner or operator plans to perform OCS activities.

(e) *Required reporting time of an update to an NOA.* The owner or operator of each floating facility subject to this section must submit an NOA update:

(1) If the most recently submitted NOA, or NOA update, differs by 24 hours or more from the current estimated time of arrival, the owner or operator of the floating facility must provide an updated NOA as soon as practicable but at least 24 hours before the U.S. floating facility arrives at the OCS location where the owner or operator plans to perform OCS activities; or

(2) If the most recently submitted NOA, or NOA update, differs by less than 24 hours from the current estimated time of arrival, the owner or operator of the floating facility must provide an update as soon as practicable but at least 12 hours before the U.S. floating facility arrives at the OCS location where the owner or operator plans to perform OCS activities.

(f) *Towing vessels.* When a towing vessel controls a U.S. floating facility required to submit an NOA under this subpart, the owner or operator of the towing vessel, or lead towing vessel if there is more than one, is responsible for submitting only one NOA containing the NOA information items required for the towing vessels, under § 146.405, and the U.S. floating facility under paragraph (a) of this section.

(g) This section does not apply to U.S. floating facilities merely transiting the

waters superjacent to the OCS and not engaged in OCS activities.

■ 4. Add § 146.104 to read as follows:

§ 146.104 Safety and Security notice of arrival for foreign floating facilities.

(a) *General.* At least 96 hours before a foreign floating facility arrives on the OCS from a foreign port or place or from a different OCS block area to engage in OCS activities, the owner or operator of the floating facility, except as provided in paragraph (f) of this section, must submit the following information to the National Vessel Movement Center (NVMC):

(1) The location, latitude and longitude, of the foreign floating facility at the time the NOA is reported;

(2) The area designation, block number or lease number, assigned under 30 CFR 250.154 for identification, where the owner or operator of the foreign floating facility plans to perform OCS activities;

(3) The foreign floating facility's name, if any;

(4) The date when OCS operations of the foreign floating facility are expected to begin and end;

(5) Names of the last two ports or places visited and the associated dates of arrival and departure;

(6) The following information for each individual onboard:

(i) Full name;

(ii) Date of birth;

(iii) Nationality;

(iv) Passport number or marine documentation number (type of identification and number);

(v) Position or duties on the foreign floating facility; and

(vi) Name of the port, or place, and country where the individual embarked.

(7) The date of issuance of the foreign floating facility's International Safety Management certificate (ISM), if any, and Document of Compliance certificate and the name of the flag administration, or its recognized representative, that issued those certificates; and

(8) The date of issuance of the foreign floating facility's International Ship Security certificate (ISSC), if any, and the name of the flag administration, or the recognized security organization representing the flag administration, that issued the ISSC.

(b) *Methods of submission.* The notice must be submitted to the National Vessel Movement Center by electronic Notice of Arrival and Departure format using methods specified at the NVMC's Web site at <http://www.nvmc.uscg.gov/>.

(c) *Updates to a submitted NOA.*

Unless otherwise specified in this section, whenever the most recently submitted NOA information becomes

inaccurate, the owner or operator of the foreign floating facility must revise and re-submit the NOA within the times required in paragraph (e) of this section. An owner or operator does not need to revise or re-submit an NOA for the following:

(1) A change in submitted arrival time that is less than 6 hours;

(2) Changes in the location, latitude and longitude, of the floating facility from the location at the time the NOA was reported; or

(3) Changes to personnel positions or duties on the foreign floating facility.

(d) *Required reporting time of an initial NOA.* The owner or operator of a foreign floating facility subject to this section must submit an initial NOA:

(1) If the voyage time is more than 96 hours, owners or operators of a foreign floating facility must submit an initial NOA at least 96 hours before the foreign floating facility arrives at the OCS location where the owner or operator plans to perform OCS activities; or

(2) If the voyage time is less than 96 hours, the owner or operator of a foreign floating facility must submit an initial NOA at least 24 hours before the foreign floating facility arrives at the OCS location where the owner or operator plans to perform OCS activities.

(e) *Required reporting time of an update to an NOA.* The owner or operator of a foreign floating facility subject to this section must submit an NOA update:

(1) If the most recently submitted NOA, or NOA update, differs by 24 hours or more from the current estimated time of arrival, the owner or operator of the foreign floating facility must provide an updated NOA as soon as practicable but at least 24 hours before the floating facility arrives at the OCS location where the owner or operator plans to perform OCS activities; or

(2) If the most recently submitted NOA, or NOA update, differs by less than 24 hours from the current estimated time of arrival, the owner or operator of the foreign floating facility must provide an updated NOA as soon as practicable but at least 12 hours before the floating facility arrives at the OCS location where owners or operators plan to perform OCS activities.

(f) *Towing vessels.* When a towing vessel controls a foreign floating facility required to submit an NOA under this subpart, the owner or operator of the towing vessel, or lead towing vessel if there is more than one, is responsible for submitting only one NOA containing the NOA information items required for towing vessels, under § 146.405, and the

foreign floating facility under paragraph (a) of this section.

(g) This section does not apply to a foreign floating facility merely transiting the waters superjacent to the OCS and not engaged in OCS activities.

■ 5. Add § 146.200 to subpart C to read as follows:

§ 146.200 Definitions.

For the purpose of this subpart:

Arrives on the OCS means when a MODU enters any OCS block area for the purpose of engaging in operations subject to the jurisdiction of the OCS Lands Act.

OCS block area means the names given by the Bureau of Ocean Energy Management, Regulation and Enforcement (BOE) to define the OCS areas used to facilitate management or leasing on the OCS.

■ 6. Add § 146.215 to subpart C to read as follows:

§ 146.215 Safety and Security notice of arrival for U.S. or Foreign MODUs.

(a) *General*. At least 96 hours before a MODU arrives on the OCS from a foreign port or place or from a different OCS block area to engage in OCS activities, excluding those U.S. MODUs arriving directly from a U.S. port or place, to engage in OCS activities, the owner or operator of the MODU, except as provided in paragraph (f) of this section, must submit the following information to the National Vessel Movement Center (NVMC):

- (1) The location, latitude and longitude, of the MODU at the time the notice of arrival (NOA) is reported;
- (2) The area designation, block number or lease number, assigned under 30 CFR 250.154 for identification, where the MODU owner or operator plans to perform OCS activities;
- (3) The MODU's name and IMO number, if any;
- (4) The date when operations of the MODU are expected to begin and end;
- (5) Names of the last two ports or places visited and the associated dates of arrival and departure;
- (6) The following information for each individual onboard:
 - (i) Full name;
 - (ii) Date of birth;
 - (iii) Nationality;
 - (iv) Passport number or marine documentation number (type of identification and number);
 - (v) Position or duties on the MODU; and
 - (vi) Name of the port, or place, and country where the individual embarked.
- (7) The date of issuance of the MODU's International Safety Management certificate (ISM), if any,

and Document of Compliance certificate and the name of the flag administration, or its recognized representative, that issued those certificates; and

(8) The date of issuance of the MODU's International Ship Security certificate (ISSC), if any, and the name of the flag administration, or the recognized security organization representing the flag administration, that issued the ISSC.

(b) *Methods of submission*. The notice must be submitted to the National Vessel Movement Center (NVMC) by electronic Notice of Arrival and Departure format using methods specified in the NVMC's Web site at <http://www.nvmc.uscg.gov/>.

(c) *Updates to a submitted NOA*. Unless otherwise specified in this section, whenever the most recently submitted NOA information becomes inaccurate, the owner or operator of the MODU must revise and re-submit the NOA within the times required in paragraph (e) of this section. An owner or operator does not need to revise or re-submit an NOA for the following:

- (1) A change in submitted arrival time that is less than 6 hours;
- (2) Changes in the location, latitude and longitude, of the MODUs from the location at the time the NOA was reported; or
- (3) Changes to personnel positions or duties on the MODU.

(d) *Required reporting time of an initial NOA*. The owner or operator of a MODU subject to this section must submit an initial NOA:

- (1) If the voyage time is more than 96 hours, owners and operators of a MODU must submit an initial NOA at least 96 hours before the MODU arrives at the OCS location where the owner or operator plans to perform OCS activities; or
- (2) If the voyage time is less than 96 hours, owners and operators of a MODU must submit an initial NOA at least 24 hours before the MODU arrives at the OCS location where the owner or operator plans to perform OCS activities.

(e) *Required reporting time of an update to an NOA*. The owner or operator of a MODU subject to this section must submit an NOA update:

- (1) If the most recently submitted NOA, or NOA update, differs by 24 hours or more from the current estimated time of arrival, the owner or operator of the MODU must provide an updated NOA as soon as practicable but at least 24 hours before the MODU arrives at the OCS location where the owner or operator plans to perform OCS activities; or

(2) If the most recently submitted NOA, or NOA update, differs by less than 24 hours from the current estimated time of arrival, the owner or operator of the MODU must provide an updated NOA as soon as practicable but at least 12 hours before the MODU arrives at the OCS location where the owner or operator plans to perform OCS activities.

(f) *Towing vessels*. When a towing vessel controls a MODU required to submit an NOA under this subpart, the owner or operator of the towing vessel, or lead towing vessel if there is more than one, is responsible for submitting only one NOA containing the information required for the towing vessels, under § 146.405, and the MODU under paragraph (a) of this section.

(g) This section does not apply to MODU's merely transiting the waters superjacent to the OCS and not engaged in OCS activities.

Subpart D—Vessels—Notice of Casualty

■ 7. Revise the heading in Subpart D to read as set forth above.

■ 8. Add Subpart E to read as follows:

Subpart E—Vessels—Safety and Security Notice of Arrival

Sec.

- 146.401 Applicability.
146.402 Definitions.
146.405 Safety and Security notice of arrival for vessels arriving at a place on the OCS.

Subpart E—Vessels—Safety and Security Notice of Arrival

§ 146.401 Applicability.

This subpart applies to all U.S. and foreign vessels, except those U.S. vessels traveling directly from a U.S. port or place, bound for a place on the OCS and planning to engage in OCS activities. Vessels under this subpart include, but are not limited to, standby vessels, attending vessels, offshore supply vessels, pipelay vessels, derrick ships, diving support vessels, oceanographic research vessels, towing vessels, and accommodation vessels. This subpart does not apply to MODUs, which are covered under § 146.215; nor does it apply to floating facilities, which are covered under §§ 146.103 and 146.104.

§ 146.402 Definitions.

For the purpose of this subpart:

Arrives on the OCS means when a vessel enters any OCS block area to commence operations for which it has submitted a Notice of Arrival under § 146.405(b)(2).

OCS block area means the names given by the Bureau of Ocean Energy Management, Regulation and Enforcement (BOE) to define the OCS areas used to facilitate management or leasing on the OCS.

§ 146.405 Safety and Security notice of arrival for vessels arriving at a place on the OCS.

(a) *General.* The owner or operator of each vessel subject to this section must submit an initial NOA to the National Vessel Movement Center (NVMC):

(1) If the voyage time is more than 96 hours, at least 96 hours before the vessel arrives at a place on the OCS from a foreign port or place or from a different OCS block area to engage in OCS activities;

(2) If the voyage time is less than 96 hours and more than 24 hours, before departure, or;

(3) If the voyage time is less than 24 hours, at least 24 hours before the vessel arrives at a place on the OCS.

(b) *Information required in an NOA.* The following information is required from the owners or operators of vessels submitting an NOA:

(1) All the information specified in 33 CFR Table 160.206 with the exception of information required in items (2)(iii) through (2)(vi) and item (6). Item (8) is also not required except as pursuant to the laws on vessel entry (19 U.S.C. 1434) and clearance (46 U.S.C. 60105). Vessel owners and operators should protect any personal information they gather in preparing notices for transmittal to the NVMC so as to prevent unauthorized disclosure of that information;

(2) The area in which they are conducting their operations. This area can be submitted as either the name of the places, the BOE block numbers, or the latitudes and longitudes of the places on the OCS where operations are being conducted; and

(3) If any person onboard, including a crewmember, is not required to carry a passport for travel, then passport information required in Table 160.206, items (4)(iv) through (vi), and (5)(iv) through (vi), need not be provided for that person.

(c) *Updates to a submitted NOA.* Unless otherwise specified in this section, whenever the most recently submitted NOA information becomes inaccurate, the owner or operator of that vessel must revise and re-submit the NOA within the times required in paragraph (e) of this section. An owner or operator does not need to revise and re-submit an NOA for the following:

(1) A change in submitted arrival time that is less than 6 hours;

(2) Changes in the location, latitude and longitude, of the vessel from the location at the time the NOA was reported; or

(3) Changes to personnel positions or duties on the vessel.

(d) *Methods of submission.* The notice must be submitted to the NVMC by electronic Notice of Arrival and Departure format using methods specified at the NVMC's Web site at <http://www.nvmc.uscg.gov/>.

(e) *Required reporting time of an NOA update.* The owner or operator of each vessel subject to this section must submit an NOA update:

(1) If the most recently submitted NOA, or NOA update, differs by 24 hours or more from the current estimated time of arrival, the owner or operator of the vessel must provide an update as soon as practicable but at least 24 hours before the vessel arrives at the OCS location where the owner or operator plans to perform OCS activities;

(2) If the most recently submitted NOA, or NOA update, differs by less than 24 hours from the current estimated time of arrival, the owner or operator of the vessel must provide an update as soon as practicable but at least 12 hours before the vessel arrives at the OCS location where the owner or operator plans to perform OCS activities; or

(3) If the remaining voyage time is less than 24 hours, the owner or operator of the vessel must provide an update as soon as practicable, but at least 12 hours before the vessel arrives at a place on the OCS.

(f) *Towing vessels.* When a towing vessel controls a vessel required to submit an NOA under this subpart, the owner or operator of the towing vessel, or lead towing vessel if there is more than one, is responsible for submitting only one NOA containing the information required for the towing vessels and the vessel under its control.

(g) This section does not apply to vessels merely transiting the waters superjacent to the OCS and not engaged in OCS activities.

Dated: December 22, 2010.

Robert J. Papp, Jr.,

Admiral, U.S. Coast Guard Commandant.

[FR Doc. 2011-569 Filed 1-12-11; 8:45 am]

BILLING CODE 9110-04-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R05-OAR-2010-0675; FRL-9250-8]

Approval and Promulgation of Air Quality Implementation Plans; Minnesota; Gopher Resource, LLC

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving a request submitted by the Minnesota Pollution Control Agency (MPCA) on July 29, 2010, to revise the Minnesota State Implementation Plan (SIP) for lead (Pb) under the Clean Air Act (CAA). The State has submitted a joint Title I/Title V document (joint document) in the form of Air Emission Permit No. 03700016-003, and has requested that the conditions laid out with the citation "Title I Condition: SIP for Lead NAAQS" replace an existing Administrative Order (Order) as the enforceable SIP conditions for Gopher Resource, LLC. The existing Order was approved by EPA on October 18, 1994. MPCA's July 29, 2010, revisions were meant to satisfy the maintenance requirements for the 1978 Pb National Ambient Air Quality Standard (NAAQS), promulgated at 1.5 micrograms per cubic meter, or 1.5 µg/m³.

DATES: This direct final rule will be effective March 14, 2011, unless EPA receives adverse comments by February 14, 2011. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R05-OAR-2010-0675, by one of the following methods:

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

2. *E-mail:* mooney.john@epa.gov.

3. *Fax:* (312) 692-2551.

4. *Mail:* John Mooney, Chief, Attainment Planning and Maintenance Section (AR-18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

5. *Hand Delivery:* John Mooney, Chief, Attainment Planning and Maintenance Section (AR-18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed

information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA-R05-OAR-2010-0675. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through <http://www.regulations.gov> your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. We recommend that you telephone Andy Chang, Environmental Engineer, at (312) 886-0258 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT:

Andy Chang, Environmental Engineer, Attainment Planning and Maintenance Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886-0258, chang.andy@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document whenever "we," "us," or "our" is used, we mean EPA. This supplementary information section is arranged as follows:

- I. Background
 - A. When and why did the State make this submittal?
 - B. Did the State hold public hearings for this submittal?
- II. What is EPA's analysis of MPCA's submittal?
 - A. Gopher Resource, LLC, and General SIP Conditions
 - B. Emissions Units, Processes, and Limits
 - C. Stack Emissions Testing
 - D. Consistency With the Existing Order
 - E. Rescission of the Order.
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I. Background

A. When and why did the State make this submittal?

MPCA submitted this revision to the Minnesota SIP on July 29, 2010. Air Emission Permit No. 03700016-003 was submitted as a joint document, and MPCA requested that the conditions labeled "Title I Condition: SIP for Lead NAAQS" serve as the enforceable SIP conditions for the Gopher Resource, LLC, (Gopher) facility. The State's submittal, as well as EPA's analysis of the submittal elements, will be discussed in subsequent sections of this document.

Portions of Dakota County were designated as nonattainment for the 1978 Pb NAAQS on January 6, 1992. It was found that Gopher was the primary source of elevated Pb levels in the area. Gopher was formerly known as Gopher Smelting and Refining Company, and the change to Gopher Resource, LLC will be discussed in Section IIA, below.

EPA approved a request to redesignate Dakota County as attainment for the 1978 Pb NAAQS on October 18, 1994. The redesignation request was part of a SIP revision which also included a maintenance plan in accordance with section 175A of the CAA, as interpreted by a September 4, 1992, EPA memorandum entitled, "Procedures for Processing Requests to Redesignate Areas to Attainment." EPA also approved the Order for Gopher on October 18, 1994. This Order was originally issued by MPCA for the facility on June 22, 1993, and contained

emissions limits and other requirements ensuring attainment of the 1978 Pb NAAQS.

Section 175A(b) of the CAA required MPCA to submit an update to its maintenance plan, which the agency did on November 18, 2002. On this date, the State also submitted a request to replace the existing Order with a joint document, in this case, a permit. This concept does not set any new precedent, because Minnesota routinely houses the conditions necessary to attain and maintain the NAAQS in facility permits. The required SIP conditions are denoted as, "Title I Condition: SIP for (pollutant) NAAQS." However, EPA did not act on the submittal because, among other things, the revisions to the SIP for Gopher removed contingency measures from the maintenance plan.

On November 19, 2007, MPCA formally withdrew the request to replace the Order with the joint document, but asked that EPA consider the maintenance plan update, which EPA approved on June 3, 2008 (73 FR 31614). On November 16, 2010, the Administrator of EPA signed designations for Pb nonattainment areas for the 2008 Pb NAAQS, for those areas exceeding 0.15 µg/m³. A subsequent **Federal Register** notice published on November 22, 2010 (75 FR 71033), confirmed that portions of Eagan, located in Dakota County, and identical to the current maintenance area for the 1978 Pb NAAQS, are in nonattainment for the 2008 Pb NAAQS. However, the 1978 Pb NAAQS remains in effect for the Eagan area until December 31, 2011. MPCA's July 29, 2010, requested revisions are meant to address only the maintenance requirements of the 1978 Pb NAAQS.

MPCA has worked closely with EPA to form a joint document that meets all the requirements to replace the existing Order as the enforceable SIP conditions for the Gopher facility. As previously mentioned, Minnesota houses all conditions necessary to attain and maintain the NAAQS in facility permits through a joint document. The conditions of this joint document are established under Minnesota's Clean Air Act Title I authority and Title V permitting authority. The State's July 29, 2010, submittal from MPCA is the Title V permit for Gopher Resource, LLC, with appropriately denoted Title I SIP conditions. This joint document will replace the existing Order, and although this SIP revision has been submitted in conjunction with reissuance of the facility's operating permit, this action will focus only on the relevant changes to the facility's Title I SIP conditions for Pb.

B. Did the State hold public hearings for this submittal?

The public notice for the joint document and associated SIP revision was published in the *St. Paul Pioneer Press* on February 17, 2010. The public notice period for the joint document began on February 18, 2010, and lasted until March 19, 2010. MPCA did not receive a request to hold a public hearing, but did receive comments on the reissuance of the Title V permit. However, none of the comments that MPCA received were applicable to the maintenance requirements for the 1978 Pb NAAQS, and no changes to the joint document were made as a result of the comments.

II. What is EPA's analysis of MPCA's submittal?

A. Gopher Resource, LLC, and General SIP Conditions

The existing Order refers to the facility as "Gopher Smelting and Refining Company," whereas the joint document submitted by MPCA on July 29, 2010, correctly identifies the facility as "Gopher Resource, LLC." This change reflects only a change of ownership structure, whereas the actual ownership remained largely unchanged. General SIP conditions, such as those that describe when facility changes require a SIP revision, have been reworded or clarified to fit with MPCA's current format for such conditions. Additional conditions that allowed the facility a choice in compliance options in the Order have been updated to reflect the compliance choice made by Gopher. Lastly, the joint document organizes and names emissions units differently than the Order, thereby reflecting current operations. Aligning the current name of the facility into the SIP prevents potential confusion as to the correct name of the facility, and the enforceable conditions in the joint document now apply to the same properly designated entity on both the State and Federal levels. Therefore, EPA finds the updated name of Gopher Resource, LLC, to be approvable. The changes to the general SIP conditions as outlined in the joint document pertain to format only; these changes ensure that MPCA has been consistent with other joint documents, and because there are no significant emissions changes that stem from formatting, rewording, or clarifications, EPA finds these revisions to be approvable. Gopher has selected a set of compliance options based on EPA regulations and guidelines, or based on the previously approved Order, and therefore, EPA finds these changes to be approvable. Organizing emissions units

to reflect current operations aligns State and Federal nomenclature; therefore, EPA finds these changes to be approvable.

B. Emissions Units, Processes, and Limits

The State-submitted joint document contains updated emissions units and processes that reflect current operations. Flue dust agglomeration is no longer a process at Gopher, nor does there exist a central vacuum system. The existing Order refers to six refining kettles instead of the ten that are currently in operation; these ten kettles are reflected in the joint document. These kettles vent to the main stack SV003, and although there has been a change in the specifics of the emissions units, the emissions limits for SV003 in the joint document are identical to those found in the Order. Therefore, EPA does not expect a net effect on the emissions exiting at SV003, nor does EPA expect a violation of the 1978 Pb NAAQS to occur as a result of these added units.

Gopher has added two additional Torit dust collectors that collect fugitive Pb emissions from raw material handling, the battery breaking dock, material transfer rooms, and the furnace areas. These dust collectors exhaust into the new Torit stack SV008, and the purpose of these collectors is to control dust that was observed to "leak" from various points, *i.e.*, it was assumed that the dust at these new collectors was going into Torit stack SV002. Emissions that were assumed to be entering the SV002 in their entirety are now being split between SV002 and SV008.

MPCA performed a modeling analysis showing that the added Torit stack SV008 would not result in negative ambient impacts. The modeling shows that the area of maximum impact, on a monthly average level, is $0.78 \mu\text{g}/\text{m}^3$. Monitoring data from Air Quality System ID# 270370465 has corroborated compliance with the 1978 Pb NAAQS; the highest quarterly average recorded between 2007 and 2009 (consistent with the form of the 1978 Pb NAAQS) was $0.70 \mu\text{g}/\text{m}^3$. Available data from 2010 have demonstrated compliance with the 1978 Pb NAAQS as well. Based on the static emission limits, as well as supporting modeling and monitoring data, EPA finds the requested revisions concerning emissions units, processes, and limits to be approvable.

C. Stack Emissions Testing

MPCA requested in the joint document that the stack testing frequency be changed from once every year to once every two years. The basis of the request is found in the

Amendments to the National Emission Standards for Hazardous Air Pollutants (NESHAP) From Secondary Lead Smelting (62 FR 32209). The amendments affirm that if a compliance test shows a source emitted Pb compounds at 1.0 milligram of lead per dry standard cubic meter (0.00044 grains of lead per dry standard cubic foot) or less during the time of the compliance test, the owner or operator of the lead smelter would be allowed up to 24 calendar months from the previous compliance test to conduct the next annual compliance test for Pb compounds. MPCA submitted emissions test reports from 2006 and 2008; the highest average concentration was recorded in 2006 at the main stack, and the concentration was .16 milligrams of lead per dry standard cubic meter. This value is 16% of the bi-annual stack testing frequency threshold. The facility has been complying with the NESHAP for secondary lead smelters since December 23, 1997, and to the extent that the NESHAP requirements are more stringent than the requirements contained in the SIP, EPA approves Gopher's request for bi-annual stack testing.

D. Consistency With the Existing Order

EPA did not act on MPCA's November 18, 2002, joint document because provisions in that document would remove contingency plan elements from the maintenance plan. In its July 29, 2010, submittal, MPCA included contingency plans and associated record keeping requirements identical to those found in the Order. EPA finds the inclusion of contingency measures in the joint document to be appropriate and necessary in conjunction with section 175A(d) of the CAA.

Significant changes have been discussed in detail already, and EPA has determined that any other minor deviations from the existing Order are *de minimis*. For example, MPCA requested that mobile equipment traffic be allowed on non-paved areas for maintenance and inspection purposes. These activities are not expected to have a negative impact on the surrounding ambient air quality.

EPA finds that all elements included in the existing Order are included in the July 29, 2010, joint document. Adopting the joint document in lieu of the Order should not result in any applicability, emissions, or otherwise detrimental gaps. EPA also expects the Eagan area of Dakota County to continue to meet the 1978 Pb NAAQS.

E. Rescission of the Order

On July 27, 2010, MPCA revoked the Order and subsequent amendments to the Order. For the reasons discussed in previous sections, the joint document submitted by MPCA on July 29, 2010, is appropriate and sufficient to serve as the only document that contains SIP conditions for Gopher Resource, LLC. As such, EPA finds it appropriate to rescind the original Order from the SIP.

III. What action is EPA taking?

EPA is approving a joint Title I/Title V document submitted by MPCA for Gopher Resource, LLC. The conditions labeled, "Title I Condition: SIP for Lead" will replace the existing Order as the enforceable SIP conditions for the facility. Specifically, these conditions can be found in Air Emission Permit No. 03700016-003. The joint document includes elements necessary for Dakota County to continue meeting the 1978 Pb NAAQS. EPA is simultaneously rescinding the existing Order from the SIP.

We are publishing this action without prior proposal because we view this as a noncontroversial amendment and anticipate no adverse comments. However, in the Proposed Rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the State plan if relevant adverse written comments are filed. This rule will be effective March 14, 2011 without further notice unless we receive relevant adverse written comments by February 14, 2011. If we receive such comments, we will withdraw this action before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on the proposed action. EPA will not institute a second comment period; therefore, any parties interested in commenting on this action should do so at this time. If we do not receive any comments, this action will be effective March 14, 2011.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve State choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves State law as meeting

Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this action:

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

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

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a

report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 14, 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. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the Proposed Rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Lead, Reporting and recordkeeping requirements.

Dated: December 29, 2010.

Susan Hedman,

Regional Administrator, Region 5.

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 Y—Minnesota

- 2. In § 52.1220 the table in paragraph (d) is amended by removing the entry for "Gopher Smelting and Refining Company" and adding an entry for "Gopher Resource, LLC" in its place to read as follows:

§ 52.1220 Identification of plan.

*	*	*	*	*
(d) * * *				

EPA-APPROVED MINNESOTA SOURCE-SPECIFIC PERMITS

Name of source	Permit No.	State effective date	EPA approval date	Comments
* * * * * Gopher Resource, LLC	* * * * * 03700016-003	* * * * * 06/29/10	* * * * * 01/13/11, [Insert page number where the document begins].	* * * * * Only conditions cited as "Title I condition: SIP for Lead NAAQS."
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[FR Doc. 2011-337 Filed 1-12-11; 8:45 am]

BILLING CODE 6560-50-P

Proposed Rules

Federal Register

Vol. 76, No. 9

Thursday, January 13, 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 AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 103, 112, and 114

[Docket No. APHIS–2008–0008]

RIN 0579–AD19

Viruses, Serums, Toxins, and Analogous Products; Packaging and Labeling

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the Virus-Serum-Toxin Act regulations regarding the packaging and labeling of veterinary biological products to provide for the use of an abbreviated true name on small final container labeling for veterinary biologics; require labeling to bear a consumer contact telephone number; change the format used to show the establishment or permit number on labeling and require such labeling to show the product code number; change the storage temperature recommended in labeling for veterinary biologics; require vaccination and revaccination recommendations in labeling to be consistent with licensing data; require labeling information placed on carton tray covers to appear on the outside-face of the tray cover; remove the restriction requiring multiple-dose final containers of veterinary biologics to be packaged in individual cartons; require labeling for bovine virus diarrhea vaccine containing modified live virus to bear a statement warning against use in pregnant animals; reduce the number of copies of each finished final container label, carton label, or enclosure required to be submitted for review and approval; require labeling for autogenous biologics to specify the microorganism(s) and/or antigen(s) they contain; and require labeling for conditionally licensed veterinary biologics to bear a statement concerning efficacy and potency

requirements. In addition, we also propose to amend the regulations concerning the number of labels or label sketches for experimental products required to be submitted for review and approval, and the recommended storage temperature for veterinary biologics at licensed establishments. These proposed amendments are necessary in order to update and clarify labeling requirements and ensure that information provided in labeling is accurate with regard to the expected performance of the product.

DATES: We will consider all comments that we receive on or before March 14, 2011.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2008-0008> to submit or view comments and to view supporting and related materials available electronically.

- *Postal Mail/Commercial Delivery:* Please send one copy of your comment to Docket No. APHIS–2008–0008, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2008–0008.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: Additional information about APHIS and its programs is available on the Internet at <http://www.aphis.usda.gov>.

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

SUPPLEMENTARY INFORMATION:

Background

Under the Virus-Serum-Toxin Act (the Act, 21 U.S.C. 151–159) and regulations issued under the Act, the Animal and Plant Health Inspection Service (APHIS) grants licenses or permits for biological products which are pure, safe, potent, and efficacious when used according to label instructions. The regulations in 9 CFR part 112, “Packaging and Labeling” (referred to below as the regulations), prescribe requirements for the packaging and labeling of veterinary biological products including requirements applicable to final container labels, carton labels, and enclosures. The main purpose of the regulations in part 112 is to regulate the packaging and labeling of veterinary biologics in a comprehensive manner, which includes ensuring that labeling provides adequate instructions for the proper use of the product, including vaccination schedules, warnings, and cautions. Complete labeling (either on the product or accompanying the product) must be reviewed and approved by APHIS in accordance with the regulations in part 112 prior to their use.

Although the science of immunology and our understanding of how veterinary biologics work have advanced substantially in recent years, communicating such information to consumers by way of updated labeling claims, cautions, and warnings has not kept pace. Therefore, we are proposing to amend several sections of the regulations in part 112 to make veterinary biologics labeling requirements more consistent with current science and veterinary practice.

True Name, Abbreviated True Name, Functional/Chemical Name

We are proposing to amend § 112.2(a)(1) of the regulations concerning required labeling information to provide for the use of an abbreviated true name on labeling for small final containers of veterinary biologics. Currently, the regulations require the true name shown in the product license or permit under which a product is imported to be used in veterinary biologics labeling. However, due to the small size of the labeling used on small final containers of some veterinary biologics and the amount of label surface that must be devoted to

emphasizing the true name of the product, there may not be adequate remaining space on such labeling for the legible presentation of other required information. Under the proposed amendment, when issuing or reissuing licenses for veterinary biologics, APHIS would assign abbreviated true names—shortened forms of the true name of the product shown in the product license/permit—which may be used in place of the long form of the true name on labeling for small final containers of veterinary biologics. While abbreviated true names may be used on small final container labels, the complete true name along with the abbreviation for such true name would be shown on carton labels and enclosures. Thus, the association between the true name of the product and its abbreviated true name would be readily apparent to consumers, veterinarians, and others who utilize veterinary biological products. The proposed change would mean that a greater proportion of the (small) container label surface may be used to improve the presentation and legibility of other required information. The proposed amendment also would clarify in this section the requirements for showing the true name of the product and/or a functional or chemical name for the reagent on labeling for cartons, and containers of interchangeable (non-critical) reagents included in diagnostic test kits. Carton or box labeling for diagnostic test kits is required to show the true name of the test kit as it appears on the product license or permit under which such kit is imported; labeling for containers of interchangeable reagents included in test kits may show the functional and/or chemical name of such reagent(s). The proposed change would facilitate the use of a single lot of such interchangeable reagent in a variety of test kit configurations.

Consumer Contact Telephone Number

We are proposing to amend the regulations in § 112.2(a)(2) to require labeling for veterinary biologics to bear a telephone number that consumers may use to contact the licensee or permittee to report adverse events or other unfavorable experiences associated with the use of such products. Currently, veterinary biologics labeling is not required to bear a telephone number for reporting adverse experiences to APHIS and/or the licensee or permittee. In the absence of immediately available contact information for reporting such adverse experiences, the probability of harm to animals and hazards to humans posed by the use of veterinary biologics may increase. The addition to veterinary

biologics labeling of a telephone number that consumers may use to report adverse events and other unfavorable experiences to the manufacturer and to APHIS would facilitate the reporting of such adverse vaccine experiences and help to ensure that the licensee/permittee is able to initiate appropriate corrective action in a timely manner.

Veterinary License/Permit Number and Product Code Number

In order to better facilitate product identification, we are proposing to amend the regulations in § 112.2(a)(3) to: (1) Require labeling for veterinary biologics to bear the product code number (PCN) that APHIS assigns to such product and communicates to the manufacturer when the product license application is submitted, and (2) specify a revised format for showing the veterinary establishment license number (VLN) or veterinary establishment permit number (VPN) in veterinary biologics labeling. The license or permit number would be shown side-by-side with the product code number using the format VLN/PCN or VPN/PCN, as applicable. For example, the VLN/PCN relationship for a product prepared by veterinary biologics licensee number 100 (VLN 100) under product code number 1A34.XX (PCN 1A34.XX) would be shown in labeling as: VLN/PCN 100/1A34.XX. Currently, the regulations in § 112.2(a)(3) specify that the license number must be shown in labeling as “U.S. Veterinary License No. __,” or “U.S. Vet License No. __,” or “U.S. Vet Lic. No. __,” and the permit number must be shown as “U.S. Veterinary Permit No. __,” or “U.S. Permit No. __,” but there is no requirement for the PCN to appear in labeling. The true name of the product, the veterinary license or permit number, and the product serial or lot number, all currently required to be shown in labeling, are used for product identification. In most instances, such information is sufficient for product identification. However, such information may be insufficient if the licensee or permittee prepares or distributes two or more products that have the same true name and use an overlapping sequence of serial numbers; in those instances, consumers may need additional information in order to accurately identify a product. The addition of the PCN to veterinary biologics labeling would provide that additional piece of information. The side-by-side presentation of the VLN/VPN and PCN in veterinary biologics labeling, along with the true name of the product and its serial or lot number, would better facilitate product identification and help to ensure the

accuracy of information provided to the manufacturer and/or APHIS concerning product performance.

Storage Temperature

We are proposing to amend the regulations in §§ 112.2(a)(4) and 114.11 regarding the storage temperature recommendation for veterinary biologics to prescribe a range of 2 to 8 °C (35 to 46 °F) as the recommended storage temperature for both released serials of veterinary biologics stored in distribution channels and completed serials of veterinary biologics stored at a licensed establishment. Currently, the regulations provide that the storage temperature for veterinary biological product in distribution channels should be stated as “not over 45 °F or stated as not over 7 °C or stated as not over 45 °F or 7 °C.” The regulations do not prescribe a minimum recommended storage temperature for released product in distribution channels. Under § 114.11 of the regulations, completed product stored at licensed establishments should be kept under refrigeration at temperatures that may range from 35 to 45 °F (2 to 7 °C). Under the proposed amendment, the maximum recommended storage temperature for released product in distribution channels would increase to 8 EC (the widely recognized standard, and 1 °C above the currently prescribed 7 °C), and 2 °C would be established as the minimum recommended storage temperature. For completed product stored in bulk or final containers at licensed establishments, the minimum recommended storage temperature of 2 °C would remain unchanged, and the maximum recommended storage temperature would be increased to 8 °C (1 °C above the currently prescribed 7 °C). The proposed amendment would standardize veterinary biologics storage temperature recommendations in the regulations and, thereby, reduce the likelihood that dissimilar recommendations may result in mishandling during storage.

Instructions for Use of the Product

We propose to amend the regulations in § 112.2 (a)(5) to clarify that “full instructions for the proper use of the product” refers to vaccination schedules, revaccination schedules (if necessary), indications for use, target species, recommended age for vaccination, vaccination route(s), and product license restrictions prescribed by APHIS that have a bearing on product use. Currently, the regulations in § 112.2(a)(5) specify that “full instructions for the proper use of the product” refers to “vaccination

schedules, warnings, cautions, and the like.” Although APHIS has always considered indications for use, target species, age of vaccination, route of vaccination, and product license restrictions to be included under “full instructions for the proper use of the product,” the fact that such information is not specifically identified as “required” in the regulations may have caused some confusion with regard to interpretation, which resulted in requests for clarification from licensees and permittees. The proposed amendment would ensure consistency in labeling by setting forth under the regulations the minimum information that must be provided under instructions for use of the product.

Disposal of Containers and Warnings

We are proposing to amend the regulations in §§ 112.2(a)(7) and 112.3(f)(2) to require chemical treatment prior to disposal of containers of veterinary biologics containing viable or dangerous organisms or viruses. In addition, under § 112.2(a)(7) of the regulations, the proposed amendment would require labeling to bear statements that: (1) Warn persons who inject themselves with veterinary biologics to seek medical attention and, (2) warn against treating animals with mixtures of veterinary biologics that are not approved for administration as combination products. Currently, the regulations require labeling to bear the warning “Burn this container and all unused contents” if a biological product contains viable or dangerous organisms or viruses. At the time the regulation was promulgated, disposal of discarded veterinary biologics containers by burning was in accordance with existing environmental guidelines. At this time, however, environmental guidelines in many States prohibit disposal of potentially environmentally harmful materials by burning. The proposed amendment would update the regulations by specifying chemical inactivation as the method for ensuring that the unused contents of vaccine containers are made non-hazardous prior to disposal.

With regard to the use of unapproved combinations of veterinary biologics in the treatment of animals and what constitutes an appropriate course of action in the event of accidental self injection of a veterinary biologic, the regulations do not currently address either topic. In the case of using unapproved combinations of veterinary biologics in the treatment of animals, many veterinarians (and consumers) have made “judgment” decisions to inoculate animals using mixtures of two

or more veterinary biologics that are not approved for administration as combination products. In addition to the fact that such mixing of product(s) is not recommended in labeling, such off-label use disregards the important consideration that antigen interference, a frequent occurrence when administering two or more antigens concurrently, may render the combined products ineffective and could present a disease and/or safety risk in animals. A label statement warning against administering unapproved combinations of veterinary biologics to animals would ensure that veterinary professionals and consumers have the information necessary to use veterinary biologics in a safe and effective manner. We propose to require labeling to bear a statement advising users to seek medical attention should they accidentally inject themselves with veterinary biologics because such products frequently contain chemical compounds that may cause serious injury or harm when left untreated. We believe that it is prudent to make consumers aware of the possibility of serious injury as a result of accidental injection of a veterinary biologic, and encourage such persons to seek immediate medical attention.

Non-Antibiotic Preservatives

We are proposing to amend the regulations in § 112.2(a)(10) to require labeling to indicate the presence of non-antibiotic preservatives (anti-infective substances) added during the preparation of veterinary biologics. Currently, the regulations only require labeling to disclose the presence of antibiotics added at preservative levels during the production process. Such disclosure may help to identify, and aid in testing for drug residues that may be present in the edible portions of food-producing animals that are treated with veterinary biologics. In addition to antibiotic preservatives, many veterinary biologics also may contain non-antibiotic preservatives that are added during the production process. Non-antibiotic preservatives also may cause residues in food, unfavorable reactions in animals, and/or environmental harm. The proposed amendment would treat non-antibiotic preservatives added during the production process the same as antibiotic preservatives, and require labeling disclosure. Antibiotic preservatives used in the reagents that are included in diagnostic test kits would be exempted from this labeling requirement because they are not administered to animals and would not be expected to cause food residues. The

proposed amendment would ensure that all anti-infective substances with the potential to cause harm would be disclosed in labeling.

For Animal Use Only

We are proposing to amend the regulations in § 112.2(d)(3) to provide that carton labels and enclosures for veterinary biologics may bear the statement “For animal use only” in place of the statement “For veterinary use only.” Currently, the regulations specify that veterinary biologics labeling may bear the statement “For veterinary use only” or an equivalent statement when referring to product that is recommended specifically for animals, and not for humans. However, “For veterinary use only” is often confused with the similar statement in the regulations, “Restricted to use by or under the direction of a veterinarian,” which is required to be shown on labeling for products that have a restriction on the license specifying use by or under the direction of a veterinarian. Typically, special knowledge and/or expertise is not required when using veterinary biologics labeled for “animal use only,” whereas professional training and/or knowledge may be required for proper use of veterinary biologics that are labeled “restricted to use by or under the direction of a veterinarian.” For example, veterinary biologics for use in animal disease control and eradication and wildlife vaccination programs may be restricted to use by or under the direction of a veterinarian because of concern about disease spread and/or public health implications. The proposed amendment would help to clarify the distinction between product recommended for use in animals and product that should only be administered by or under the direction of a veterinarian.

Special Labels for Export

We are proposing to amend the regulations in § 112.2(e) pertaining to the approval of special labels for use on biological products to be exported to a foreign country to specify that when the labeling requirements of a foreign country conflict with the requirements prescribed in the regulations in 9 CFR part 112, such request for the approval of special labeling for use on product to be exported must be accompanied by a signed document issued by the appropriate regulatory official of the importing country that affirms the need for such special labeling in order to satisfy the country’s regulatory requirements. As a condition for the approval, we would specify that such

special labeling may not contain false or misleading information. Currently, the regulations provide for the approval of special labels for use on biological products for export to a country in which labeling requirements conflict with the requirements of the United States; however, the regulations do not prescribe the requirements for obtaining approval of such special labeling. The proposed amendment would clarify the procedure for obtaining approval of special labeling for veterinary biological product for export.

Carton Tray Covers

We are proposing to amend the regulations in § 112.2(f) to specify that when carton tray covers are used to show required labeling information concerning veterinary biologics, all such information should appear on the outer face of the tray cover where it can be read without opening the carton. Currently, the use of carton tray covers to show required labeling information is not addressed under the regulations concerning packaging and labeling. However, carton tray covers have come to be extensively used in the packaging of diagnostic test kits. Frequently, such tray covers may be used for the presentation of required labeling information; and some firms have been placing required information on both the outer and inner faces of the tray covers. In such situations, information on the inner face of the tray cover cannot be read by the consumer because of its placement. The proposed change would ensure that required labeling information shown on carton tray covers is presented in a manner that is accessible to the consumer and consistent with the requirements in the regulations that pertain to other labeling media.

Minor Label Changes

We are proposing to amend the regulations in § 112.5(c)(2) to specify additional minor changes that may be made to labeling for products with approved labels or master labels without prior approval from APHIS. The minor label changes that may be made include changes to labeling background color that do not affect legibility of the label; changing the telephone number used to contact the licensee or permittee; changing or revising an e-mail or Web site address; changing the name and/or address of a distributor; or adding, revising, or repositioning universal product code bars or other inventory control numbers. Changes to the name and/or address of the licensee or permittee and changes to the Veterinary License Number or Veterinary Permit

Number that are made pursuant to the reissuance of an Establishment License or Product Permit by APHIS also would be considered minor label changes. Currently, § 112.5 of the regulations specifies that labeling for veterinary biological product must be submitted to APHIS for review for compliance with the regulations and approval in writing prior to use. In § 112.5, paragraph (c) provides that certain minor changes may be made in labels for products with approved labels or master labels, and the revised labels may be used prior to review by APHIS if the specified requirements are met. In § 112.5, paragraph (c)(2) provides a listing of such minor changes that may be made to approved labels and master labels. The proposed amendment would specify additional minor changes to labeling that need not be submitted to APHIS for review and written approval prior to use and, thereby, help to reduce and/or eliminate marketing delays.

Submission of Labels

We are proposing to amend the regulations in §§ 112.5(d)(1)(iii) and (iv) and 103.3(d) to specify that only two copies of each finished final container label, carton label, enclosure, and experimental label should be submitted for APHIS review and approval. Currently, the regulations require three copies of each finished final container label, carton label, enclosure, and experimental label to be submitted. The third copy of labeling is no longer needed as the result of a restructuring of the Center for Veterinary Biologics.

Designation of Label Specimens

Currently, the regulations in § 112.5(d)(4) require that the reason for, and information relevant to, the submission of labels and sketches be added to the bottom of each page of label mounting sheets for the purpose of facilitating label review. The designations of label specimens are to be presented as:

- Master label dose sizes approved for code _____.
- Replacement for label, master label, and/or sketch No. _____.
- Reference to label or master label No. _____.
- Addition to label No. _____.
- License Application Pending _____.
- Foreign language copy of label No. _____.

We would amend paragraph (d)(4) of § 112.5 to make it clear that only the applicable designation or designations, and not all of them, need to appear at the bottom of the label mounting sheets. In addition, we would reduce the

number of designations by combining some and eliminating others. Specifically, the specimen designations “Reference to label or master label No.” and “Addition to label No.” would be combined into a single “Refer to APHIS-assigned label number” designation, and the “License Application Pending” and “Foreign Language copy of Label No.” designations would be removed. These proposed amendments would clarify the regulations with regard to specimen designation and facilitate a more efficient label submission and review process.

Foreign Language Labels

We are proposing to amend the regulations in § 112.5(e) pertaining to special requirements for foreign language labels to require that an accurate English translation be provided with all foreign language labeling submitted for review and approval. The proposal also would require that the foreign language text of multilingual labeling for a veterinary biological product distributed in the United States must be an accurate translation of the approved English text. Currently, the regulations in § 112.5(e)(1) and (e)(2) provide, respectively, that either the addition of a statement affirming the wording of the foreign language label to be a direct translation from a corresponding domestic label, or the submission of an English version of the foreign language label with an explanation for the difference in texts may be used to certify that foreign language text in labeling complies with the regulations. Under the proposed amendment, the option to either affirm the foreign language label to be a direct translation of an approved domestic label or explain the difference in the English and foreign language text would be removed from the regulations. Instead, all foreign language labels would be required to include an accurate English translation and a statement affirming the accuracy of such translation that APHIS would keep on file.

The presence of foreign language text in labeling for product intended for domestic distribution is not currently addressed in the regulations. However, foreign language text and its translation have become a domestic labeling issue due to the implementation of multilingual labeling by multinational firms that market globally and the fact that such foreign language text may not translate word for word into English. The proposed amendment would standardize the presentation of information in multilingual labeling and help to facilitate the timely resolution of

questions concerning approved labeling content.

Packaging Multiple-Dose Final Containers

We propose to amend the regulations in § 112.6(a) pertaining to the packaging of biological products by removing a requirement which specifies that multiple-dose final containers of veterinary biological products that require a diluent for administration must be packaged in an individual carton with a container of the proper volume of diluent for that dose. Currently, the regulations require multiple-dose containers of veterinary biologics to be packaged in individual containers in order to ensure that vaccine will be used within a reasonable time after reconstitution in order to prevent a significant loss of vaccine potency. This requirement was promulgated when much less was known about the stability of vaccines, and it was assumed that vaccine would lose potency after dilution faster than animals could be treated. However, advances in vaccine technology, improved husbandry practices, and new methods for administering vaccines have made the continued imposition of this requirement an unnecessary burden on the veterinary biologics industry.

Special Additional Requirements

Currently, the regulations in § 112.7 provide for labeling requirements that are “additional to” the labeling requirements prescribed elsewhere in 9 CFR part 112. These additional labeling requirements are only applicable to products that have characteristics which make the “special requirements” necessary. Paragraph (f) of § 112.7 requires that, unless otherwise authorized in a filed Outline of Production, labels for inactivated bacterial products shall contain an unqualified recommendation for a repeat dose to accomplish primary immunization to be given at an appropriate time interval. Similarly, paragraph (i) of that section has the special requirement that labels for feline panleukopenia vaccines shall include a recommendation for annual revaccination of cats.

Such recommendations for annual boosters and/or revaccination are predicated on the premise that the protective immunity achieved with the primary immunization diminishes with time and, in order to ensure continued protection, animals must be revaccinated; the typical recommendation is to revaccinate annually. Although all veterinary biologics must be shown to provide

protective immunity prior to the issuance of a license, firms have not been required, except for rabies vaccines, to provide data to establish the duration of protective immunity and/or the need for and frequency of revaccination to maintain such immunity. Despite not having demonstrated that revaccination is needed, it is now common practice for veterinary biologics labeling to recommend annual booster vaccinations for most products. Consequently, for products that were licensed without duration of immunity data, the need for annual revaccination is uncertain, and may not benefit the animal under certain circumstances. In fact, annual revaccination may be harmful in some situations such as with administering feline panleukopenia vaccine to cats annually. Alternatively, it could be that optimal protection of the animal requires that booster vaccinations be administered more frequently than on an annual basis.

In the absence of data, it is difficult or impossible to prescribe the appropriate revaccination interval for the animal. Thus, we are proposing to amend § 112.7(f) to require annual booster (annual revaccination) recommendations in labeling to be supported by data acceptable to APHIS. If such data are not available, we would require labeling to bear the following statement: “A specific revaccination schedule has not been established for this product; consultation with a veterinarian is recommended.” In keeping with the above proposed requirement that annual revaccination recommendations should be based on a demonstrated need for same, we would also amend § 112.7(i) by removing the recommendation for annual revaccination of cats with feline panleukopenia vaccine.

We are also proposing to amend § 112.7 to require that labeling for all modified live and inactivated vaccines for use in mammals bear an appropriate statement concerning the use of the product in pregnant animals. Currently, the regulations in § 112.7(e) require that labeling for (infectious) bovine rhinotracheitis (IBR) vaccine containing modified live virus bear the statement: “Do not use in pregnant cows or calves nursing pregnant cows” unless the vaccine has been shown to be safe for use in pregnant cows and has been exempted from the labeling requirement by the Administrator. The purpose of the warning statement concerning use in pregnant animals is to inform users of the risk to the developing fetus should pregnant cows be treated with or exposed to IBR vaccine containing

modified live virus. We would extend the requirement for such a warning statement to bovine virus diarrhea vaccine (BVDV) containing modified live virus.

For IBR vaccine containing modified live virus and BVDV containing modified live virus, labeling would have to bear the statement “Do not use in pregnant animals or in calves nursing pregnant animals.” However, the current exemption found in § 112.7(e) that states that a vaccine that has been shown by data acceptable to APHIS to be safe for use in pregnant animals may be exempted from this label requirement would remain. It should be noted that even when an exemption is granted, the label would still have to include a statement concerning residual risks, *i.e.*: “Fetal health risks associated with the vaccination of pregnant animals with this vaccine cannot be unequivocally determined during clinical trials conducted for licensure. Appropriate strategies to address the risks associated with vaccine use in pregnant animals should be discussed with a veterinarian.”

In the case of other modified live and inactivated vaccines, we would require that the labeling bear a statement that is appropriate to the level of safety that has been demonstrated in pregnant animals. For example, a statement such as “Do not use in pregnant animals” or “Unsafe for use in pregnant animals” would be an appropriate statement for a product that scientific evidence has shown to be unsafe in pregnant animals. For products that do not have safety documentation acceptable to APHIS, but are not known to be unsafe, the labeling would have to include the statement “This product has not been evaluated for safety in pregnant animals” or an equivalent statement that is acceptable to APHIS.

The extension of such a warning statement to labeling for BVDV, and the proposal that both IBR vaccine and BVDV bear a residual risk statement concerning the reliability of data developed during limited clinical trials in pregnant animals would be new requirements. APHIS is proposing to require labeling for BVDV containing modified live virus to bear this warning in response to reports in the veterinary literature showing that vaccination and/or exposure of pregnant cows to BVDV represents a risk to the developing fetus similar to that of IBR vaccine containing modified live virus. In proposing to require labeling for vaccine for use in pregnant animals to bear a residual risk safety statement, APHIS is responding to concerns expressed within the veterinary community about vaccine

safety. The proposed amendment acknowledges the safety and risk considerations associated with vaccine use and would convey such considerations to consumers.

Currently, the regulations in § 112.7(l) require that all labels for autogenous biologics bear the statement "Potency and efficacy of autogenous biologics have not been established. This product is prepared for use only by or under the direction of a veterinarian or approved specialist," but there is no requirement for the label to identify the microorganism(s) used in the preparation of the product and the animal species for which the product is recommended. However, for all other veterinary biologics, the identity of the microorganism(s) and/or antigen(s) used in the preparation of the product and the species of animal for which it is intended are incorporated into the true name and indications for use statement shown in the labeling. We would amend § 112.7(l) to require that labeling for autogenous biologics identify the microorganism(s) used in its preparation, and the species for which it is prepared. This proposed change would standardize veterinary biologics labeling requirements across product categories.

The regulations in § 102.6(c) set forth the requirements for the issuance of conditional licenses. These requirements include a restriction which specifies that "Labeling for the [conditionally licensed] product may be required to contain information on the conditional status of the license." This restriction prescribes a special requirement applicable to labeling for conditionally licensed product, and therefore should be included in the packaging and labeling requirements specified in 9 CFR part 112. We would amend the regulations in § 112.7 by adding a new paragraph (o) to require that labeling for all conditionally licensed products must bear the statement, "This product license is conditional, efficacy and/or potency requirements have not been completed." This proposed requirement would ensure that consumers receive clear information regarding a product's conditionally licensed status.

If adopted, veterinary biologics manufacturers would have 3 years to bring all of their product labeling into compliance with the rule.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been determined to be significant for the purposes of Executive Order 12866 and,

therefore, has been reviewed by the Office of Management and Budget.

For this proposed rule, we have prepared an economic analysis. The analysis, which is set out below, provides a cost-benefit analysis, as required by Executive Order 12866, as well as an initial regulatory flexibility analysis that considers the potential economic effects of this proposed rule on small entities, as required by the Regulatory Flexibility Act (RFA, 5 U.S.C. 601 *et seq.*).

This proposed rule would amend the Virus-Serum-Toxin Act regulations regarding the packaging and labeling of veterinary biological products to provide for the use of an abbreviated true name on small final container labeling for veterinary biologics; require labeling to bear a consumer contact telephone number; change the format used to show the veterinary biologics establishment or permit number on labeling and require such labeling to show the product code number; change the storage temperature recommended in labeling for veterinary biologics; require vaccination and revaccination recommendations in labeling to be consistent with licensing data; require labeling information placed on carton tray covers to appear on the outside-face of the tray cover; remove the restriction requiring multiple-dose final containers of veterinary biologics to be packaged in individual cartons; require labeling for bovine virus diarrhea vaccine containing modified live virus to bear a statement warning against use in pregnant animals; reduce the number of copies of each finished final container label, carton label, or enclosure required to be submitted for review and approval; require labeling for autogenous biologics to specify the microorganism(s) and/or antigen(s) they contain; and require labeling for conditionally licensed veterinary biologics to bear a statement concerning efficacy and potency requirements. In addition, this proposed rule would amend the regulations concerning the number of labels or label sketches for experimental products required to be submitted for review and approval, and the recommended storage temperature for veterinary biologics at licensed establishments. These proposed amendments are necessary in order to update and clarify labeling requirements and ensure that information provided in labeling is accurate with regard to the expected performance of the product.

The proposed rule is not expected to have a significant economic impact on most veterinary biologics manufacturers. There are several reasons. First, most manufactures

should be able to comply with the rule without having to acquire new labeling equipment or new supplies of labels; their existing equipment for generating labels, as well as their existing inventory of blank labels, should still be usable if the proposal is adopted. This is because the proposed rule primarily affects the type of information required to be shown on the label, not the volume of that information. Since any increase in the volume of information required on labels as a result of the rule should be small, most manufacturers should be able to continue using their existing label equipment and their existing inventory of blank labels. Even manufacturers' existing inventory of preprinted labels (based on the current label requirements) would still likely be usable under the proposal, since it would give manufacturers a total of 3 years to bring all their product labeling into compliance with the rule. It is very likely, therefore, that most or all manufacturers would be able to fully exhaust their existing inventories of preprinted labels before the new label requirements became effective.

Second, the new information that would be required on labels as a result of the rule is basic in nature and should be readily available from manufacturers' existing records; accordingly, manufacturers' cost of obtaining the new information should be negligible, at most.

Third, manufacturers' cost to prepare the new label prototypes (for submission to APHIS) should be minimal, since it is largely an exercise in label editing and formatting.

Finally, any cost increases stemming from the inclusion of the new information on labels should be minimal for most manufacturers.

Benefits of the Proposed Changes: The proposed rule has the potential to benefit consumers of veterinary biologic products (*e.g.*, farmers, veterinarians, and pet stores) and, ultimately, the animals they treat with those products. This is because it ensures that consumers have complete and up-to-date instructions for the proper use of those products, including vaccination schedules, warnings, and cautions. For animal owners, the monetary benefits are difficult to estimate, because they would depend on several factors that are currently unknown, *i.e.*, the significance, or gravity, of the harm to animals that would be avoided with the rule in effect, and the number, and value, of animals that would avoid harm with the rule in effect. For some animal owners, especially those with large numbers of high value animals, the

potential monetary benefits could be substantial.

Costs of the Proposed Changes: For the reasons discussed above, costs to comply with the rule should be minimal for most manufacturers.

Effects on Small Entities

The RFA requires agencies to evaluate the potential effects of their proposed and final rules on small entities. Section 603 of the RFA calls for an agency to prepare and make available for public comment an initial regulatory flexibility analysis describing the expected impact of a proposed rule on small entities, unless the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. The following initial regulatory flexibility analysis is presented in order that the public may have the opportunity to offer comments on expected small-entity effects of the proposed rule.

The businesses most directly affected by the proposed rule are the approximately 125 U.S. veterinary biologics manufacturers, including permittees. We believe that all of these entities would be affected, as none is currently in full compliance with the proposed requirements on a voluntary basis. However, for the reasons stated above, the proposed rule is not expected to have a significant economic impact on most veterinary biologics manufacturers.

The size of the affected manufacturers is unknown. However, it is reasonable to assume that most are small in size, under the U.S. Small Business Administration's (SBA) standards (13 CFR 121.201). This assumption is based on composite data for providers of the same and similar services in the U.S. In 2002, there were 296 U.S. establishments in the North American Industry Classification System (NAICS) 325414, a classification comprised of establishments primarily engaged in manufacturing vaccines, toxoids, blood fractions, and culture media of plant or animal origin (except diagnostic). Of the 296 establishments, 285 (or 96 percent) had fewer than 500 employees, the SBA's small entity threshold for establishments in that NAICS category. Similarly, in 2002, there were 236 U.S. establishments in NAICS 325413, a classification comprised of establishments primarily engaged in manufacturing in-vitro diagnostic substances, including biological substances. Of the 236 establishments, 223 (or 95 percent) had fewer than 500 employees, the SBA's small entity

threshold for establishments in NAICS 325413.¹

The proposed rule has no mandatory reporting, recordkeeping, or other compliance requirements for biologic manufacturers, other than the requirement that noncompliant labels would need to be revised and submitted to APHIS for review and approval.

APHIS has not identified any relevant Federal rules which may duplicate, overlap, or conflict with this proposed rule.

Finally, the RFA requires agencies to describe any significant alternatives to the proposed rule that accomplish the stated objectives of applicable statutes and that minimize any significant economic impact of the proposed rule on small entities. One alternative would be to leave the regulations unchanged. Leaving the regulations unchanged would be unsatisfactory, because it would perpetuate the current situation, *i.e.*, one that does not provide full information to users of veterinary biologic products. Another alternative would be to require that manufacturers show less, or different, information on their labels. That alternative was rejected because APHIS considers the proposed label information to be of the type, and the minimum, necessary to accomplish the rule's objectives. A third alternative would be to require that manufacturers bring all their product labeling into compliance with the rule immediately, rather than 3 years after the rule becomes effective. This third alternative was unacceptable because it does not minimize the impact on manufacturers, especially those with an inventory of preprinted labels based on the current label requirements.

Notwithstanding the analysis above, APHIS invites public comment on the proposed rule's expected economic impact, including any comment on the impact for small entities.

Executive Order 12372

This program/activity is listed in the category of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (*See* 7 CFR part 3015, subpart V.)

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. This rule would not preempt any State or local laws, regulations, or policies where they are

necessary to address local disease conditions or eradication programs. However, where safety, efficacy, purity, and potency of biological products are concerned, it is the Agency's intent to occupy the field. This includes, but is not limited to, the regulation of labeling. Under the Act, Congress clearly intended that there be national uniformity in the regulation of these products. There are no administrative proceedings which must be exhausted prior to a judicial challenge to the regulations under this rule.

Paperwork Reduction Act

This proposed rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

List of Subjects

9 CFR Parts 103 and 114

Animal biologics, Reporting and recordkeeping requirements.

9 CFR Part 112

Animal biologics, Exports, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

Accordingly, we propose to amend 9 CFR parts 103, 112, and 114 as follows:

PART 103—EXPERIMENTAL PRODUCTION, DISTRIBUTION, AND EVALUATION OF BIOLOGICAL PRODUCTS PRIOR TO LICENSING

1. The authority citation for part 103 continues to read as follows:

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

2. In § 103.3, paragraph (d) is revised to read as follows:

§ 103.3 Shipment of experimental biological products.

* * * * *

(d) Two copies of labels or label sketches which show the name or identification of the product and bear the statement "Notice! For experimental use only-Not For Sale" or equivalent. Such statement shall appear on final container labels, except that it may appear on the carton in the case of very small final container labels and labeling for diagnostic test kits. The U.S. Veterinary License legend shall not appear on such labels; and

* * * * *

PART 112—PACKAGING AND LABELING

3. The authority citation for part 112 continues to read as follows:

¹ Source: U.S. Census Bureau (2002 Economic Census) and SBA.

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

4. Section 112.2 is amended as follows:

a. By revising paragraphs (a)(1), (a)(2), (a)(3), (a)(4), (a)(5), (a)(7), (a)(10), (d)(3), (e), and (f) to read as set forth below.

b. At the end of paragraphs (a)(6) and (a)(9)(iv), by removing the semicolon and adding a period in its place.

§ 112.2 Final container label, carton label, and enclosure.

(a) * * *

(1) The complete true name of the biological product which name shall be identical with that shown in the product license under which such product is prepared or the permit under which it is imported, shall be prominently lettered and placed giving equal emphasis to each word composing it. Descriptive terms used in the true name on the product license or permit shall also appear. Abbreviations of the descriptive terms may be used on the final container label if complete descriptive terms appear on the carton label and enclosure. The following exceptions are applicable to small final containers, and containers of interchangeable reagents included in diagnostic test kits:

(i) For small final containers, an abbreviated true name of the biological product, which shall be identical with that shown in the product license under which the product is prepared or the permit under which it is imported, may be used: *Provided*, That the complete true name of the product must appear on the carton label and enclosures;

(ii) In addition to the true name of the kit, the functional and/or chemical name of the reagent must appear on labeling for small final containers of reagents included in diagnostic kits: *Provided*, That the true name is not required on labeling for small final containers of interchangeable (non-critical) components of diagnostic kits.

(2) For biological product prepared in the United States or in a foreign country, the name and address of the producer (licensee, or subsidiary) or permittee and of the foreign producer, and an appropriate consumer contact telephone number: *Provided*, That in the case of a biological product exported from the United States in labeled final containers, a consumer contact telephone number is not required.

(3) The United States Veterinary Biologics Establishment License Number (VLN) or the United States Veterinary Biological Product Permit Number (VPN), and the Product Code Number (PCN) assigned by the Department, which shall be shown only

as “VLN/PCN” and “VPN/PCN,” respectively, except that only the VLN or VPN is required on container labels of interchangeable (non-critical) components of diagnostic kits.

(4) Storage temperature recommendation for the biological product stated as 2 to 8 °C or 35 to 46 °F, or both.

(5) Full instructions for the proper use of the product, including indications for use, target species, minimum age of administration, route of administration, vaccination schedule, product license restriction(s) that bear on product use, warnings, cautions, and any other vital information for the product’s use; except that:

(i) In the case of very small final container labels or carton, a statement as to where such information is to be found, such as “See enclosure for complete directions,” “Full directions on carton,” or comparable statement; and,

(ii) The true name or abbreviated true name, and product code number are not required on very small final container labels for interchangeable (non-critical) components of diagnostic kits.

* * * * *

(7) If the product is an injectable biological product, and/or if it contains viable or dangerous organisms or viruses, the following warning statements shall appear on the labeling as applicable:

(i) “Do not mix with other biological products, except as specified on this label.”

(ii) “In the case of accidental human exposure, contact a physician or other health care provider.”

(iii) “Inactivate all unused contents prior to disposal.”

* * * * *

(10) In the case of a product that contains an antibiotic or non-antibiotic preservative that is added during the production process, the statement “Contains [name of preservative] as a preservative” or an equivalent statement must appear on cartons and enclosures, if used. If cartons are not used, such information must appear on the final container label. Labels for diagnostic test kits are exempt from the antibiotic statement, but must specify non-antibiotic preservatives.

* * * * *

(d) * * *

(3) The statement “For use in animals only” may appear on the carton labels and enclosures for a product to indicate that the product is recommended specifically for animals and not for humans.

(e) When label requirements of a foreign country conflict with the

requirements as prescribed in this part, special labels may be approved by APHIS for use on biological products to be exported to such country upon receipt of signed written certification from regulatory officials of the importing country that such labeling has been approved by those officials, provided that the labeling does not contain information which is false or misleading. When laws, regulations, or other requirements of foreign countries require exporters of biological products prepared in a licensed establishment to furnish official certification that such products have been prepared in accordance with the Virus-Serum-Toxin Act and regulations issued pursuant to the Act, such certification may be made by the Animal and Plant Health Inspection Service upon request of the licensee.

(f) Multiple-dose final containers of liquid biological product and carton tray covers showing required labeling information are subject to paragraphs (f)(1) and (f)(2) of this section, respectively.

(1) If a carton label or an enclosure is required to complete the labeling for a multiple-dose final container of liquid biological product, only one final container shall be packaged in each carton: *Provided*, That if the multiple-dose final container is fully labeled without a carton label or enclosure, two or more final containers may be packaged in a single carton which shall be considered a shipping box. Labels or stickers for shipping boxes shall not contain false or misleading information, but need not be submitted to APHIS for approval.

(2) When required labeling information is shown on a carton tray cover, it must be printed on the outside face of such tray cover where it may be read without opening the carton. The inside face of the tray cover may contain information suitable for an enclosure.

* * * * *

5. In § 112.3, paragraph (f)(2) is revised to read as follows:

§ 112.3 Diluent labels.

* * * * *

(f) * * *

(2) The biological product is composed of viable or dangerous organisms or viruses, the notice, “Inactivate all unused contents prior to disposal.”

* * * * *

6. Section 112.5 is amended as follows:

a. By revising paragraphs (c)(2)(ii), (c)(2)(v), (d)(1)(iii), (d)(1)(iv), (d)(4), and (e)(1) to read as set forth below and, at

the end of paragraph (c)(2)(vi), by removing the period and adding a semicolon in its place.

b. By adding new paragraphs (c)(2)(vii) through (c)(2)(x) to read as set forth below.

c. By removing paragraph (e)(2) and redesignating paragraph (e)(3) as paragraph (e)(2).

§ 112.5 Review and approval of labeling.

* * * * *

(c) * * *

(2) * * *

(ii) Changes in the color of label print or background, provided that such a change does not affect the legibility of the label;

* * * * *

(v) Adding, changing, deleting, or repositioning label control numbers, universal product codes, or other inventory control numbers;

* * * * *

(vii) Changing the telephone contact number;

(viii) Adding, changing, or deleting an e-mail and/or Web site address;

(ix) Changing the establishment license or permit number assigned by APHIS, and/or changing the name and/or address of the manufacturer or permittee, provided that such changes are identical to information on the current establishment license or permit; and

(x) Adding or changing the name and/or address of a distributor.

(d) * * *

(1) * * *

(iii) For finished labels, submit two copies of each finished final container label, carton label, and enclosure: *Provided*, That when an enclosure is to be used with more than one product, one extra copy shall be submitted for each additional product. One copy of each finished label will be retained by APHIS. One copy will be stamped and returned to the licensee or permittee. Labels to which exceptions are taken shall be marked as sketches and handled under paragraph (d)(1)(i) of this section.

(iv) For finished master labels, submit for each product two copies each of the enclosure and the labels for the smallest size final container and carton. Labels for larger sizes of containers or cartons of the same product that are identical, except for physical dimensions, need not be submitted. Such labels become eligible for use concurrent with the approval of the appropriate finished master label, provided that the marketing of larger size final containers is approved in the filed Outline of Production, and the appropriate larger

sizes of containers or cartons are identified on the label mounting sheet. When a master label enclosure is to be used with more than one product, one extra copy for each additional product shall be submitted. One copy of each finished master label will be retained by APHIS. One copy will be stamped and returned to the licensee or permittee. Master labels to which exception are taken will be marked as sketches and handled under paragraph (d)(1)(ii) of this section.

* * * * *

(4) To appear on the bottom of each page in the lower left hand corner, if applicable:

(i) The dose size(s) to which the master label applies.

(ii) The APHIS assigned number for the label or sketch to be replaced.

(iii) The APHIS assigned number for the label to be used as a reference for reviewing the submitted label.

(e) * * *

(1) An accurate English translation must accompany each foreign language label submitted for approval. A statement affirming the accuracy of the translation must also be included.

* * * * *

7. In § 112.6, paragraph (a) is revised to read as follows:

§ 112.6 Packaging biological products.

(a) Multiple-dose final containers of a biological product whose final container labeling includes all information required under the regulations may be packaged one or more per carton with a container(s) of the proper volume of diluent, if required, for that dose as specified in the filed Outline of Production: *Provided*, That cartons containing more than one final container of product must comply with the conditions set forth in paragraphs (c)(1) through (c)(4) of this section. Multiple-dose final containers of a product that require a carton or enclosure in order to provide all information required under the regulations shall be packaged in an individual carton with the proper volume of diluent, if required, for that dose as specified in the filed Outline of Production.

* * * * *

8. Section 112.7 is amended as follows:

a. By redesignating paragraphs (a) through (m) as paragraphs (b) through (n), respectively, and by adding new paragraphs (a) and (o) to read as set forth below.

b. By revising newly redesignated paragraphs (f), (j), and (m) to read as set forth below.

c. In newly redesignated paragraph (g), by adding a new paragraph (g)(4) to read as set forth below.

§ 112.7 Special additional requirements.

* * * * *

(a) In the case of biological products recommending annual booster vaccinations, such recommendations must be supported by data acceptable to APHIS. In the absence of data that establishes the need for annual booster vaccinations, labeling must bear the following statement: "The need for annual booster vaccinations has not been established for this product; consultation with a veterinarian is recommended."

* * * * *

(f) Labeling for all products for use in mammals must bear an appropriate statement concerning use in pregnant animals:

(1) For bovine rhinotracheitis vaccine containing modified live virus and bovine virus diarrhea vaccine containing modified live virus, all labeling, except small final container labels, shall bear the following statement: "Do not use in pregnant animals or in calves nursing pregnant animals.": *Provided*, That such vaccine which has been shown to be safe for use in pregnant animals may be exempted from this label requirement by the Administrator. However, if an exemption is granted, the label must include the following statement concerning residual risk: "Fetal health risks associated with the vaccination of pregnant animals with this vaccine cannot be unequivocally determined during clinical trials conducted for licensure. Appropriate strategies to address the risks associated with vaccine use in pregnant animals should be discussed with a veterinarian."

(2) In the case of other modified live and inactivated vaccine, labeling shall bear a statement appropriate to the level of safety that has been demonstrated in pregnant animals, for example, either "Do not use in pregnant animals" or "Unsafe for use in pregnant animals" would be an appropriate statement for products known to be unsafe in pregnant animals. For those products without safety documentation acceptable to APHIS, but not known to be unsafe, labeling shall include the statement "This product has not been evaluated for safety in pregnant animals" or an equivalent statement acceptable to APHIS.

(g) * * *

(4) In the case of biological products recommending annual booster vaccinations, such recommendations must be supported by data acceptable to

APHIS. In the absence of data establishing the need for annual booster vaccinations, labeling must bear the following statement: "The need for annual booster vaccination has not been established for this product; consultation with a veterinarian is recommended."

* * * * *

(j) All but very small final container labels for feline panleukopenia vaccines shall contain the following recommendations for use:

(1) *Killed virus vaccines.* Vaccinate healthy cats with one dose, except that if the animal is less than 12 weeks of age, a second dose should be given at 12 to 16 weeks of age.

(2) *Modified live virus vaccines.* Vaccinate healthy cats with one dose, except that if the animal is less than 12 weeks of age, a second dose should be given at 12 to 16 weeks of age.

* * * * *

(m) All labels for autogenous biologics must specify the name of the microorganism(s) or antigen(s) that they contain, and shall bear the following statement: "Potency and efficacy of autogenous biologics have not been established. This product is prepared for use only by or under the direction of a veterinarian or approved specialist."

* * * * *

(o) All labels for conditionally licensed products shall bear the following statement: "This product license is conditional; efficacy and potency have not been fully demonstrated."

* * * * *

PART 114—PRODUCTION REQUIREMENTS FOR BIOLOGICAL PRODUCTS

9. The authority citation for part 114 continues to read as follows:

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

10. Section 114.11 is revised to read as follows:

§ 114.11 Storage and handling.

Biological products at licensed establishments must be protected at all times against improper storage and handling. Completed product must be kept under refrigeration at 35 to 46 °F (2 to 8 °C), unless the inherent nature of the product makes storage at different temperatures advisable, in which case, the proper storage temperature must be specified in the filed Outline of Production. All biological products to be shipped or delivered must be securely packed.

Done in Washington, DC this 7th day of January 2011.

John Ferrell,

Deputy Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 2011–648 Filed 1–12–11; 8:45 am]

BILLING CODE 3410–34-P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

RIN 3150—A189

[NRC–2011–0002]

List of Approved Spent Fuel Storage Casks: NUHOMS® HD System Revision 1

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or the Commission) is proposing to amend its spent fuel storage cask regulations by revising the Transnuclear, Inc. (TN) NUHOMS® HD System listing within the "List of Approved Spent Fuel Storage Casks" to include Amendment No. 1 to Certificate of Compliance (CoC) Number 1030. Amendment No. 1 would revise the definitions for Damaged Fuel Assembly and Transfer Operations; add definitions for Fuel Class and Reconstituted Fuel Assembly; add Combustion Engineering 16x16 class fuel assemblies as authorized contents; reduce the minimum off-normal ambient temperature from –20 °F to –21 °F; expand the authorized contents of the NUHOMS® HD System to include pressurized water reactor fuel assemblies with control components; reduce the minimum initial enrichment of fuel assemblies from 1.5 weight percent uranium-235 to 0.2 weight percent uranium-235; clarify the requirements of reconstituted fuel assemblies; add requirements to qualify metal matrix composite neutron absorbers with integral aluminum cladding; clarify the requirements for neutron absorber tests; delete use of nitrogen for draining the water from the dry shielded canister (DSC), and allow only helium as a cover gas during DSC cavity water removal operations; and make corresponding changes to the technical specifications (TS).

DATES: Comments on the proposed rule must be received on or before February 14, 2011.

ADDRESSES: Please include Docket ID NRC–2011–0002 in the subject line of your comments. For instructions on

submitting comments and accessing documents related to this action, see Section I, "Submitting Comments and Accessing Information" in the **SUPPLEMENTARY INFORMATION** section of this document. You may submit comments by any one of the following methods.

Federal Rulemaking Web site: Go to <http://www.regulations.gov> and search for documents filed under Docket ID NRC–2011–0002. Address questions about NRC dockets to Carol Gallagher, telephone: 301–492–3668, e-mail: Carol.Gallagher@nrc.gov.

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

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

Hand-deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. Federal workdays (Telephone 301–415–1677).

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

FOR FURTHER INFORMATION CONTACT: Gregory Trussell, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–6445, e-mail: Gregory.Trussell@nrc.gov.

SUPPLEMENTARY INFORMATION:

Submitting Comments and Accessing Information

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

You can access publicly available documents related to this document using the following methods:

NRC's Public Document Room (PDR): The public may examine and have

copied for a fee publicly available documents at the NRC's PDR, Room O-1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

NRC's Agencywide Documents Access and Management System (ADAMS): Publicly available documents created or received at the NRC are available electronically at the NRC's Electronic Reading Room at <http://www.nrc.gov/reading-rm/adams.html>. From this page, the public can gain entry into ADAMS, which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to PDR.Resource@nrc.gov.

Federal Rulemaking Web site: Public comments and supporting materials related to this proposed rule can be found at <http://www.regulations.gov> by searching on Docket ID NRC-2011-0002.

For additional information, see the Direct Final Rule published in the Rules and Regulations section of this **Federal Register**.

Procedural Background

On May 6 and 7, 2010, respectively, a direct final rule (75 FR 24786) and companion proposed rule (75 FR 25120) were published in the **Federal Register** to revise the cask system listing for the TN NUHOMS® HD System by adding Amendment No. 1 to the list of approved spent fuel storage casks in Title 10 of the Code of Federal Regulations (10 CFR) 72.214. After the rules were published, the applicant identified that a certain TS for Boral characterization (TS 4.3.1, "Neutron Absorber Tests") was not written precisely and in a manner that could be readily and demonstrably implemented. On July 16, 2010, the NRC withdrew the direct final rule (75 FR 41369) and the companion proposed rule (75 FR 41404). The applicant submitted revised language for TS 4.3.1 (and Final Safety Analysis Report (FSAR) sections incorporated into the TS by reference) on July 26 and August 24, 2010, which NRC staff reviewed and found to be acceptable. This proposed rule includes the original Amendment No. 1 changes and the revised TS 4.3.1 and FSAR sections incorporated into the TS by reference.

This rule is limited to the changes contained in Amendment No. 1 to CoC No. 1030 and does not include other aspects of the NUHOMS® HD System design. Because NRC considers this action noncontroversial and routine, the

NRC is publishing this proposed rule concurrently as a direct final rule in the Rules and Regulations section of this **Federal Register**. Adequate protection of public health and safety continues to be ensured. The direct final rule will become effective on March 29, 2011. However, if the NRC receives significant adverse comments on the direct final rule by February 14, 2011, then the NRC will publish a document that withdraws the direct final rule. If the direct final rule is withdrawn, the NRC will address the comments received in response to the proposed revisions in a subsequent final rule. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action in the event the direct final rule is withdrawn.

A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when:

(a) The comment causes the NRC staff to reevaluate (or reconsider) its position or conduct additional analysis;

(b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(c) The comment raises a relevant issue that was not previously addressed or considered by the NRC staff.

(2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the NRC staff to make a change (other than editorial) to the rule, CoC, or TS.

For additional procedural information and the regulatory analysis, see the direct final rule published in the Rules and Regulations section of this **Federal Register**.

List of Subjects in 10 CFR Part 72

Administrative practice and procedure, Hazardous waste, Nuclear materials, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements, Security measures, Spent fuel, Whistleblowing.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended;

the Energy Reorganization Act of 1974, as amended; the Nuclear Waste Policy Act of 1982, as amended, and 5 U.S.C. 553; the NRC is proposing to adopt the following amendments to 10 CFR Part 72.

PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL, HIGH-LEVEL RADIOACTIVE WASTE, AND REACTOR-RELATED GREATER THAN CLASS C WASTE

1. The authority citation for Part 72 continues to read as follows:

Authority: Secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2232, 2233, 2234, 2236, 2237, 2238, 2282); sec. 274, Pub. L. 86-373, 73 Stat. 688, as amended (42 U.S.C. 2021); sec. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); Pub. L. 95-601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102-486, sec. 7902, 106 Stat. 3123 (42 U.S.C. 5851); sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332); secs. 131, 132, 133, 135, 137, 141, Pub. L. 97-425, 96 Stat. 2229, 2230, 2232, 2241, sec. 148, Pub. L. 100-203, 101 Stat. 1330-235 (42 U.S.C. 10151, 10152, 10153, 10155, 10157, 10161, 10168); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109-58, 119 Stat. 806-10 (42 U.S.C. 2014, 2021, 2021b, 2111).

Section 72.44(g) also issued under secs. 142(b) and 148(c), (d), Pub. L. 100-203, 101 Stat. 1330-232, 1330-236 (42 U.S.C. 10162(b), 10168(c), (d)). Section 72.46 also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97-425, 96 Stat. 2230 (42 U.S.C. 10154). Section 72.96(d) also issued under sec. 145(g), Pub. L. 100-203, 101 Stat. 1330-235 (42 U.S.C. 10165(g)). Subpart J also issued under secs. 2(2), 2(15), 2(19), 117(a), 141(h), Pub. L. 97-425, 96 Stat. 2202, 2203, 2204, 2222, 2244 (42 U.S.C. 10101, 10137(a), 10161(h)). Subparts K and L are also issued under sec. 133, 98 Stat. 2230 (42 U.S.C. 10153) and sec. 218(a), 96 Stat. 2252 (42 U.S.C. 10198).

2. In § 72.214, Certificate of Compliance 1030 is revised to read as follows:

§ 72.214 List of approved spent fuel storage casks.

* * * * *

Certificate Number: 1030.

Initial Certificate Effective Date: January 10, 2007.

Amendment Number 1 Effective Date: March 29, 2011.

SAR Submitted by: Transnuclear, Inc.
SAR Title: Final Safety Analysis Report for the NUHOMS® HD Horizontal Modular Storage System for Irradiated Nuclear Fuel.

Docket Number: 72–1030.

Certificate Expiration Date: January 10, 2027.

Model Number: NUHOMS® HD–32PTH.

* * * * *

Dated at Rockville, Maryland this 13th day of December 2010.

For the Nuclear Regulatory Commission.

R.W. Borchardt,

Executive Director for Operations.

[FR Doc. 2011–644 Filed 1–12–11; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2010–1310; Directorate Identifier 2010–NM–067–AD]

RIN 2120–AA64

Airworthiness Directives; Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model ERJ 170 and ERJ 190 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 has been reported during operational checks that some failures of the Escape Slide * * * installed on the forward passenger and service door have occurred which prevented the door from opening.

* * * [T]his condition * * * could delay an emergency evacuation and increase the chance of injury to passengers and flight crew * * *.

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 February 28, 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 W12–40, 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 Empresa Brasileira de Aeronautica S.A. (EMBRAER), Technical Publications Section (PC 060), Av. Brigadeiro Faria Lima, 2170–Putim–12227–901 São Jose dos Campos–SP–BRASIL; telephone +55 12 3927–5852 or +55 12 3309–0732; fax +55 12 3927–7546; e-mail distrib@embraer.com.br; Internet: <http://www.flyembraer.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: Kenny Kaulia, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–2848; 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–2010–1310; Directorate Identifier 2010–NM–067–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 Agência Nacional de Aviação Civil (ANAC), which is the aviation authority for Brazil, has issued Brazilian Airworthiness Directive 2009–11–01, dated November 30, 2009, applicable to Model ERJ 170 airplanes; and Airworthiness Directive 2009–08–02, dated August 18, 2009, applicable to Model ERJ 190 airplanes; (referred to after this as “the MCAI”), to correct an unsafe condition for the specified products.

MCAI 2009–11–01 states:

It has been reported during operational checks that some failures of the Escape Slide P/N [part number] 4A4030–2 and P/N 4A4030–4 installed on the forward passenger and service door have occurred which prevented the door from opening.

Since this condition * * * could delay an emergency evacuation and increase the chance of injury to passengers and flight crew, a corrective action is required.

MCAI 2009–08–02 states:

It has been reported during operational checks some failures in the deployment of the Escape Slide P/N 104003–1 installed in the forward passenger and service door, preventing the door opening.

Since this condition * * * could impede an emergency evacuation and increase the chance of injury to passengers and flight crew, a corrective action is required.

The required actions include modifying the escape slides of the forward passenger and service doors, and doing boroscope inspections for damage of the aspirator body and inlet cross valve. Corrective actions include replacing the aspirator body. You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Goodrich Interiors has issued Service Bulletin 4A4030–25A379, dated August 10, 2009, for Model ERJ 170 airplanes; and Service Bulletin 104003–25A380, Revision 2, dated July 7, 2009, for Model ERJ 190 airplanes. 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 236 products of U.S. registry. We also estimate that it would take about 12 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 \$0 per product. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these costs. 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 \$240,720, or \$1,020 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:

Empresa Brasileira de Aeronautica S.A. (EMBRAER): Docket No. FAA-2010-1310; Directorate Identifier 2010-NM-067-AD.

Comments Due Date

- (a) We must receive comments by February 28, 2011.

Affected ADs

- (b) None.

Applicability

(c) This AD applies to Empresa Brasileira de Aeronautica S.A. (EMBRAER) airplanes as identified in paragraphs (c)(1) and (c)(2) of this AD, certificated in any category.

(1) Model ERJ 170-100 LR, -100 STD, -100 SE, and -100 SU airplanes; and Model ERJ 170-200 LR, -200 SU, and -200 STD airplanes; equipped with Goodrich escapes slide having part number (P/N) 4A4030-2 or P/N 4A4030-4.

(2) Model ERJ 190-100 STD, -100 LR, -100 ECJ, and -100 IGW airplanes; and Model ERJ 190-200 STD, -200 LR, and -200 IGW airplanes; equipped with Goodrich escapes slide having P/N 104003-1.

Subject

(d) Air Transport Association (ATA) of America Code 25: Equipment/furnishings.

Reason

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

It has been reported during operational checks that some failures of the Escape Slide * * * installed on the forward passenger and service door have occurred which prevented the door from opening.

* * * [T]his condition * * * could delay an emergency evacuation and increase the chance of injury to passengers and flight crew * * *.

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 18 months after the effective date of this AD, modify the forward escape slide and do a boroscope inspection of the aspirator body and inlet cross valve, in accordance with the Accomplishment Instructions of the Goodrich service bulletin identified in paragraph (g)(1) or (g)(2) of this AD, as applicable. Do all applicable corrective actions before further flight.

(1) For any forward door escape slide having P/N 4A4030-2 or P/N 4A4030-4: Goodrich Service Bulletin 4A4030-25A379, dated August 10, 2009.

(2) For any forward door escape slide having P/N 104003-1: Goodrich Service Bulletin 104003-25A380, Revision 2, dated July 7, 2009.

Credit for Actions Accomplished in Accordance With Previous Service Information

(h) Actions accomplished before the effective date of this AD in accordance with Goodrich Service Bulletin 104003-25A380, Revision 1, dated April 15, 2009, are considered acceptable for compliance with the corresponding action specified in this AD.

Parts Installation

(i) After 6 months from the effective date of this AD, no airplane may operate with the forward door escape slide having P/N 4A4030-2 or P/N 4A4030-4 (for Model ERJ 170 airplanes), or P/N 104003-1 (for Model

ERJ 190 airplanes), on which 18 months or more has elapsed from the slide date of manufacture (for slides that have not been repacked) or the date of last slide repack (for slides that have been repacked).

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. Send information to ATTN: Kenny Kaulia, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057-3356; telephone (425) 227-2848; fax (425) 227-1149. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

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

(3) *Reporting Requirements:* A Federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120-0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave., SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES-200.

Related Information

(k) Refer to MCAI Brazilian Airworthiness Directive 2009-11-01, dated November 30, 2009; MCAI Brazilian Airworthiness Directive 2009-08-02, dated August 18, 2009; Goodrich Service Bulletin 4A4030-25A379, dated August 10, 2009; and Goodrich Service Bulletin 104003-25A380, Revision 2, dated July 7, 2009; for related information.

Issued in Renton, Washington, on January 6, 2011.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011-584 Filed 1-12-11; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2010-1308; Directorate Identifier 2009-NM-069-AD]

RIN 2120-AA64

Airworthiness Directives; BAE SYSTEMS (OPERATIONS) LIMITED Model BAe 146 Airplanes, and Model Avro 146-RJ 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:

During the period 2001/2002, skin cracking was found adjacent to the butt joint forward of frame 19 * * *. The cracks emanated from chemically-etched pockets on the internal surface of the skin. * * * [C]racking in multiple adjacent bays * * * could compromise the structural integrity of the fuselage in the event that the multiple cracks joined into a single crack. * * *

During 2008, a further report was received at BAE Systems of a 13.78 inch crack in an AVRO 146-RJ that occurred 514 flight cycles (FC) short of the next 4 000-FC repetitive inspection interval. * * *

* * * * *

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 February 28, 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 W12-40, 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 BAE SYSTEMS (OPERATIONS) LIMITED, Customer Information Department, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, United Kingdom; telephone +44 1292 675207; fax +44 1292 675704; e-mail RApublications@baesystems.com; Internet <http://www.baesystems.com/Businesses/RegionalAircraft/index.htm>. 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: Todd Thompson, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057-3356; telephone (425) 227-1175; 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-2010-1308; Directorate Identifier 2009-NM-069-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 June 14, 2005, we issued AD 2005–13–19, Amendment 39–14156 (70 FR 37022, June 28, 2005). That AD required actions intended to address an unsafe condition on the products listed above.

Since we issued AD 2005–13–19, a further report of cracking has been received at an interval shorter than the repetitive inspection interval required by AD 2005–13–19. The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2009–0070R1, dated July 2, 2010 (referred to after this as “the MCAI”), to correct an unsafe condition for the specified products. The MCAI states:

During the period 2001/2002, skin cracking was found adjacent to the butt joint forward of frame 19 when unrelated in-service maintenance inspections of the forward fuselage structure were being completed. The cracks emanated from chemically-etched pockets on the internal surface of the skin. The then current MRB [maintenance review board] inspection requirements were not adequate to address cracking in multiple adjacent bays, which could compromise the structural integrity of the fuselage in the event that the multiple cracks joined into a single crack. Investigations resulted in the publication of BAE Systems (Operations) Limited Inspection Service Bulletin (ISB).53–167 in June [27.] 2003, which was made mandatory by CAA UK AD 007–06–2003. The ISB was subsequently re-issued at Revision 1 during 2004 [May 18, 2004] to clarify the inspection requirements and provide an improved inspection procedure. CAA UK AD G–2005–0002 [which corresponds to FAA AD 2005–13–19] (EASA approval number 2005–313) was issued to require accomplishment of the improved inspections.

During 2008, a further report was received at BAE Systems of a 13.78 inch crack in an AVRO 146–R] that occurred 514 flight cycles (FC) short of the next 4 000–FC repetitive inspection interval. A reassessment of ISB instructions and its supporting data concluded that these original inspection periods were too long, and the method for defining the areas requiring inspection could be open to misinterpretation. In response, BAE Systems has updated the ISB to Revision 2 [dated December 12, 2008] to reduce the inspection intervals, introducing different inspection intervals associated with specific areas of the forward fuselage skins and instructions to inspect additional areas of the forward fuselage skin.

For the reasons described above, this AD retains the requirements of CAA UK AD G–2005–0002, which is superseded, and requires the implementation of revised

repetitive inspections, including inspection of additional areas of the forward fuselage skin panels for cracking and follow-on repair action(s), depending on findings.

This AD is [further] revised to acknowledge the issuance of BAE Systems (Operations) Limited ISB.53–167 Revision 3, [dated June 17, 2009] which allows the repetitive inspection intervals to be extended and introduces grace periods to carry out the initial inspections. In addition, this AD at Revision 1 [EASA AD 2009–0070R1, dated July 2, 2010] acknowledges the issuance of BAE Systems ISB.53–167 Revision 4 [dated June 10, 2010] which corrects the grace period for the initial inspections on BAe 146 aeroplane types.

You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

BAE SYSTEMS (OPERATIONS) LIMITED has issued Inspection Service Bulletin ISB.53–167, Revision 4, dated June 10, 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 1 product of U.S. registry.

The actions that are required by AD 2005–13–19 and retained in this proposed AD take about 40 work-hours per product, at an average labor rate of \$85 per work hour. Based on these figures, the estimated cost of the currently required actions is \$3,400 per product.

We estimate that it would take about 32 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 \$2,720, or \$2,720 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 39–14156 (70 FR 37022, June 28, 2005) and adding the following new AD:

BAE SYSTEMS (OPERATIONS) LIMITED:

Docket No. FAA–2010–1308; Directorate Identifier 2009–NM–069–AD.

Comments Due Date

(a) We must receive comments by February 28, 2011.

Affected ADs

(b) This AD supersedes AD 2005–13–19, Amendment 39–14156.

Applicability

(c) This AD applies to all BAE SYSTEMS (OPERATIONS) LIMITED Model BAe 146–100A, –200A, and –300A airplanes; and Model Avro 146–RJ70A, 146–RJ85A, and 146–RJ100A airplanes; certificated in any category.

Subject

(d) Air Transport Association (ATA) of America Code 53: Fuselage.

Reason

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

During the period 2001/2002, skin cracking was found adjacent to the butt joint forward of frame 19 * * *. The cracks emanated from chemically-etched pockets on the internal surface of the skin. * * * [C]racking in multiple adjacent bays * * * could compromise the structural integrity of the fuselage in the event that the multiple cracks joined into a single crack. * * *

During 2008, a further report was received at BAE Systems of a 13.78 inch crack in an AVRO 146–RJ that occurred 514 flight cycles (FC) short of the next 4 000–FC repetitive inspection interval. * * *

* * * * *

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 2005–13–19:

Inspections and Repair

(g) Within the applicable compliance time specified in paragraph (g)(1) or (g)(2) of this AD, perform an external eddy current inspection of the forward fuselage skin to detect cracking, in accordance with the Accomplishment Instructions of BAE Systems (Operations) Limited Modification Service Bulletin ISB.53–167, including Appendix 2, Revision 1, dated May 18, 2004. Doing the inspection required by paragraph (j) of this AD terminates the requirements of this paragraph of this AD.

(1) For Model BAe 146 series airplanes: Inspect before the accumulation of 16,000 total landings, or within 4,000 landings after the August 2, 2005 (the effective date of AD 2005–13–19), whichever is later.

(i) For areas where no crack is found, repeat the inspection at intervals not to exceed 8,000 landings.

(ii) For areas where any crack is found, before further flight, perform repairs in accordance with a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, the Civil Aviation Authority (CAA) (or its delegated agent), or EASA (or its delegated agent). No further inspection of any repaired area is required by paragraph (g) of this AD.

(2) For Model Avro 146–RJ series airplanes: Inspect before the accumulation of 10,000 total landings, or within 2,000 landings after August 2, 2005, whichever is later.

(i) For areas where no crack is found, repeat the inspection at intervals not to exceed 4,000 landings.

(ii) For areas where any crack is found, before further flight, perform repairs in accordance with a method approved by the Manager, International Branch, ANM–116, the CAA (or its delegated agent), or EASA (or its delegated agent). No further inspection of any repaired area is required by paragraph (g) of this AD.

Inspections Accomplished According to Previous Issue of Service Bulletin

(h) Inspections accomplished before August 2, 2005, in accordance with BAE Systems (Operations) Limited Inspection Service Bulletin ISB.53–167, including Appendices 2 and 3, all dated June 27, 2003, are considered acceptable for compliance with the corresponding action specified in paragraph (g) of this AD.

No Reporting Requirement for AD 2005–13–19

(i) Although BAE Systems (Operations) Limited Modification Service Bulletin ISB.53–167, including Appendix 2, Revision 1, dated May 18, 2004, specifies to submit Appendix 1 of that service bulletin with certain information to the manufacturer, this AD does not include that requirement.

New Requirements of this AD:

Inspection and Repair—Expanded Area of Forward Fuselage Skin and Reduced Inspection Intervals

(j) For Model BAe 146 airplanes: At the later of the times specified in paragraphs (j)(1), (j)(2), and (j)(3) of this AD, do an external eddy current inspection of the forward fuselage skin to detect cracking, in

accordance with the Accomplishment Instructions of BAE Systems (Operations) Limited Inspection Service Bulletin ISB.53–167, including Appendix 2, Revision 4, dated June 10, 2010. Repeat the inspection thereafter at intervals not to exceed 3,600 flight cycles for areas specified in Drawings 2, 3, 4, 5, and 7 of BAE Systems (Operations) Limited Inspection Service Bulletin ISB.53–167, including Appendix 2, Revision 4, dated June 10, 2010, and at intervals not to exceed 4,600 flight cycles for areas specified in Drawings 1, 6, 8, and 9 of BAE Systems (Operations) Limited Inspection Service Bulletin ISB.53–167, including Appendix 2, Revision 4, dated June 10, 2010. Doing the inspection required by this paragraph terminates the requirements of paragraph (g) of this AD for that airplane.

(1) Before the accumulation of 16,000 total flight cycles.

(2) Within 2,000 flight cycles after the effective date of this AD.

(3) Within the applicable times specified in paragraphs (j)(3)(i) and (j)(3)(ii) of this AD.

(i) For areas specified in Drawings 2, 3, 4, 5, and 7 of BAE Systems (Operations) Limited Inspection Service Bulletin ISB.53–167, including Appendix 2, Revision 4, dated June 10, 2010: Within 3,600 flight cycles after the last inspection done in accordance with paragraph (g) of this AD.

(ii) For areas specified in Drawings 1, 6, 8, and 9 of BAE Systems (Operations) Limited Inspection Service Bulletin ISB.53–167, including Appendix 2, Revision 4, dated June 10, 2010: Within 4,600 flight cycles after the last inspection done in accordance with paragraph (g) of this AD.

(k) For Model Avro 146–RJ airplanes: At the later of the times specified in paragraph (k)(1), (k)(2), and (k)(3) of this AD, do an external eddy current inspection of the forward fuselage skin to detect cracking, in accordance with the Accomplishment Instructions of BAE Systems (Operations) Limited Inspection Service Bulletin ISB.53–167, including Appendix 2, Revision 4, dated June 10, 2010. Repeat the inspection thereafter at intervals not to exceed 2,400 flight cycles for areas specified in Drawings 2, 3, 4, 5, and 7 of BAE Systems (Operations) Limited Inspection Service Bulletin ISB.53–167, including Appendix 2, Revision 4, dated June 10, 2010, and 3,000 flight cycles for areas specified in Drawings 1, 6, 8, and 9 of BAE Systems (Operations) Limited Inspection Service Bulletin ISB.53–167, including Appendix 2, Revision 4, dated June 10, 2010. Doing the inspection required by this paragraph terminates the requirements of paragraph (g) of this AD for that airplane.

(1) Before the accumulation of 10,000 total flight cycles.

(2) Within 1,000 flight cycles after the effective date of this AD.

(3) Within the applicable times specified in paragraphs (k)(3)(i) and (k)(3)(ii) of this AD.

(i) For areas specified in Drawings 2, 3, 4, 5, and 7 of BAE Systems (Operations) Limited Inspection Service Bulletin ISB.53–167, including Appendix 2, Revision 4, dated June 10, 2010: Within 3,600 flight cycles after the last inspection done in accordance with paragraph (g) of this AD.

(ii) For areas specified in Drawings 1, 6, 8, and 9 of BAE Systems (Operations) Limited

Inspection Service Bulletin ISB.53–167, including Appendix 2, Revision 4, dated June 10, 2010; Within 4,600 flight cycles after the last inspection done in accordance with paragraph (g) of this AD.

(l) If any cracking is found during any inspection required by paragraph (j) or (k) of this AD, before further flight, accomplish the repair in accordance with a method approved by the FAA or EASA (or its delegated agent). Repair of an airplane in accordance with the requirements of this paragraph of this AD does not constitute terminating action for the inspection requirements of this AD.

Credit for Actions Accomplished in Accordance With Previous Service Information

(m) Inspections done before the effective date of this AD in accordance with BAE Systems (Operations) Limited Inspection Service Bulletin ISB.53–167, including Appendix 2, Revision 2, dated November 17, 2008; or Revision 3, dated June 17, 2009; are acceptable for compliance with the corresponding requirements of paragraphs (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, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Todd Thompson, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1175; fax (425) 227–1149. Before using any approved AMOC on any airplane to which the AMOC applies, notify your principal maintenance inspector (PMI) or principal avionics inspector (PAI), as appropriate, or lacking a principal inspector, your local Flight Standards 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.

(3) *Reporting Requirements:* A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to

be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave., SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

Related Information

(o) Refer to MCAI EASA Airworthiness Directive 2009–0070R1, dated July 2, 2010; and BAE Systems (Operations) Limited Modification Service Bulletin ISB.53–167, including Appendix 2, Revision 1, dated May 18, 2004; and BAE Systems (Operations) Limited Inspection Service Bulletin ISB.53–167, including Appendix 2, Revision 4, dated June 10, 2010; for related information.

Issued in Renton, Washington, on January 5, 2011.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–585 Filed 1–12–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2010–1309; Directorate Identifier 2010–NM–060–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A330–300, A340–200, and A340–300 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 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:

Surface defects were visually detected on the rudder of one Airbus A319 and one A321 in-service aeroplane. Investigation has determined that the defects reported on both rudders corresponded to areas that had been reworked in production. The investigation confirmed that the defects were the result of de-bonding between the skin and honeycomb core. Such reworks were also performed on some rudders fitted on A330–300 and A340–200/–300 aeroplanes.

An extended de-bonding, if not detected and corrected, may degrade the structural

integrity of the rudder. The loss of the rudder leads to degradation of the handling qualities and reduces the controllability 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 February 28, 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 W12–40, 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—Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone + 33 5 61 93 36 96; fax + 33 5 61 93 45 80, e-mail airworthiness.A330–A340@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: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–1138; 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–2010–1309; Directorate Identifier 2010–NM–060–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 aviation authority for the Member States of the European Community, has issued EASA Airworthiness Directive 2010–0021, dated February 9, 2010 (referred to after this as “the MCAI”), to correct an unsafe condition for the specified products. The MCAI states:

Surface defects were visually detected on the rudder of one Airbus A319 and one A321 in-service aeroplane. Investigation has determined that the defects reported on both rudders corresponded to areas that had been reworked in production. The investigation confirmed that the defects were the result of de-bonding between the skin and honeycomb core. Such reworks were also performed on some rudders fitted on A330–300 and A340–200/–300 aeroplanes.

An extended de-bonding, if not detected and corrected, may degrade the structural integrity of the rudder. The loss of the rudder leads to degradation of the handling qualities and reduces the controllability of the aeroplane.

EASA AD 2009–0156 required inspections of specific areas and, depending on findings, the application of corrective actions for those rudders where production reworks have been identified.

This AD retains the requirements of EASA AD 2009–0156, which is superseded, and in addition requires for the vacuum loss hole restoration:

- a local ultrasonic inspection for reinforced area instead of the local thermography inspection, which is maintained for non-reinforced areas, and
- an additional work for aeroplanes on which this thermography inspection has been performed in the reinforced area.

The inspections include vacuum loss inspections and repetitive elasticity laminate checker inspections for defects including de-bonding between the skin and honeycomb core of the rudder, and

ultrasonic inspections for defects on rudders on which temporary restoration with resin or permanent vacuum loss hole restoration has been performed. The corrective action is repair, if necessary. You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Airbus has issued All Operators Telexes (AOTs) A330–55A3040 and A340–55A4036, both Revision 02, both dated September 30, 2009. 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

Currently, there are no affected airplanes on the U.S. Register. However, if an affected airplane is imported and placed on the U.S. Register in the future, the required actions would take about 21 work hours, at an average labor rate of \$85 per work hour. Based on these figures, we estimate the cost of this AD to be \$1,785 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 adding the following new AD:

Airbus: Docket No. FAA-2010-1309; Directorate Identifier 2010-NM-060-AD.

Comments Due Date

(a) We must receive comments by February 28, 2011.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Airbus Model A330-301, -302, -303, -321, -322, -323, -341, -342, and -343 airplanes, Model A340-211, -212, and -213 airplanes; and Model A340-311, -312, and -313 airplanes; all manufacturer serial numbers; certificated in any category; equipped with carbon fiber reinforced plastic rudders having part numbers and serial numbers listed in Table 1 of this AD.

TABLE 1—AFFECTED RUDDERS

Rudder part number	Rudder serial number
F554-70000-000-00	TS-2013
F554-70000-000-00	TS-2015
F554-70000-000-00	TS-2016
F554-70000-000-00	TS-2017
F554-70000-000-00	TS-2018
F554-70000-000-00	TS-2020
F554-70000-000-00	TS-2021
F554-70000-000-00	TS-2024
F554-70000-000-00	TS-2026
F554-70000-000-00	TS-2035
F554-70000-000-00	TS-2036
F554-70000-000-00	TS-2040
F554-70000-000-00	TS-2042
F554-70000-000-00	TS-2055
F554-70000-000-00	TS-2056
F554-70000-000-00	TS-2058
F554-70000-000-00	TS-2059
F554-70000-000-00	TS-2061
F554-70000-000-00	TS-2062
F554-70000-000-00	TS-2063
F554-70000-000-00	TS-2065
F554-70000-002-00	TS-2074
F554-71000-000-00	TS-3003
F554-71000-000-00	TS-3004
F554-71000-000-00	TS-3005
F554-71000-000-00	TS-3006
F554-71000-000-00	TS-3007
F554-71000-000-00	TS-3008
F554-71000-000-00	TS-3011
F554-71000-000-00	TS-3015
F554-71000-000-00	TS-3033
F554-71000-000-00	TS-3061
F554-71000-000-00	TS-3064
F554-71000-000-00	TS-3066
F554-71000-000-00	TS-3071
F554-71000-000-00	TS-3072
F554-71000-000-00	TS-3075
F554-71000-000-00	TS-3079
F554-71000-000-00	TS-3084
F554-71000-000-00	TS-3087
F554-70005-000-00	TS-3100
F554-70005-000-00	TS-3106
F554-70005-000-00	TS-3107
F554-70005-000-00	TS-3119
F554-70005-000-00	TS-3124

Subject

(d) Air Transport Association (ATA) of America Code 55: Stabilizers.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states: Surface defects were visually detected on the rudder of one Airbus A319 and one A321 in-service aeroplane. Investigation has determined that the defects reported on both rudders corresponded to areas that had been reworked in production. The investigation confirmed that the defects were the result of de-bonding between the skin and honeycomb core. Such reworks were also performed on some rudders fitted on A330-300 and A340-200/-300 aeroplanes.

An extended de-bonding, if not detected and corrected, may degrade the structural integrity of the rudder. The loss of the rudder leads to degradation of the handling qualities and reduces the controllability 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) Do the actions required by paragraphs (g)(1) through (g)(8) of this AD, in accordance with the Instructions of Airbus All Operators Telex (AOT) A330-55A3040 or A340-55A4036, both Revision 02, both dated September 30, 2009, as applicable.

(1) In the reinforced location of the rudder: Within 1,800 flight hours after the rudder has accumulated 13,000 total flight cycles since first installation, or within 1,800 flight hours after the effective date of this AD, whichever is later, do a vacuum loss inspection to detect defects, including de-bonding between the skin and honeycomb core of the rudder.

(2) In the trailing edge location of the rudder: Within 21 months after the rudder has accumulated 13,000 total flight cycles since first installation, or within 21 months after the effective date of this AD, whichever is later, do an elasticity laminate checker inspection to detect defects, including de-bonding between the skin and honeycomb core of the rudder. If no defects are found, repeat the inspection two times at intervals not to exceed 4,500 flight cycles, but not fewer than 4,000 flight cycles from the most recent inspection.

(3) In locations other than those identified in paragraphs (g)(1) and (g)(2) of this AD (e.g., lower rib, upper edge, leading edge, and other locations): Within 1,800 flight hours after the rudder has accumulated 13,000 total flight cycles since first installation, or within 1,800 flight hours after the effective date of this AD, whichever is later, do an elasticity laminate checker inspection to detect defects, including de-bonding between the skin and honeycomb core of the rudder. Repeat the inspection thereafter at intervals not to exceed 1,800 flight hours.

(4) If no defects are found during any inspection required by paragraph (g)(3) of this AD: Within 21 months after the rudder

has accumulated 13,000 total flight cycles since first installation, or within 21 months after the effective date of this AD, whichever is later, do a vacuum loss inspection on the other locations (e.g., lower rib, upper edge, leading edge, and other locations) to detect defects, including de-bonding between the skin and honeycomb core of the rudder.

(5) Accomplishment of the inspection required by paragraph (g)(4) of this AD terminates the initial and repetitive inspections required by paragraph (g)(3) of this AD.

(6) If any defect is found during any inspection required by this AD, before further flight, repair using a method approved by either the Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency Airworthiness (EASA) (or its delegated agent).

(7) If no defects are found during any inspection required by paragraphs (g)(1) and (g)(4) of this AD, before further flight, restore the vacuum loss holes by doing a temporary restoration with self-adhesive patches, a temporary restoration with resin, or a permanent restoration. Do the applicable actions specified in paragraph (g)(7)(i) or (g)(7)(ii) of this AD.

(i) For airplanes on which a temporary restoration with patch is done: Within 900 flight hours after the restoration, do a detailed inspection for defects of the restored area and repeat the inspection thereafter at intervals not to exceed 900 flight hours until the permanent restoration is done. Do the permanent restoration within 21 months after the temporary restoration.

(ii) For airplanes on which a temporary restoration with resin is done: Within 21 months after doing the temporary restoration, do the permanent restoration.

(8) If any defect is found during any initial inspection required by paragraphs (g)(1), (g)(3), and (g)(4) of this AD, at the applicable time in paragraph (g)(8)(i) or (g)(8)(ii) of this AD: Report the inspection results to Airbus SAS, SEER1/SEER2/SEER3, Customer Services, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; fax +33 (0) 5 61 93 28 73; or e-mail to region1.StructureRepairSupport@airbus.com, region2.StructureRepairSupport@airbus.com, or region3.StructureRepairSupport@airbus.com.

(i) Inspections done before the effective date of this AD: Within 30 days after the effective date of this AD.

(ii) Inspections done on or after the effective date of this AD: Within 30 days after accomplishment of the inspection.

Credit for Actions Accomplished in Accordance With Previous Service Information

(h) Actions accomplished before the effective date of this AD in accordance with the service information identified in Table 2 of this AD, are considered acceptable for compliance with the corresponding actions specified in paragraphs (g)(1) through (g)(5) and paragraph (g)(7) of this AD for only the areas inspected. For all areas, the repetitive inspections required by this AD remain applicable.

TABLE 2—CREDIT SERVICE INFORMATION

Document	Revision	Date
Airbus AOT A330–55A3040	Original	May 27, 2009.
Airbus AOT A330–55A3040	01	July 8, 2009.
Airbus AOT A340–55A4036	Original	May 27, 2009.
Airbus AOT A340–55A4036	01	July 8, 2009.

(i) For rudders on which temporary vacuum loss hole restoration with resin or permanent vacuum loss hole restoration has been done, as required by paragraph (g)(7) of this AD, in accordance with the applicable AOT in Table 2 of this AD before the effective date of this AD: Within 21 months after the restoration date, or within 3 months after the effective date of this AD, whichever occurs later, do an ultrasonic inspection for defects, including debonding of the reinforced area, in accordance with the Accomplishment Instructions of Airbus AOT A330–55A3040 or A340–55A4036, both Revision 02, both dated September 30, 2009, as applicable. If any defect is found, before further flight, repair using a method approved by either the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the EASA (or its delegated agent).

(j) As of the effective date of this AD, no person may install any rudder identified in Table 1 of this AD on any airplane, unless the rudder has been inspected and all applicable corrective actions have been done in accordance with paragraph (g) or (i) of this AD, as applicable.

FAA AD Differences

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

Other FAA AD Provisions

(k) 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. Send information to ATTN: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1138; fax (425) 227–1149. Before using any approved AMOC on any airplane to which the AMOC applies, notify your principal maintenance inspector (PMI) or principal avionics inspector (PAI), as appropriate, or lacking a principal inspector, your local Flight Standards 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.

(3) Reporting Requirements: A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave., SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

Related Information

(l) Refer to MCAI EASA Airworthiness Directive 2010–0021, dated February 9, 2010; and Airbus AOTs A330–55A3040 and A340–55A4036, both Revision 02, both dated September 30, 2009; for related information.

Issued in Renton, Washington, on January 5, 2011.

Ali Bahrani,

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

[FR Doc. 2011–586 Filed 1–12–11; 8:45 am]

BILLING CODE 4910–13–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 240 and 249

[Release No. 34–63347; File No. S7–35–10]

RIN 3235–AK79

Security-Based Swap Data Repository Registration, Duties, and Core Principles; Correction

Correction

In proposed rule document C1–2010–29719 beginning on page 79320 in the issue of December 20, 2010, make the following correction:

On page 79320, in the second column, in instruction 5, footnote 165 is corrected to read as follows:

¹⁶⁵ See Public Law 111–203 (adding Exchange Act Section 13(n)(5)(D)(i)).

[FR Doc. C2–2010–29719 Filed 1–12–11; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–345C]

Schedules of Controlled Substances: Temporary Placement of Five Synthetic Cannabinoids Into Schedule I; Correction

AGENCY: Drug Enforcement Administration (DEA), U.S. Department of Justice.

ACTION: Notice of Intent; correction.

SUMMARY: On November 24, 2010, the Drug Enforcement Administration (DEA) published a Notice of Intent announcing its intention to temporarily place five synthetic cannabinoids into Schedule I of the Controlled Substances Act. This notice corrects two administrative errors made in that document.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152, telephone (202) 307–7183, fax (202) 353–1263, or e-mail ode@dea.usdoj.gov.

SUPPLEMENTARY INFORMATION: In a November 24, 2010, Notice of Intent published in the *Federal Register* (75 FR 71635), DEA announced its intention to temporarily place five synthetic cannabinoids into schedule I of the Controlled Substances Act (CSA) pursuant to 21 U.S.C. 811(h). Due to an administrative error, DEA included in that notice a paragraph addressing the Regulatory Flexibility Act (RFA) in the “Regulatory Certifications” section of that document. The provisions of the RFA have no application to temporary scheduling orders issued under 21 U.S.C. 811(h) or to notices of intention to issue such orders. Accordingly, DEA certification under the RFA is not

legally required for this temporary scheduling order. Therefore, I hereby order that this paragraph (the first full paragraph in the right column on page 71637), as well as the "Regulatory Flexibility Act" heading that precedes it, be stricken.

DEA also inadvertently included in its Notice of Intent a certification relating to the Congressional Review Act. The Congressional Review Act only applies to "final" rules. Accordingly, inclusion of the paragraph relating to the Congressional Review Act in the Notice of Intent was premature. Therefore, I hereby order that this paragraph (the fifth paragraph in the right column on page 71637 and continued on the top of page 71638), as well as the "Congressional Review Act" heading that precedes it, also be stricken.

Dated: January 7, 2011.

Michele M. Leonhart,
Administrator.

[FR Doc. 2011-683 Filed 1-10-11; 4:15 pm]

BILLING CODE 4410-09-P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DoD-2010-HA-0113; RIN 0720-AB46]

TRICARE; Changes Included in the National Defense Authorization Act for Fiscal Year 2010; Enhancement of Transitional Dental Care for Members of the Reserve Component on Active Duty for More Than 30 Days in Support of a Contingency Operation

AGENCY: Office of the Secretary, DoD.

ACTION: Proposed rule.

SUMMARY: The Department is publishing this proposed rule to implement section 703 of the National Defense Authorization Act for Fiscal Year 2010 (NDAA for FY10). Specifically, that legislation amends the transitional health care dental benefits for Reserve Component members on active duty for more than 30 days in support of a contingency operation. The legislation entitles these Reserve Component members to dental care in the same manner as a member of the uniformed services on active duty for more than 30 days, thus providing care to the Reserve member in both military dental treatment facilities and authorized private sector dental care. This proposed rule does not eliminate any medical or dental care that is currently covered as transitional health care for the member. However the member's

dependents are not entitled to this enhanced benefit.

At present, the transitional health care dental benefits for Reserve Component members includes space available care in military dental treatment facilities and eligibility for the TRICARE Dental Program (TDP). The implementation of section 703 of NDAA for FY10 will enhance the dental benefit to include space required care in military dental treatment facilities; military dental treatment facility referred care to the private sector; and authorized remote dental care in the private sector during the 180 day transitional health care period. Both dental treatment facility referred care and remote care will be administered by TRICARE's Active Duty Dental Program (ADDP). TDP eligibility will begin after the transitional health care period ends.

Reserve Component family members are also eligible for the TRICARE Dental Program (TDP). These family members pay 100% of the premiums while their sponsor is in Reserve status. If their sponsor is activated for more than 30 days, the TDP enrolled Reserve Component family members obtain the same benefits as any other TDP enrolled active duty family members with the Government subsidizing 60 percent of the premium cost for enrolled active duty family members. This change in status and subsidy occurs automatically. Upon the sponsor's deactivation, the family members automatically revert to Reserve Component family member TDP status and pay 100% of the TDP premium cost. With the proposed rule, there is no change to status or eligibility for family members.

DATES: Written comments received at the address indicated below by March 14, 2011 will be accepted.

ADDRESSES: You may submit comments, identified by docket number and/or RIN number and title, by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Room 3C843, Washington, DC 20301-1160.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at <http://regulations.gov> as they are received without change, including any

personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: CAPT Robert H. Mitton, Office of the Assistant Secretary of Defense (Health Affairs), TRICARE Management Activity, telephone (703) 681-0039.

SUPPLEMENTARY INFORMATION:

I. Background

Currently, Reserve Component members who separate from active duty after serving for more than 30 days in support of a contingency operation are entitled to dental care under the transitional assistance medical program in the same manner as a dependent. This consists of only space-available dental care in a military dental treatment facility and is very limited.

This proposed rule amends the transitional health care dental benefit for Reserve Component members who were on active duty for more than 30 days in support of a contingency operation by providing those members' dental care the same as that for a member of the uniformed services on active duty for more than 30 days. This enhanced benefit does not apply to members' dependents.

As mentioned, the transitional health care dental benefits for Reserve Component members include space available care in military dental treatment facilities. Additionally, Reserve Component members are eligible for the TRICARE Dental Program (TDP). The TDP provides comprehensive dental care insurance and requires premium and cost-share payments but includes an annual maximum per enrollee per contract year for non-orthodontic services. This means that the total payments for covered dental services (except orthodontic services) for each enrolled member will not exceed the annual maximum amount in any contract year. The Government subsidizes 60 percent of the premium cost for enrolled Reserve Component members. If activated for more than 30 days in support of a contingency operation, a TDP enrolled Reserve Component member is automatically disenrolled from the TDP and automatically re-enrolled upon deactivation.

Under the proposed rule, a TDP enrolled Reserve Component member activated for more than 30 days is still automatically disenrolled from the TDP; however, the Reserve Component member will not be automatically re-enrolled upon deactivation because the member will be entitled to the same dental benefits as an active duty member. The Reserve Component

member will be TDP eligible and automatically re-enrolled in the TDP after the Transitional Health Care period is completed.

Reserve Component family members are also eligible for the TRICARE Dental Program (TDP). These family members pay 100% of the premiums while their sponsor is in Reserve status. If their sponsor is activated for more than 30 days, the TDP enrolled Reserve Component family members obtain the same benefits as any other TDP enrolled active duty family members with the Government subsidizing 60 percent of the premium cost for enrolled active duty family members. This change in status and subsidy occurs automatically. Upon the sponsor's deactivation, the family members automatically revert to Reserve Component family member TDP status and pay 100% of the TDP premium cost. With the proposed rule, there is no change to status or eligibility for family members.

II. Regulatory Procedures

Executive Order 12866 requires that a comprehensive regulatory impact analysis be performed on any economically significant regulatory action, defined as one that would result in an annual effect of \$100 million or more on the national economy or which would have other substantial impacts. The Regulatory Flexibility Act (RFA) requires that each Federal agency prepare, and make available for public comment, a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities. This rule is not an economically significant regulatory action and will not have a significant impact on a substantial number of small entities for purposes of the RFA. Thus this proposed rule is not subject to any of these requirements. This proposed rule would amend the Code of Federal Regulations to conform to the new statutory authority. Public comments are invited. All comments will be carefully considered. A discussion of the major issues received by public comments will be included with the issuance of the final rule.

This rule does not contain unfunded mandates. It does not contain a Federal mandate that may result in the expenditure by State, local and tribal governments, in aggregate, or by the private sector, of \$100 million or more in any one year.

This rule will not impose additional information collection requirements on the public under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3511).

We have examined the impact(s) of the proposed rule under Executive Order 13132 and it does not have policies that have federalism implications that would have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, therefore, consultation with State and local officials is not required.

List of Subjects in 32 CFR Part 199

Claims, Dental health, Health care, Health insurance, Individuals with disabilities, Military personnel.

Accordingly, 32 CFR Part 199 is proposed to be amended as follows:

PART 199—CIVILIAN HEALTH AND MEDICAL PROGRAM OF THE UNIFORMED SERVICES (CHAMPUS)

1. The authority citation for Part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55.

2. Section 199.3 is amended by revising paragraph (e)(3) to read as follows:

§ 199.3 Eligibility.

* * * * *

(e) * * *
(3) TAMP benefits under TRICARE begin on the day after the member is separated from active duty, and, if such separation occurred on or after November 6, 2003, end 180 days after such date. TRICARE benefits available to both the member and eligible family members are generally those available to family members of members of the uniformed services under this Part. However, during TAMP eligibility, a member of a Reserve Component as described in paragraph (e)(1)(ii) of this section, is entitled to dental care to which a member of the uniformed services on active duty for more than 30 days is entitled. Each branch of service will determine eligibility for its members and eligible family members and provide data to DEERS.

* * * * *

3. § 199.13 is amended by revising paragraph (c)(3)(ii)(E)(1) to read as follows:

§ 199.13 TRICARE Dental Program.

* * * * *

(c) * * *

(3) * * *

(ii) * * *

(E) * * *

(1) Changes in status of active duty, Selected Reserve or Individual Ready

Reserve member. When the active duty, Selected Reserve or Individual Ready Reserve member is separated, discharged, retired, transferred to the Standby or Retired Reserve, his or her enrolled dependents and/or the enrolled Selected Reserve or Individual Ready Reserve member loses eligibility and enrollment as of 11:59 p.m. on the last day of the month in which the change in status takes place. When the Selected Reserve or Individual Ready Reserve member is ordered to active duty for a period of more than 30 days without a break in service, the member loses eligibility and is disenrolled, if previously enrolled; however, their enrolled dependents maintain their eligibility and previous enrollment subject to eligibility, enrollment and disenrollment provisions described in this section and in the TDP contract.

(i) Reserve component members separated from active duty in support of a contingency operation. When a member of a reserve component who is separated from active duty to which called or ordered in support of a contingency operation if the active duty is for more than 30 days, the member becomes eligible for Transitional Health Care pursuant to 10 U.S.C. 1145(a) and the member is entitled to dental care to which a member of the uniformed services on active duty for more than 30 days is entitled. Thus the member has no requirement for the TDP and is not eligible to purchase the TDP. Upon the termination of Transitional Health Care eligibility, the member regains TDP eligibility and is reenrolled, if previously enrolled.

(ii) Dependents of members separated from active duty in support of a contingency operation. Dependents of a member of a reserve component who is separated from active duty to which called or ordered in support of a contingency operation if the active duty is active for more than 30 days maintain their eligibility and previous enrollment, subject to eligibility, enrollment and disenrollment provisions described in this section and in the TDP contract. During the member's Transitional Health Care eligibility, the dependents are considered family members of Reserve Component members.

(iii) Members separated from active duty and not covered by 10 U.S.C. 1145(a)(2)(B). When the previously enrolled active duty member is transferred back to the Selected Reserve or Individual Ready Reserve, other than pursuant to 10 U.S.C. 1145(2)(B), without a break in service, the member regains TDP eligibility and is reenrolled; however, enrolled dependents maintain

their eligibility and previous enrollment subject to eligibility, enrollment and disenrollment provisions described in this section and in the TDP contract.

(iv) Eligible dependents of an active duty, Selected Reserve or Individual Ready Reserve member serving a sentence of confinement in conjunction with a sentence of punitive discharge are still eligible for the TDP until such time as the active duty, Selected Reserve or Individual Ready Reserve member's discharge is executed.

* * * * *

Dated: January 4, 2011.

Patricia L. Toppings,

*OSD Federal Register Liaison Officer,
Department of Defense.*

[FR Doc. 2011-623 Filed 1-12-11; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DOD-2010-HA-0094; RIN 0720-AB42]

TRICARE; Reimbursement for Travel for Specialty Care Under Exceptional Circumstances

AGENCY: Office of the Secretary, DoD.

ACTION: Proposed rule.

SUMMARY: This proposed rule implements section 634 of the National Defense Authorization Act for Fiscal Year 2010 which amends Section 1074i of title 10, United States Code, to permit reimbursement for reasonable travel expenses for active duty members of the uniformed Services and their dependents, and accompaniment, to a specialty care provider under such exceptional circumstances as the Secretary of Defense may proscribe. The Department of Defense through its military treatment facilities and its robust managed care program, TRICARE Prime, is able to fulfill the medical needs of the majority of its active duty members and their families. However, in some locations where active duty members and their families live due to the duty assignment of the member, the medical resources in the military treatment facilities and the managed care networks may not meet all of the specialty care needs of these members and their families within normal access standards. Reimbursement of reasonable travel expenses for required specialty care that is more than 100 miles from the primary care manager's office is currently a benefit under paragraph (a) of section 1074i, title 10, United States

Code for any covered beneficiary enrolled in the TRICARE Prime program, including the active duty members and their dependents. However this proposed rule extends a travel reimbursement for active duty members of the armed forces and their families who, because of an exceptional circumstance involving the duty assignment of the active duty member of the armed forces, are required to travel less than 100 miles but more than 60 minutes in drive time to access needed specialty care. This travel reimbursement benefit is limited to those active duty members and their dependents, and accompaniment, enrolled in Prime or TRICARE Prime Remote. The Director, TRICARE Management Activity, shall issue procedures and guidelines under which authorization for reimbursement of travel expenses will be issued after verification that the member, family member, and/or accompaniment, must travel less than 100 miles but more than 60 minutes drive time from the military treatment facility or their primary care manager's office to receive required specialty care.

DATES: Comments must be received on or before March 14, 2011.

ADDRESSES: You may submit comments, identified by docket number and/or RIN number and title, by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301-1160.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for viewing on the Internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: TRICARE Policy and Operations, TRICARE Management Activity, 5111 Leesburg Pike, Suite 810, Falls Church, VA 22041.

SUPPLEMENTARY INFORMATION:

I. Introduction and Background

The TRICARE benefit was directed by Congress in section 1097 of the National Defense Authorization Act for Fiscal Year 1995. For further information on TRICARE, the reader may refer to the final rule regarding TRICARE published

in the **Federal Register** on October 5, 1995.

Travel for Specialty Care

Managed care support contractors are required to establish adequate networks throughout regions to complement military treatment facilities and support TRICARE Prime and Extra. However, there are many active duty members of the uniformed Services and their families who are required by the member's duty assignment to live in certain more remote areas where there are insufficient numbers or types of specialty or subspecialty providers to provide care within normal drive-time access standards notwithstanding the due diligence of the contractors in developing the network around the military treatment facilities or their diligence in finding network providers for those members or families enrolled in TRICARE Prime Remote. Under such exceptional circumstances as identified under procedures and guidelines issued by the Director, TRICARE Management Activity, reasonable travel expenses to obtain specialty care for which the enrollee has been referred may be reimbursed. The specific location or identity of these military treatment facilities and the specific TRICARE Prime Remote locations and the types of specialists or sub-specialists shall be determined in accordance with guidelines issued by the Assistant Secretary of Defense for Health Affairs. The guidelines shall include identity of the specific military treatment facility or TRICARE Prime Remote area, validation by either, or both, the facility commander and/or the Director of the TRICARE Regional Office that the specialty care provider or category of specialty care provider required to provide care to the active duty member and their dependents, are not available within a 60 minute drive time, but are available within 100 miles of the military treatment facility or primary care manager's office. The Director of the TRICARE Regional Office shall also verify that the Managed Care Support Contractor has used due diligence in attempting to enroll the needed specialists who do meet the drive time specialty care access standards, into the network. The Director, TRICARE Management Activity shall establish and make available a list of military treatment facilities and category of specialty providers for which these reasonable travel expenses shall be allowed. For members, and families, enrolled in TPR the Director shall ensure that adequate coordination of care and travel benefits is provided to

those qualifying members and their families.

II. Regulatory Procedures

Executive Order 12866, "Regulatory Planning and Review" and Public Law 96-354, "Regulatory Flexibility Act" (5 U.S.C. 601)

Executive Order 12866 requires that a comprehensive regulatory impact analysis be performed on any economically significant regulatory action, defined as one that would result in an annual effect of \$100 million or more on the national economy or which would have other substantial impacts. The Regulatory Flexibility Act (RFA) requires that each Federal Agency prepare, and make available for public comment, a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities. This proposed rule is not a significant regulatory action and will not have a significant impact on a substantial number of small entities for purposes of the RFA. Thus this proposed rule is not subject to any of these requirements.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3511)

This rule will not impose additional information collection requirements on the public.

Executive Order 13132, "Federalism"

We have examined the impacts of the rule under Executive Order 13132 and it does not have policies that have federalism implications that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government, therefore, consultation with State and local officials is not required.

Sec. 202, Public Law 104-4, "Unfunded Mandates Reform Act"

This rule does not contain unfunded mandates. It does not contain a Federal mandate that may result in the expenditure by State, local and Tribal governments, in aggregate, or by the private sector, of \$100 million or more in any one year.

List of Subjects in 32 CFR Part 199

Claims, Dental health, Health care, Health insurance, Individuals with disabilities, Military personnel.

Accordingly, 32 CFR part 199 is proposed to be amended as follows:

PART 199—[AMENDED]

1. The authority citation for part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55.

2. Section 199.17 is amended by revising paragraph (n)(2)(vi) to read as follows:

§ 199.17 TRICARE program

* * * * *

(n) * * *

(2) * * *

(vi) In accordance with guidelines issued by the Assistant Secretary of Defense for Health Affairs, reasonable travel expenses may be reimbursed for a TRICARE Prime enrollee and, when an adult non-medical attendant is necessary, for a parent or guardian of the enrollee or another member of the enrollee's family who is at least 21 years of age. Such guidelines shall be consistent with appropriate provisions of generally applicable Department of Defense rules and procedures governing travel expenses. Reimbursement of reasonable travel expenses shall be provided under the following conditions:

(A) When a Prime enrollee is referred by the primary care manager for medically necessary specialty care more than 100 miles away from the primary care manager's office.

(B) When an exceptional circumstance exists involving referral for specialty care for an active duty member of the uniformed Services or a dependent of an active duty member of the uniformed Services enrolled in Prime or in TRICARE Prime Remote. An exceptional circumstance exists when the enrollee is referred for medically necessary specialty care requiring travel beyond a 60-minute drive time but within 100 miles of the military treatment facility or the TRICARE Prime Remote primary care manager's office. The Director, TRICARE shall issue guidelines and procedures under which authorization of travel expenses will be issued based on verification that a specialty care provider or specific category of specialty care provider is not available within 60-minute drive time but less than 100 miles from a referring military treatment facility or TRICARE Prime Remote primary care manager's office. The guidelines and procedures shall also include verification that the Managed Care Support Contractor has used due diligence in attempting to enroll into the network needed specialists who meet the normal drive time specialty care access standards or has otherwise identified non-network providers within the specialty care

access standards to whom a Prime enrollee may be referred without incurring point of service costs. The Director, TRICARE may establish and make available a list of military treatment facilities and specialty providers for each for which these reasonable travel expenses shall be allowed and shall ensure that members and their families enrolled in TRICARE Prime Remote obtain assistance in receiving this benefit when appropriate.

* * * * *

Dated: January 4, 2011.

Patricia L. Toppings,

*OSD Federal Register Liaison Officer,
Department of Defense.*

[FR Doc. 2011-622 Filed 1-12-11; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DOD-2011-HA-0007]

RIN 0720-AB43

TRICARE Reimbursement Revisions

AGENCY: Office of the Secretary, DoD.

ACTION: Proposed rule.

SUMMARY: The rule proposes several revisions to the regulation necessary to be consistent with Medicare, to include: hospice periods of care; reimbursement of physician assistants and assistant-at-surgery claims; and this rule revises the regulation by removing references to specific numeric Diagnosis Related Group (DRG) values, and replacing them with their narrative description.

DATES: Written comments received at the address indicated below by March 14, 2011 will be accepted.

ADDRESSES: You may submit comments, identified by docket number and or Regulatory Information Number (RIN) number and title, by either of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301-1160.

Instructions: All submissions received must include the agency name and docket number or RIN for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at <http://www.regulations.gov> as they are

received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Ann N. Fazzini, TRICARE Management Activity, Medical Benefits and Reimbursement Systems, telephone (303) 676-3803.

SUPPLEMENTARY INFORMATION:

I. Hospice

This proposed rule revises the regulation for hospice periods of care. The Defense Authorization Act for FY 1992-1993, Public Law 102-190, directed TRICARE to provide hospice care in the manner and under the conditions provided in section 1861(dd) of the Social Security Act (42 U.S.C. 1395x(dd)). Congress' intent was for TRICARE to establish a benefit in the same manner as Medicare. TRICARE originally had the same periods of hospice care used by Medicare; however, over time the Medicare benefit changed, but TRICARE's regulation has not. The TRICARE regulation currently provides for an initial period of 90 days, a subsequent period of 90 days, a second subsequent period of 30 days, and a final period of unlimited duration. Rather than maintaining this level of specificity in the regulation and to ensure that TRICARE and Medicare's benefit periods are equal, we are revising the regulation to state that the distinct periods of care available under the hospice benefit shall be the same as those offered under Medicare's hospice program. Currently under Medicare, patients are entitled to two 90-day election periods, followed by an unlimited number of 60-day periods. The level of specific benefits shall be included in the TRICARE Reimbursement Manual, and may be accessed at <http://www.tricare.mil>.

II. Physician Assistants and Assistant-at-Surgery

The current regulatory language references specific reimbursement percentages for assistant-at-surgery reimbursement. Rather than including these specific percentage amounts, which would require a regulatory change any time the percentage amounts change, we are making a general statement referring to the current percentages used by Medicare. Our authority for this is 10 U.S.C. 1079(h) which states: Except as provided in paragraphs (2) and (3), payment for a charge for services by an individual health care professional (or other noninstitutional health care provider) for which a claim is submitted under a plan contracted for under subsection (a)

shall be equal to an amount determined to be appropriate, to the extent practicable, in accordance with the same reimbursement rules as apply to payments for similar services under title XVIII of the Social Security Act (42 U.S.C. 1395 *et seq.*). The Secretary of Defense shall determine the appropriate payment amount under this paragraph in consultation with the other administering Secretaries. The specific percentages are more appropriately included in the TRICARE Reimbursement Manual, and may be accessed at <http://www.tricare.mil>.

III. DRG

10 U.S.C. 1079(j)(2) provides that the amount to be paid to a provider of services for services provided under a plan covered by this section shall be determined under joint regulations to be prescribed by the administering Secretaries which provide that the amount of such payments shall be determined to the extent practicable in accordance with the same reimbursement rules as apply to payments to providers of services of the same type under title XVIII of the Social Security Act (42 U.S.C. 1395 *et seq.*).

In accordance with the above statute, the TRICARE/CHAMPUS DRG-based payment system transitioned to adopting the Medicare Severity-DRG based payment system on October 1, 2008. When TRICARE transitioned to the severity-based system, it was necessary to renumber the existing DRGs, and to assign different narrative descriptions to the DRG numbers. As a result, the existing regulatory reference to specific DRG numbers and descriptions became obsolete, so we are removing the numeric references in the regulation and utilizing only the descriptive terminology.

Regulatory Procedures

Executive Order 12866, "Regulatory Planning and Review"

Section 801 of title 5, United States Code, and Executive Order (E.O.) 12866 require certain regulatory assessments and procedures for any major rule or significant regulatory action, defined as one that would result in an annual effect of \$100 million or more on the national economy or which would have other substantial impacts. It has been certified that this rule is not economically significant. It has been reviewed by the Office of Management and Budget as required under the provisions of E.O. 12866.

Public Law 104-4, Section 202, "Unfunded Mandates Reform Act"

Section 202 of Public Law 104-4, "Unfunded Mandates Reform Act," requires that an analysis be performed to determine whether any Federal mandate may result in the expenditure by State, local and Tribal governments, in the aggregate, or by the private sector of \$100 million in any one year. It has been certified that this proposed rule does not contain a Federal mandate that may result in the expenditure by State, local and Tribal governments, in aggregate, or by the private sector, of \$100 million or more in any one year, and thus this proposed rule is not subject to this requirement.

Public Law 96-354, "Regulatory Flexibility Act" (RFA) (5 U.S.C. 601)

Public Law 96-354, "Regulatory Flexibility Act" (RFA) (5 U.S.C. 601), requires that each Federal agency prepare a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities. This proposed rule is not an economically significant regulatory action, and it has been certified that it will not have a significant impact on a substantial number of small entities. Therefore, this proposed rule is not subject to the requirements of the RFA.

Public Law 96-511, "Paperwork Reduction Act" (44 U.S.C. Chapter 35)

This rule does not contain a "collection of information" requirement, and will not impose additional information collection requirements on the public under Public Law 96-511, "Paperwork Reduction Act" (44 U.S.C. Chapter 35).

Executive Order 13132, "Federalism"

E.O. 13132, "Federalism," requires that an impact analysis be performed to determine whether the rule has federalism implications that would have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. It has been certified that this proposed rule does not have federalism implications, as set forth in E.O. 13132.

List of Subjects in 32 CFR Part 199

Claims, Dental health, Health care, Health insurance, Individuals with disabilities, Military personnel.

Accordingly, 32 CFR Part 199 is proposed to be amended as follows:

PART 199—[AMENDED]

1. The authority citation for Part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55.

2. Section 199.4 is amended by revising paragraph (e)(19)(v) to read as follows:

§ 199.4 Basic program benefits

* * * * *

(e) * * *

(19) * * *

(v) Periods of care. Hospice care is divided into distinct periods of care. The periods of care that may be elected by the terminally ill CHAMPUS beneficiary shall be as the Director, TRICARE determines to be appropriate, but shall not be less than those offered under Medicare's Hospice Program.

* * * * *

3. Section 199.14 is amended by revising paragraphs (a)(1)(ii)(C)(3), (a)(1)(iii)(A)(2), and (j)(1)(ix) to read as follows:

§ 199.14 Provider reimbursement methods

* * * * *

(a) * * *

(1) * * *

(ii) * * *

(C) * * *

(3) All services related to heart and liver transplantation for admissions prior to October 1, 1998, which would otherwise be paid under the respective DRG.

* * * * *

(iii) * * *

(A) * * *

(2) Remove DRGs. Those DRGs that represent discharges with invalid data or diagnoses insufficient for DRG assignment purposes are removed from the database.

* * * * *

(j) * * *

(1) * * *

(ix) The allowable charge for physician assistant services other than assistant-at-surgery shall be at the same percentage, used by Medicare, of the allowable charge for a comparable service rendered by a physician performing the service in a similar location. For cases in which the physician assistant and the physician perform component services of a procedure other than assistant-at-surgery (e.g., home, office or hospital visit), the combined allowable charge for the procedure may not exceed the allowable charge for the procedure rendered by a physician alone. The allowable charge for physician assistant services performed as an assistant-at-

surgery shall be at the same percentage, used by Medicare, of the allowable charge for a physician serving as an assistant surgeon when authorized as CHAMPUS benefits in accordance with the provisions of § 199.4(c)(3)(iii).

Physician assistant services must be billed through the employing physician who must be an authorized CHAMPUS provider.

* * * * *

Dated: January 5, 2011.

Patricia L. Toppings,

*OSD Federal Register Liaison Officer,
Department of Defense.*

[FR Doc. 2011-624 Filed 1-12-11; 8:45 am]

BILLING CODE 5001-06-P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52**

[EPA-R05-OAR-2010-0675; FRL-9250-9]

Approval and Promulgation of Air Quality Implementation Plans; Minnesota; Gopher Resource, LLC

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a request submitted by the Minnesota Pollution Control Agency (MPCA) on July 29, 2010, to revise the Minnesota State Implementation Plan (SIP) for lead (Pb) under the Clean Air Act (CAA). The State has submitted a joint Title I/Title V document (joint document) in the form of Air Emission Permit No. 03700016-003, and has requested that the conditions laid out with the citation "Title I Condition: SIP for Lead NAAQS" replace an existing Administrative Order (Order) as the enforceable SIP conditions for Gopher Resource, LLC. EPA approved the existing Order on October 18, 1994. MPCA's July 29, 2010, revisions were meant to satisfy the maintenance requirements for the 1978 Pb National Ambient Air Quality Standard (NAAQS), promulgated at 1.5 micrograms per cubic meter, or 1.5 µg/m³.

DATES: Comments must be received on or before February 14, 2011.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R05-OAR-2010-0675, by one of the following methods:

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

2. *E-mail:* mooney.john@epa.gov.

3. *Fax:* (312) 692-2551.

4. *Mail:* John M. Mooney, Chief, Attainment Planning and Maintenance Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

5. *Hand Delivery:* John M. Mooney, Chief, Attainment Planning and Maintenance Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Please see the direct final rule which is located in the Final Rules section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT:

Andy Chang, Environmental Engineer, Attainment Planning and Maintenance Section, Air Programs Branch (AR-18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886-0258, chang.andy@epa.gov.

SUPPLEMENTARY INFORMATION: In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If we do not receive any adverse comments in response to this rule, we do not contemplate taking any further action. If EPA receives adverse comments, we will withdraw the direct final rule, and will address all public comments in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule, which is located in the Final Rules section of this **Federal Register**.

Dated: December 29, 2010.

Susan Hedman,

Regional Administrator, Region 5.

[FR Doc. 2011-342 Filed 1-12-11; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R09-OAR-2010-1078; FRL-9252-7]

Revision to the South Coast Portion of the California State Implementation Plan, CPV Sentinel Energy Project AB 1318 Tracking System

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed Rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a source-specific State Implementation Plan (SIP) revision for the South Coast Air Quality Management District (District) portion of the California SIP. This source-specific SIP revision is known as the CPV Sentinel Energy Project AB 1318 Tracking System. The submitted SIP revision, which consists of enabling language and the AB 1318 Tracking System, supplements the District's SIP approved New Source Review (NSR) program to allow the District to transfer offsetting emission reductions for particulate matter less than 10 microns in diameter (PM₁₀) and one of its precursors, sulfur oxides (SO_x), to the CPV Sentinel Energy Project. The District's SIP approved NSR program currently allows the District to provide offsetting emission reductions for certain exempt sources and sources that qualify as essential public services. The Sentinel Energy Project, which will be a natural gas fired power plant, does not qualify under either of these SIP approved exceptions. This proposed action supplements the District's SIP to allow the District to transfer offsetting emission reductions to the Sentinel Energy Project. In this action, EPA is proposing to incorporate the District's enabling language, which in turn incorporates the AB 1318 Tracking System by reference into the SIP. EPA's proposal to approve this source-specific SIP revision is based on finding that the offsetting emission reductions the District has transferred to the AB 1318 Tracking System meet the requirements of the Clean Air Act (CAA).

DATES: Comments on this Notice of Proposed Rulemaking (NPR) must be submitted no later than February 14, 2011.

ADDRESSES: Submit comments, identified by docket number EPA-R09-OAR-2010-1078, by one of the following methods:

1. *Federal eRulemaking Portal:*

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

2. *E-mail:* r9airpermits@epa.gov.

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

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

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

FOR FURTHER INFORMATION CONTACT: Laura Yannayon, EPA Region IX, (415) 972-3524, yannayon.laura@epa.gov.

SUPPLEMENTARY INFORMATION:

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

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I. Background

A. Facility Description and Background

The proposed Sentinel Energy Project is designed to be a nominally rated 850 megawatt electrical generating facility covering approximately 37 acres within Riverside County, adjacent to Palm Springs, California. The Sentinel Energy Project will emit air pollutants from eight General Electric LMS100 combustion turbine generators equipped with oxidation catalyst and selective catalytic reduction equipment, eight single cell mechanical draft cooling towers, and a 240 brake horsepower Tier III diesel emergency fire pump engine.

The California Energy Commission (CEC) approved the application for certification for Sentinel on December 1, 2010. The District issued a Final Determination of Compliance (FDOC) and an Addendum to the FDOC, known as Appendix N, on March 2, 2010. Appendix N to the FDOC has evolved into the AB 1318 Tracking System submitted as part of this SIP revision. The CEC certification and the District's FDOC require the Sentinel Energy Project to install and operate stringent emissions controls to reduce emissions of NO_x, VOC, CO and PM₁₀ to the lowest achievable emissions rates.

B. Emission Offsets

Pursuant to section 173 of the CAA, new major stationary sources are required to provide offsetting emission reductions for any non-attainment pollutants that continue to be emitted after operation of the most stringent emissions controls, if those levels exceed certain thresholds. 42 U.S.C. 7503(a)(1)(A). The District implements these requirements through its NSR program in Regulation XIII, which EPA approved into the SIP in 1996 as

meeting the requirements for CAA Section 110, Part D. 61 FR 64291.

The District estimated the amount of offsetting emission reductions that Sentinel must provide to comply with District Rule 1303 and CAA § 173 for all non-attainment pollutants. For all pollutants other than PM₁₀ and SO_x, Sentinel has purchased Emission Reduction Credits (ERCs) on the open market. Those ERCs comply with Rule 1309.

For PM₁₀ and SO_x emissions, the California Legislature enacted California Assembly Bill (AB) 1318, which went into effect on January 1, 2010. AB 1318 requires the District, upon making a specified finding, to transfer SO_x and PM₁₀ emission offsets from its internal bank to eligible electric generating facilities. The District determined that the Sentinel Energy Project met all of the requirements of an eligible electric generating facility and made the required finding.

AB 1318 also establishes requirements for the District's implementation of transferring the offsetting emission reductions from its internal bank to an eligible electric generating facility and for tracking the transfer of offsetting emissions reductions. The District completed those requirements as documented in Appendix N to the FDOC, which has evolved into the AB 1318 Tracking System for this SIP revision. The offsetting emission reductions transferred to the AB 1318 Tracking System from the District's internal bank were created by permitted equipment that permanently ceased or reduced operations in District. The District examined each of these offsetting emission reductions and determined that they met the "integrity criteria" established in CAA § 173(c). Specifically, the District determined that the offsetting emission reductions were real, permanent, quantifiable, enforceable and surplus. The District then transferred those specific PM₁₀ and SO_x offsetting emission reductions out of its internal bank and into the AB 1318 Tracking System. These offsetting emission reductions are no longer available for use in any other action.

The amounts of offsetting emission reductions the District transferred from its internal bank to the AB 1318 Tracking System are based on estimated actual PM₁₀ and SO_x emissions reported to the District according to its Annual Emissions Reporting Program. For each source of offsetting emission reductions from a permanent shutdown of equipment, the District has inactivated that source's permit. For each offsetting emission reduction created by a source reducing emissions, the District has

revised the source's federally enforceable permit to ensure the reduction is permanent. The complete list of PM₁₀ and SO_x offsetting emission reductions is provided in the AB 1318 Tracking System which is attached to EPA's Technical Support Document (TSD). Documentation for each of these offsetting emission reductions is included in the docket for this proposal.

C. Procedural History of Source Specific SIP Revision

The District adopted the CPV Sentinel Energy Project AB 1318 Tracking System on July 9, 2010. The California Air Resources Board (CARB) submitted the CPV Sentinel Energy Project AB 1318 Tracking System to EPA as a source specific SIP revision on September 10, 2010. EPA issued a completeness letter on October 27, 2010, finding that the submittal had met the completeness criteria in 40 CFR Part 51 Appendix V.

II. Evaluation of Source Specific SIP Revision

A. What is in the SIP revision?

The package that the District, through CARB, submitted to EPA consists of text to be included as a revision to the District's portion of the California SIP, and the Sentinel Energy Project AB 1318 Tracking System created to implement this new SIP provision. The District's SIP text incorporates the Sentinel Energy Project AB 1318 Tracking System by reference. The AB 1318 Tracking System includes specific offsetting emission reductions that were identified from reductions of SO_x and PM₁₀ occurring between 1999 and 2008 from permitted equipment that has either permanently ceased operations in the District or became subject to federally enforceable conditions that reduced actual emissions. The District has not issued any Rule 1309 ERCs for these specific emissions reductions and has inactivated the permits for the equipment that has been shut down. These SO_x and PM₁₀ offsetting emission reductions were transferred out of the District's internal bank and into the AB 1318 Tracking System. These reductions have not been used by any other source and cannot be used for any other source in the future if they are used to construct the CPV Sentinel Energy Project. A copy of the AB 1318 Tracking System for CPV Sentinel is included as an attachment to the TSD for this action.

The text of the proposed source-specific SIP revision, in relevant part, is:

The Executive Officer of the South Coast Air Quality Management District shall transfer sulfur oxides and particulate

emission credits from the CPV Sentinel Energy Project AB 1318 Tracking System, attached hereto and incorporated by reference herein, to eligible electrical generating facilities pursuant to Health and Safety Code section 40440.14, as in effect January 1, 2010, (*i.e.* the CPV Sentinel Power Plant to be located in Desert Hot Springs, CA) in the full amounts needed to issue permits to construct and to meet requirements for sulfur oxides and particulate matter emissions. Notwithstanding District Rule 1303, this SIP revision provides a federally enforceable mechanism for transferring offsets from the AQMD's internal accounts to the CPV Sentinel Project.

The SIP revision is intended to provide a federally approved and enforceable mechanism for the District to transfer PM₁₀ and SO_x offsetting emissions reductions from the District's internal bank to the Sentinel Energy Project and to track those emissions credits through the AB 1318 Tracking System.

B. What are the Federal Clean Air Act requirements?

The South Coast Air Basin is an extreme non-attainment area for ozone and a serious non-attainment area for PM₁₀. Sulfur oxide emissions are PM₁₀ precursors and are therefore also treated as a PM₁₀ non-attainment pollutant. As required by CAA § 110(a)(2)(C), SIPs are required to include provisions to comply with CAA Part D for non-attainment pollutants. Among the Part D requirements, § 173(a)(1)(A) requires offsetting emission reductions for new and modified major stationary sources. Section 173(c) requires the offsetting emission reductions to be real, quantifiable, surplus, permanent, and enforceable.

The District's NSR permitting program is contained in District Regulation XIII, which was approved into the South Coast portion of the California SIP on December 4, 1996, for purposes of complying with the CAA Part D. (61 FR 64291). District Rule 1303(b)(2) requires the District to deny a permit to construct a new source or modify an existing source unless it is exempt from offset requirements pursuant to Rule 1304, emissions increases are offset by ERCs approved pursuant to Rule 1309, or the source obtains allocations from the District's Priority Reserve accounts in accordance with the provisions of Rule 1309.1. For PM₁₀ and SO_x emissions, Sentinel is not exempt pursuant to Rule 1304 and does not qualify for allocations from the Priority Reserve.¹

¹ When sources are exempt from offsets pursuant to Rule 1304 or entitled to allocations pursuant to

However, the California legislature directed the District to provide offsetting emission reductions from the District's internal bank to the Sentinel Energy Project (providing it qualified) to offset its PM₁₀ and SO_x emissions. This source-specific SIP revision approves the Sentinel Energy Project AB 1318 Tracking System to provide the federally enforceable mechanism allowing the District to transfer PM₁₀ and SO_x offsetting emission reductions to meet the requirements of Rule 1303(b).

EPA has reviewed the documents provided for each offsetting emission reduction the District has transferred to the AB 1318 Tracking System. We are proposing to find that the PM₁₀ and SO_x offsetting emission reductions transferred to the AB 1318 Tracking System meet the CAA Section 173 requirements that emission reductions used as offsets be real, quantifiable, surplus, permanent, and enforceable prior to use. The TSD for this action provides more detail regarding how the offsetting emission reductions transferred to the AB 1318 Tracking System meet these requirements.

C. SIP Relaxation

Under section 110(l) of the CAA, EPA may not approve any SIP revision that would interfere with attainment, reasonable further progress (RFP) or any other CAA requirement.

We believe this revision will not interfere with attainment or RFP because the emission credits in the AB 1318 Tracking System are not relied on for attainment or RFP in the District's most recent attainment demonstrations. We are also not aware of this revision interfering with any other CAA requirement. For example, this source-specific SIP revision provides a new but equivalent mechanism to provisions in Regulation XIII for satisfying the offset requirements of CAA § 173 because the offsetting emission reductions the District is transferring from its internal bank to the AB 1318 Tracking System meet all Federal requirements. In addition, the District supplied a copy of its air quality analysis for the CPV Sentinel Energy Project which shows that operation of the facility will not interfere with the ability of the District to reach attainment.²

Rule 1309.1, the District deducts sufficient emission credits from its internal bank of credits to offset any emissions that would be subject to Federal offset requirements. The District prepares annual reports to show that it has adequate emissions credits in its internal bank.

² *Air Quality Demonstration: SIP Revision for CPV Sentinel Energy Project*

D. Public Comment and Final Action

Because EPA believes the submittal fulfills all relevant requirements, we are proposing to fully approve it as described in section 110(k)(3) of the Act. We will accept comments from the public on this proposal for the next 30 days. Unless we receive convincing new information during the comment period, we intend to publish a final approval action that will incorporate this submittal into the federally enforceable SIP.

III. Administrative Requirements

A. Executive Order 12866, Regulatory Planning and Review

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order 12866, entitled "Regulatory Planning and Review."

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* Burden is defined at 5 CFR 1320.3(b).

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions.

This rule will not have a significant impact on a substantial number of small entities because SIP approvals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities.

Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of flexibility analysis would constitute Federal inquiry into the economic reasonableness of State action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co., v. U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

D. Unfunded Mandates Reform Act

Under sections 202 of the Unfunded Mandates Reform Act of 1995 ("Unfunded Mandates Act"), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to the private sector, of \$100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action proposed does not include a Federal mandate that may result in estimated costs of \$100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action proposes to approve pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

E. Executive Order 13132, Federalism

Federalism (64 FR 43255, August 10, 1999) revokes and replaces Executive Orders 12612 (*Federalism*) and 12875 (*Enhancing the Intergovernmental Partnership*). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal Government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a

regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, because it merely approves a State rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

F. Executive Order 13175, Coordination With Indian Tribal Governments

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." This proposed rule does not have tribal implications, as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments, 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. Thus, Executive Order 13175 does not apply to this rule.

G. Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5-501 of the Executive Order has the potential to influence the regulation. This rule is not subject to Executive Order 13045, because it approves a State rule implementing a Federal standard.

H. Executive Order 13211, Actions That Significantly Affect Energy Supply, Distribution, or Use

This rule is not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) because it is

not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use "voluntary consensus standards" (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

The EPA believes that VCS are inapplicable to this action. Today's action does not require the public to perform activities conducive to the use of VCS.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Population

Executive Order 12898 (59 FR 7629 (Feb. 16, 1994)) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA lacks the discretionary authority to address environmental justice in this rulemaking.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

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

Dated: December 30, 2010.

Jared Blumenfeld,

Regional Administrator, Region IX.

[FR Doc. 2011-647 Filed 1-12-11; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 20

[PS Docket No. 10-255; FCC 10-200]

Framework for Next Generation 911 Deployment

AGENCY: Federal Communications Commission

ACTION: Notice of inquiry.

SUMMARY: The Notice of Inquiry (NOI) initiates a comprehensive proceeding to address how Next Generation 911 (NG911) can enable the public to obtain emergency assistance by means of advanced communications technologies beyond traditional voice-centric devices. The NOI seeks to gain a better understanding of how the gap between the capabilities of modern networks and devices and today's 911 system can be bridged and seeks comment on how to further the transition to IP-based communications capabilities for emergency communications and NG911.

DATES: Submit comments on or before February 28, 2011. Submit reply comments March 14, 2011.

ADDRESSES: Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments. Comments may be filed using: (1) the Commission's Electronic Comment Filing System (ECFS), (2) the Federal Government's eRulemaking Portal, or (3) by filing paper copies. See Electronic Filing of Documents in Rulemaking Proceedings, 63 FR 24121 (May 1, 1998).

- *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the ECFS: <http://fjallfoss.fcc.gov/ecfs2/> or the Federal eRulemaking Portal: <http://www.regulations.gov>.

- *Paper Filers:* Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

- Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

- All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445

12th St., SW., Room TW–A325, Washington, DC 20554. The filing hours are 8 a.m. to 7 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building.

- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.

- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street, SW., Washington DC 20554.

FOR FURTHER INFORMATION CONTACT: Patrick Donovan, Public Safety and Homeland Security Bureau, at (202) 418–2413, Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554; or via the Internet to Patrick.Donovan@fcc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

1. As recommended in the National Broadband Plan, this Notice of Inquiry (NOI) initiates a comprehensive proceeding to address how Next Generation 911 (NG911) can enable the public to obtain emergency assistance by means of advanced communications technologies beyond traditional voice-centric devices. In the telecommunications industry overall, competitive forces and technological innovation have ushered in an era of advanced Internet-Protocol (IP)-based devices and applications that have vastly enhanced the ability of the public to communicate and send and receive information. At the same time, our legacy circuit-switched 911 system is unable to accommodate the capabilities embedded in many of these advanced technologies, such as the ability to transmit and receive photos, text messages, and video. Accordingly, in this proceeding, we seek to gain a better understanding of how the gap between the capabilities of modern networks and devices and today's 911 system can be bridged. We also seek comment on how to further the transition to IP-based communications capabilities for emergency communications and NG911.

II. Background

2. Since AT&T first made the digits "911" available nationally in 1968 for wireline access to emergency services, the American public increasingly has come to depend on the service. Today, the National Emergency Number Association (NENA) estimates that some form of 911 service is available to 99 percent of the population in 96 percent of the counties in the United States, and

240 million calls are made to 911 in the United States each year. "911" is as well known as any popular brand, and is what we routinely teach to children as the way to summon help from police, fire, and ambulance services. In more recent times, 911 has become increasingly important for homeland security, as the means for ordinary citizens—in some ways the true "first responders"—to report suspicious activity or summon emergency assistance for themselves and others in times of natural or man-made disasters. It should therefore come as no surprise that the American public has developed clear expectations with respect to the availability of 911 emergency services via certain classes of communications devices.

3. The availability of this critical service is due largely to the dedicated efforts of State, local, and Tribal authorities and telecommunications carriers, who have used the 911 abbreviated dialing code to provide access to increasingly advanced and effective emergency service capabilities. Indeed, absent appropriate action by, and funding for, states, Tribes, and local jurisdictions, there can be no effective 911 service.

4. At the same time, new voice communications technologies have posed technical and operational challenges to the 911 system, necessitating the adoption of a uniform national approach to preserve the quality and reliability of 911 services for such communications technologies. This was first recognized following the introduction of commercial mobile radio services (CMRS) in the United States, when the Commission in 1996 established rules requiring CMRS carriers to implement basic 911 and Enhanced 911 (E911) services.

5. In 1999, Congress continued this recognition when it enacted the Wireless Communications and Public Safety Act (911 Act) to promote and enhance public safety through the use of wireless communications services. The 911 Act directed the Commission to designate 911 as the universal emergency assistance number for wireless and wireline calls, and to establish a transition period for areas of the country where 911 was not yet available. In 2000, the Commission adopted an order which established 911 as the universal emergency telephone number in the United States. In 2003, the Commission revised "the scope of [its] enhanced 911 rules to clarify which technologies and services will be required to be capable of transmitting enhanced 911 information." In adopting rules tailored to specific services, the

Commission clarified, inter alia, the following matters: (1) Telematics service providers offering interconnected CMRS voice calling service may have an E911 service requirement and need to coordinate with the underlying wireless carriers, so that, regardless of the legal relationship between them, E911 requirements can be met; and (2) resold and prepaid mobile wireless service providers must meet 911 rules to the extent the underlying licensee has deployed the necessary technology for E911 service. The Commission declined, however, to impose E911 requirements on: (1) Telematics-only services providers, reserving the right to revisit E911 obligations in the future, (2) manufacturers of disposable phones or personal data assistants (PDAs) that contain a voice service component, and (3) multi-line telephone systems, except for the Commission's monitoring of states' progress on implementing E911 for those systems.

6. The next significant step in the evolution of 911 followed the introduction of Voice over Internet Protocol (VoIP) services in the United States. In this regard, in 2005, the Commission established rules requiring interconnected VoIP service providers to supply E911 capabilities to their customers as a standard feature from wherever the customer is using the service.

7. While the Commission and the 911 industry acted to enable 911 service availability for wireless and VoIP providers, today's 911 system remains reliant on increasingly antiquated analog or digital circuit-switched facilities. It is thus not capable of supporting certain functionalities made possible by a transition to broadband IP-based communications technologies—functionalities that have become commonplace in other communications systems. At the same time, the introduction of these new technologies has created the potential for development of and transition to NG911 to take advantage of the enhanced capabilities of IP-based devices and networks.

8. In the last few years, there have been several important efforts to address the need for a transition to a NG911 network. In the New and Emerging Technologies 911 Improvement Act of 2008, Congress tasked the National E9–1–1 Implementation Coordination Office (ICO) to develop "a national plan for migrating to a national [Internet Protocol] IP-enabled emergency network capable of receiving and responding to all citizen-activated emergency communications and improving information sharing among all

emergency response entities.” The ICO, managed jointly by the Department of Commerce’s National Telecommunications and Information Administration (NTIA) and the Department of Transportation’s National Highway Traffic Safety Administration (NHTSA), released its migration plan in September 2009. In March 2010, NENA released a handbook to serve as a guide for public safety personnel and government officials responsible for ensuring that Federal, State, and local 911 laws and regulations effectively enable the implementation of NG911 systems. Specifically, the NENA Handbook provides an overview of key policy, regulatory, and legislative issues that need to be considered to enable the transition to NG911. The NENA Handbook states that “it is critical that State regulatory bodies and the FCC take timely and carefully scrutinized action to analyze and update existing 9–1–1, PSTN, and IP rules and regulations to ensure they optimize 9–1–1 governing authority choices for E9–1–1 and NG9–1–1 and foster competition by establishing a competitively neutral marketplace.”

9. On March 16, 2010, the Commission delivered the National Broadband Plan to Congress, which included several recommendations related to NG911. Specifically, the Plan noted that the Commission was already considering changes to its E911 location accuracy requirements and recommended that the Commission expand that proceeding to explore how NG911 may affect location accuracy and provision of automated location information. The Plan further recommended that the Commission initiate a new proceeding “to address how NG911 can accommodate communications technologies, networks and architectures beyond traditional voice-centric devices,” and to “explore how public expectations may evolve in terms of the communications platforms the public would rely upon to request emergency services.”

10. In September 2010, addressing the National Broadband Plan recommendation with respect to location accuracy, we adopted a *Further Notice of Proposed Rulemaking and Notice of Inquiry* in our E911 Location Accuracy proceeding, in which we sought comment on a number of issues pertaining to the Commission’s location accuracy rules, including the impact of NG911 deployments on location accuracy and Automatic Location Identification (ALI). The *FNPRM* and *NOI* was published in the **Federal Register** at 75 FR 67321, November 2, 2010. In the Location Accuracy *FNPRM*/

NOI, we limited the scope of our NG911 inquiry to location issues in the provision of voice-based services. In this *Notice of Inquiry*, we initiate the broader proceeding recommended in the National Broadband Plan concerning the migration to NG911.

11. Most recently, on October 8, 2010, the Twenty-First Century Communications and Video Accessibility Act of 2010 (Twenty-First Century Act) was signed into law. The Twenty-First Century Act directs the Chairman of the Commission to establish an advisory committee, to be known as the Emergency Access Advisory Committee (EAAC), for the purpose of achieving equal access to emergency services by individuals with disabilities as part of our nation’s migration to NG911. The Twenty-First Century Act also directs the EAAC to conduct a national survey with people with disabilities and make recommendations on the most effective and efficient technologies and methods to enable NG911 access. The EAAC will be composed generally of State and local government representatives responsible for emergency management and emergency responder representatives, national organizations representing people with disabilities and senior citizens, communications equipment manufacturers, service providers, and subject matter experts.

III. Technical Comparison of Legacy 911 and Next Generation 911

12. In order to understand the opportunities and challenges involved with deploying an NG911 system across the country, it is instructive to first briefly review how, as a technical matter, the current 911 system operates for wireline, wireless and interconnected VoIP 911 calls, and how NG911 will differ from legacy 911 in its applications and network architecture. For brevity, the discussion simplifies some of the technical details of both legacy and NG911 systems.

A. Legacy 911

13. In the United States, legacy 911 service generally falls into two categories—basic and enhanced. Basic 911 service transmits 911 calls from the service provider’s switch to a single geographically appropriate Public Safety Answering Point (PSAP) or public safety agency, usually over dedicated emergency trunks. Basic 911 networks are not capable of taking into account the caller’s location, but simply forward all 911 calls from a particular PSTN switch to the appropriate PSAP or public safety agency. E911 service expands basic 911 service by not only

delivering 911 calls to the appropriate PSAP or agency, but also providing the call taker with the caller’s calling back number, referred to as Automatic Numbering Information (ANI), and location information—a capability referred to as Automatic Location Identification (ALI). Most areas of the country have now implemented E911 service.

14. Wireline E911. In wireline E911, PSAPs are connected to telephone switches by dedicated trunk lines. Wireline E911 networks generally have been implemented, operated, and maintained by a subset of incumbent LECs, and are largely paid for by PSAPs through tariffs. Network implementation varies from carrier to carrier and jurisdiction to jurisdiction, but usually is based on traditional circuit-switched architecture and implemented with legacy components that place significant limitations on the functions that can be performed over the network. Typically, a wireline E911 network utilizes a selective router, which receives 911 calls from competitive and incumbent LEC central offices over dedicated trunks. The selective router then queries an incumbent LEC-maintained selective router database (SRDB) to determine which PSAP serves the caller’s geographic area. The selective router will then forward the call, along with the caller’s phone number (i.e., ANI) to the PSAP that has been designated to serve the caller’s area. The PSAP then forwards the caller’s ANI to an incumbent LEC-maintained Automatic Location Identification database (ALI database). The ALI database returns to the PSAP the caller’s physical address (that has previously been verified by comparison to the MSAG). Wireline E911 networks also include a Database Management System (DBMS), which provides a method for competitive and incumbent LECs to enter customer data into both the SRDB and the ALI Database.

15. Wireless E911. Under the Commission’s wireless E911 rules, wireless carriers are obligated to provide the telephone number of the originator of a 911 call (i.e., ANI) and information regarding the caller’s location (i.e., ALI) to any PSAP that has requested that such information be delivered with 911 calls. As explained in the VoIP 911 Order and VoIP 911 NPRM, the mobile nature of wireless technology and other IP-enabled services presents significant obstacles to making E911 effective—in particular the provision to PSAPs of accurate ALI. Specifically, the mobility of wireless service renders the use of permanent street addresses as a location indicator useless, and often requires the

provision of real-time location updates to the PSAP. In addition, the caller's phone number (*i.e.*, the ANI information) may not be usable by the selective router for PSAP routing purposes within the specific geographic region in which the mobile 911 call was placed. To overcome this mobility problem, wireless carriers have developed various techniques to provision ANI and ALI to the PSAP that involve enhancements or "add-ons" to existing Wireline E911 networks.

16. Interconnected VoIP E911. Under the Commission's rules, interconnected VoIP providers must provide E911 service to their customers. As with wireless service, the mobile nature of interconnected VoIP service presents challenges in making E911 effective. Since an emergency call may be placed from outside the caller's home area code, completing the call may require the use of "pseudo-ANI" (p-ANI). The most difficult challenge, however, is the inability of the VoIP device or service provider to determine the current geographic location of the caller. As a result, the Commission requires interconnected VoIP providers to obtain location information, called "Registered Location," from their subscribers, which is either entered manually or based on the subscriber's billing record. Under this approach, if a VoIP subscriber does not update his or her location, the subscriber's 911 call may be routed to the wrong PSAP, which may delay the emergency response.

17. Beyond the basic functionality above, the Commission imposes additional obligations on interconnected VoIP service providers. Under the Commission's rules, interconnected VoIP providers must forward all 911 calls made over their interconnected VoIP service, as well as a call back number and the caller's Registered Location for each call, to the appropriate PSAP. These calls must be routed through the use of ANI and, if necessary, and similar to wireless carriers, p-ANI, via the dedicated wireline E911 network, and the caller's Registered Location must be available from or through the ALI Database. Additionally, interconnected VoIP providers must comply with several customer notification requirements that include apprising their subscribers of any limitations in providing E911 service.

B. Next Generation 911

18. Next Generation 911 relies on IP-based architecture rather than the PSTN-based architecture of legacy 911 to provide an expanded array of emergency communications services

that encompasses both the core functionalities of legacy E911 and additional functionalities that take advantage of the enhanced capabilities of IP-based devices and networks. NENA defines NG911 as "a system comprised of hardware, software, data and operational policies and procedures * * *, to: Provide standardized interfaces from call and message services; process all types of emergency calls including non-voice (multi-media) messages; acquire and integrate additional data useful to call routing and handling; deliver the calls/messages and data to the appropriate PSAPs and other appropriate emergency entities; support data and communications needs for coordinated incident response and management provide a secure environment for emergency communications."

19. In an NG911 environment, IP-based technologies and applications are used to provide call identification, location determination, call routing, and call signaling for emergency calls. Call identification determines that a call (which may be a voice call or some other form of communication) is indeed an emergency call, mapping a user-visible identifier (such as the digits 911 or 112) to a network-standard uniform emergency call identifier, such as an emergency service Uniform Resource Name (URN). Location determination provides the civic or geospatial location of the caller to the initiating call router, which will then use the emergency call identifier and the location information, along with other information, to route the call to the nearest IP-enabled PSAP.

20. The NG911 architecture also redefines the functions and capabilities of PSAPs, who receive and process emergency calls by means of Emergency Services IP Networks (ESInets). An ESInet is an IP-based network used by the PSAP and other agencies that may be involved in responding to an emergency. Emergency calls can be delivered to an ESInet from several types of originating networks, including both NG911 networks and legacy 911 networks. The ESInet, in turn, completes the call to the appropriate PSAP. The call signaling uses the same standard protocols as non-emergency calls, but user devices may use other protocols via gateways.

21. The nature of NG911 technology and architecture leads to certain key differences when compared to legacy 911, as detailed in the paragraphs below:

- NG911 networks can be accessed by a wide variety of end users and devices, many of which will have identifiers other than telephone numbers.

- NG911 networks are capable of supporting multiple voice and non-voice services, whereas legacy 911 supports voice only.

- In NG911, the difference between mobile, nomadic, and fixed services is blurred, because a single device may operate in mobile, nomadic, and fixed configurations at different times and locations.

- In NG911, network access and communications service may be provided by separate entities rather than the same entity.

- NG911 network services can be provided by servers largely independent of location.

22. As pointed out by the Internet Engineering Task Force, Emergency Context Resolution with Internet Technologies (IETF-ECRIT) working group, the use of the Internet rather than circuit-switched networks changes the requirements and operating conditions of IP-based emergency calling. For example, in an NG911 call scenario, the caller's provider of Internet access services may not be the same entity that provides voice calling services, *i.e.*, that routes calls and bridges them to the PSTN when needed. Moreover, the voice service provider may be located far away from the caller, possibly in another country, while the Internet access provider remains, by physical necessity, local to the caller. The voice service provider may also not be a traditional telecommunications provider, particularly as the need to interconnect with the PSTN diminishes.

23. Unlike communications systems that interconnect with the PSTN, IP-based communication systems are media-neutral, *i.e.*, they can transport any digital information, regardless of content, and are not limited to voice or voice-band data (TTY). As a result, a wide variety of voice and non-voice services can share the same Internet infrastructure. Moreover, while wireless or wireline E911 network users need no special capabilities to dial 911, current standards-based architectures for NG911 envision a more active role for end-user devices and systems in identifying emergency calls and acquiring the caller's location information. This makes it easier for NG911 networks to add media beyond voice, although it also creates additional challenges such as security.

24. NG911 will also require a new and more multi-faceted approach to caller identification. In legacy E911 networks, all callers have telephone numbers as identifiers, most of which are domestic (+1) numbers. Initially, most users of IP-based systems (*e.g.*, interconnected VoIP) will also have telephone numbers,

but an increasing percentage of these users are likely to have international rather than domestic numbers. Moreover, in the longer term, as IP-based networks support an increasing diversity of non-interconnected and non-voice services, potential NG911 end users and devices are less likely to have any type of telephone number and more likely to have identifiers such as email addresses, Session Initiation Protocol (SIP) URLs or service-specific “handles.”

25. In contrast to the device-specific connection protocols in legacy 911 networks for wireline, wireless, and interconnected VoIP phones, NG911 will need to provide IP-enabled devices with multiple means of accessing the NG911 network, resulting in a blurring of the difference between stationary, nomadic and mobile devices. For example, an IP-enabled mobile device may be capable of accessing the Internet via a Wi-Fi hotspot, a cable modem, or a 4G wireless broadband network. NG911 networks will need mechanisms to recognize which form of access the device is using when an emergency call is made and to provide the appropriate caller identification, location determination, call routing, and call signaling in each case.

26. NG911 also provides far more flexibility to provide network services that are not constrained by the location of the caller or the nearest PSAP to the caller. In circuit-switched networks, the location of many types of network services is constrained by the network topology. For example, a selective router has to be relatively close to the PSAPs it serves. For NG911, since call routing and media transport are completely disjoint, almost any network server can be located and replicated anywhere. As an example, a SIP proxy that routes call can be in a different part of the country, incurring only a few milliseconds of additional packet propagation delays.

IV. Discussion

27. While, as detailed above, the 911 system has been adapted to accommodate wireless and interconnected VoIP services, the success of the 911 system, combined with the antiquated aspects of today's 911 infrastructure and the development of advanced IP-based devices and applications in the telecommunications industry overall, creates a gulf between consumer assumptions about the system's robust capabilities and its actual limitations. Indeed, there is widespread concurrence among academics, industry experts, and politicians that “the current communications landscape is a far cry from the one for which the current 9–

1–1 system was engineered” and, furthermore, that “our emergency communications networks are unable to accommodate what is increasingly viewed as basic functionality inherent in many of today's technologies.” In short, because 911 service was designed to succeed in the legacy wireline telephone environment, there are unmet consumer expectations concerning emergency service capability and reliability across new communications technologies (such as text messaging requests for help, sending IP-based information, including medical data, photos, videos, car collision telemetry, environmental sensors, gun shot sensors, etc. via smartphones, and delivering precise location information from behind MLTS systems).

28. The deployment of and transition to NG911 presents multiple opportunities for the benefit of public safety and homeland security. First, replacing today's system with a broadband-enabled, IP-based 911 network will offer far more flexibility, resilience, functionality, innovation potential, and competitive opportunities than is presently possible. NG911 holds the promise to bridge the gap between traditional means of voice-based communications and the advanced capabilities already in widespread use by consumers using smartphones, netbooks, and advanced wireless 4G. In particular these digital devices have powerful processor and storage capabilities and are capable of transmitting not only voice communications, but also text, data, telemetry, image, and video signals, which have benefits to particular communities such as persons with disabilities. Unlike the circuit-switched technology that lies at the heart of the legacy 911 system, today's wireless networks increasingly use all-digital packet switched technology based upon the Internet Protocol suite. Thus, while these networks are capable of conveying text, data, image, and video in addition to voice, the legacy 911 systems are not capable of receiving or processing these communications, and will not be until NG911 is deployed across the country.

29. The adoption of broadband IP-based technology also creates the potential for our 911 system to accommodate a full range of specialized devices and functionalities tailored to particular emergency response scenarios. For example, NG911 could permit the simultaneous transmission of critical health data along with a 911 call for help, both from the “caller” seeking assistance to a dispatcher, and back out from a dispatcher to a first responder arriving on scene or to an emergency

room receiving the patient. Likewise, a vehicle's Automatic Collision Notification System could automatically call for help while conveying other relevant information such as the vehicle's location and the severity of the crash. NG911 will also enable 911 call routing based on caller characteristics, not just the location of the call. For example, a 911 call might be made via a video-enabled device by a deaf caller whose native language is American Sign Language. In this situation, rather than routing the call to the “geographically appropriate” PSAP, it may be preferable to enable the 911 system to route the 911 call to a PSAP that is video-enabled and has a 911 call taker prepared to respond to the caller using the caller's native sign language. NG911 will permit this to happen. NG911 will also create the ability to utilize a “virtual PSAP.” Today's 911 system generally requires a call taker to answer a 911 call from within the walls of a physical PSAP. In a NG911 network, however, a call taker will be able to answer a 911 call from virtually any location. This capability will be particularly advantageous during disasters and high call volume situations. NG911 will also complement the deployment of related next generation emergency communications networks, such as next generation alerting systems and advanced public safety broadband networks.

30. In this proceeding, we seek to gain a general understanding of NG911 and the applications that it supports. We examine and seek comment about how the applications and architecture of NG911 will affect the interface with the general public, the internal workings of PSAPs, and the interface with Emergency Medical Services (EMS) and other first responder organizations, including dispatch and database access. We then look at issues associated with implementing NG911 and how the transition from legacy 911 will impact the current architecture, structure, and costs of today's PSAPs over time. Finally, we seek comment on the proper roles of the FCC, other Federal agencies, and State, Tribal, and local governments in developing NG911 elements and facilitating the transition to NG911 over time.

A. NG911 Capabilities and Applications

31. In this section, we review the potential capabilities that the deployment of NG911 systems will provide to the public, and the likely architecture of NG911 networks. We seek comment on each of these elements as a component of NG911. Are there core elements that should be part of every NG911 system and standardized

across all NG911 deployments? Are there non-core elements that could be part of NG911 but are optional or can be varied locally? How will these elements (both core and non-core) be affected by future technological change?

1. Potential Media Types in an NG911 Environment

32. Because NG911 architecture is IP-based, NG11 networks have the potential to support a variety of non-voice communications applications or “media types.” There is broad consensus in the public safety community that NG911 should include some combination of non-voice media types, and to this end, NENA, the IETF, and others have been actively engaged in developing and harmonizing technical standards to support such IP-based NG911 solutions. In addition, the U.S. Department of Transportation and other Federal agencies have engaged in the development of standards in this area. We identify and discuss the most likely media types below, and seek comment on the potential for each of the media types to be supported in the development and deployment of NG911 networks. We also seek comment on whether there are any additional media types that we should consider for inclusion in NG911.

33. Message-Based Text. When using message-based text, two or more parties have the ability to send complete, typically short, text messages to each other. Examples include Short Message Service (“SMS”), instant messaging (“chat”) sessions, or web-based tools. To send a message-based text, a user must make an explicit action, such as hitting an SMS send key, or the return key on a keyboard. Chat sessions are bidirectional through their protocol definition. While services such as SMS consist of independent messages, they may be presented to the user as a thread of back-and-forth messages.

34. Real-Time Text. “Real-Time Text (RTT) is conversational text that is generally sent and received on a character-by-character basis. The characters are sent immediately (in a fraction of a second) once they are typed and are also displayed immediately to the receiving person(s). This functionality allows text to be used in the same conversational mode as voice.” RTT is viewed by many in the disability community as a replacement for the dated TTY technology and preferable, from a human interface perspective, to message-based text, as it more closely approximates the speed and flow of human voice conversation. RTT also prevents messages from crossing each other during a call, and for this reason

may be preferred over SMS as a means of facilitating the exchange of information between the caller and the PSAP dispatcher.

35. Still Images (Photos). Still images are captured by a digital camera, typically encoded into a compressed file format, such as JPEG, and made available as a single data object (file). Still images may help 911 call takers and first responders assess the severity of an incident or apprehend a criminal suspect.

36. Real-Time Video. Real-time (live) video may be captured by a webcam, a camera built into a mobile phone, a networked security camera, or another video-capable device. The live nature of real-time video distinguishes it from streaming video, which is typically used for watching entertainment content. Real-time video will help first responders better gauge the scope and nature of an incident and will also help determine a caller’s precise location.

37. Telemetry Data. Telemetry data includes all sensor measurements that quantify physical, chemical, or biological phenomena. Examples include vehicular information (such as current speed and crash-related data), biological and environmental sensors that measure wind and temperature, and physiometric sensors that measure human pulse rates.

38. Auxiliary Medical and other Personal Data. Auxiliary data would include relevant information about the caller’s medical conditions and particular treatment needs, as well as information related to those categories. Such information could be provided on a prior-consent basis to the PSAP for forwarding to EMS personnel or other first responders.

2. Primary vs. Secondary Usage of Media Types

39. We also seek comment on the degree to which each of the media types discussed above will be used as a primary versus a secondary form of communication on NG911 networks. By “primary” media, we refer to media that provide the basic communications link between the 911 caller and the PSAP during the emergency call. By “secondary” media, we refer to media that may convey additional information between the caller (or the device used by the caller) and the PSAP to augment the primary communication. Primary media will likely include voice, RTT, and text-based messaging (SMS, instant messaging), because of differing degrees, all of these media types will permit live conversations between the 911 caller and the PSAP. Thus, primary media can also be considered “conversational

media.” Primary media will likely be used to convey the nature and location of an emergency to a PSAP. In some cases, primary media may not be available to a 911 caller (e.g., due to network congestion or end system limitations). In these cases, we seek comment on whether e-mail or social network status pages could possibly be used as the primary means of contacting a PSAP. Secondary media will likely include transmission of photos, live video, and sensor data (e.g., data acquired from sensors commonly found in mobile devices, vehicles, and medical monitoring systems). We envision a PSAP most frequently using secondary media to acquire supplemental information from a 911 caller or the caller’s device.

40. The Commission seeks comment on what primary and secondary media types PSAPs and service providers will likely support. Should individual PSAPs be able to choose the media types that they will support, or should all PSAPs be expected or required to support a specific set of media types? Should different standards or requirements apply to primary conversational media as opposed to secondary non-conversational media? If secondary non-conversational media include the capability to transmit sensitive personal data, what privacy protection concerns are raised and how should they be addressed? Would changes in current laws, regulations, tariffs, and overall policies be needed to enable NG911 to support these media types and system features?

3. SMS for Emergency Communications

41. In light of the popularity and ubiquity of SMS, many consumers may assume that they are or will soon be able to text to 911. Indeed, consumer use of SMS has exploded in the past decade and billions of SMS messages are sent each day. Also, unlike some of the other media types discussed above, SMS is readily available on most mobile phones, and thus its implementation into the NG911 network may be one of the first steps in moving beyond a voice-only emergency calling framework. SMS, however, has limitations that will need to be addressed if it is to become a reliable means for emergency communications. For example, a recent study noted that SMS is an asynchronous messaging service that does not provide a means for the sender to know whether and when the message has reached its destination. In addition, the study noted that because each SMS is independent of its predecessors, it is difficult to ensure that messages within

the same logical conversation are routed to the same destination.

42. Given these limitations, we seek comment on how the increasing use of SMS may impact emergency communications and whether NG911 networks should be configured to support SMS emergency communications. For example, are there any proposed technical standards or approaches that would sufficiently address routing and location concerns? Further, will it be possible to use the existing short code system to reach PSAPs? Are there measurement results for mobile-to-fixed messaging that indicate the reliability and delay of SMS delivery under specified circumstances? Would it be possible to add location information to SMS messages to help in routing such messages and, if so, how? Would it be possible to maintain session continuity across messages, *e.g.*, at the gateway between the cellular network and the IP network? Can end-system SMS applications address some of the location-related issues, *e.g.*, waiting to send an emergency SMS until location information has been acquired? Have there been trials or operational experiences using SMS within the NG911 architecture? Should SMS be considered primarily as a fall-back mechanism when voice communications are difficult or impossible to transmit? As wireless systems evolve to IP based 4G architectures, can the reliability and features of SMS messaging be improved for the purposes of emergency communications and if so, how?

43. We also seek comment on existing and future public expectations related to the use of SMS for emergency communications. Do consumers understand that currently available SMS generally does not support sending text messages to 911? Could the implementation of NG911 lead to changes in consumer expectations and public misunderstandings about SMS capabilities? Is there a need for programs to educate the public about the limitations of SMS for emergency communications, and if so, what entity should be responsible for developing such programs? Are there liability issues that could arise if consumers unsuccessfully attempt to use SMS for emergency communications?

4. NG911 Applications for Persons with Disabilities and Special Needs

44. According to the ICO Plan, “[t]he biggest gap between the technologies used for daily communication and those that can access 9–1–1 services is that for the deaf and people with hearing or speech impairments.” As noted in

paragraph 11, *supra*, the Twenty-First Century Act directs the Commission to form the EAAC with the purpose of determining the most effective and efficient technologies and methods by which to enable access to NG911 emergency services by individuals with disabilities. Moreover, the Twenty-First Century Act provides that “[t]he Commission shall have the authority to promulgate regulations to implement the recommendations proposed by the [EAAC], as well as any other regulations, technical standards, protocols, and procedures as are necessary to achieve reliable, interoperable communication that ensures access by individuals with disabilities to an Internet protocol-enabled emergency network, where achievable and technically feasible.” In addition, the National Broadband Plan recommended that NHTSA include “an analysis of the needs of persons with disabilities and should identify standards and protocols for NG911 and for incorporating VoIP and ‘Real Time Text’ standards.” ICO has noted that when it analyzed trial deployments of IP-enabled emergency networks, texting access through various IP-devices, RTT, and third-party conferencing was successfully demonstrated. Additionally, streaming video and SMS were successfully demonstrated, but with key shortcomings.

45. The Commission seeks comment on what media types and devices (*e.g.*, text, video) persons with disabilities will likely use to make an emergency call in an NG911 environment. We understand that some people with hearing and speech disabilities make emergency calls directly; others use telecommunications relay services (TRS), a more indirect method to make these calls. How can the Commission ensure that persons with disabilities receive the appropriate benefits from the NG911 system? What, if any, technical or accessibility requirements should be imposed to ensure that persons with disabilities have the necessary access to the NG911 system? To what extent can real-time text, which permits the live exchange of information with a PSAP during a call, assist individuals with hearing or speech disabilities who wish to call 911 directly? Finally, the Commission requires IP-based text and video relay providers to ensure the prompt and automatic call handling of emergency calls. What considerations are necessary to ensure effective access to NG911 services for callers who continue to rely on IP-based relay services for their 911 calls? Are there different considerations for individuals

who continue to use PSTN-based relay services?

46. The Commission recognizes the significant public safety interest in ensuring that non-English speakers have access to emergency services. We seek comment on what media types non-English speakers likely will use to make an emergency call in an NG911 environment. What types of devices may non-English speakers use to make an emergency call in an NG911 environment? How can the Commission ensure that non-English speakers receive the appropriate benefits from the NG911 system?

47. The ability to share information—including medical information—could be of particular value to EMS and other first responders. Should such information be provided in the ordinary course to EMS and other first responders in a manner similar to the provision of medical condition information described in paragraph 37, *supra*? Since privacy protection concerns would seemingly be implicated in this case, as in the case of transmitted medical information, how should such concerns be addressed?

48. Independently of the Commission’s efforts in connection with the EAAC, we seek comment on whether the Commission should conduct a separate rulemaking to ensure that individuals with disabilities have access to an Internet protocol-enabled emergency network, where achievable and technically feasible.

B. NG911 Network Architecture

1. Transport Mechanisms in an NG911 Environment

49. In this section, we seek comment on the mechanisms that will be used to transport digital content across NG911 networks. In an IP-based NG911 architecture, unlike a circuit-switched architecture, a variety of protocols can be used to transport media types across the network from the 911 caller to the PSAP. For example, still images can be carried: (1) As Multimedia Messaging Services (MMS) sent by mobile devices, (2) as attachments to Internet e-mail, (3) within instant images and uploaded to social network services, or (4) on other web services. We note that a diverse mix of physical infrastructures, networking protocols, applications, and devices may facilitate the carriage of potential NG911 media types from a 911 caller to a NG911-enabled PSAP. For example, some carriage scenarios may rely solely on “pure” IP-based solutions, some may rely heavily on existing legacy infrastructure, and some may rely on gateway packet-based communications

between callers and PSAPs. We seek comment on each of these technical approaches and request that commenters discuss operational, business, and other policy strengths and weaknesses of each approach. For example, while application of IP-based approaches has generally led to robust and unexpected innovations in communications technologies, PSAPs could face operational and funding burdens from supporting a large number of IP-based NG911 architectures, and resources could be diverted from technical solutions that incorporate standardized features and implementation approaches. Similarly, introduction of operational requirements such as reliability, scalability, and standardized technology

could result in tradeoffs between various legacy, proprietary, end-to-end open-standard, or other approaches for IP-based NG911 systems. We request that commenters identify these tradeoffs, or other relevant tradeoffs, and discuss the relative strengths and weaknesses of these technical approaches.

2. NG911 Participants

50. In the traditional 911 system, only a small number of entities participated in the provisioning of emergency calling services because an E911 call would originate from an end user device that was in practice tightly-coupled, both technically and administratively, with the service provider's transport network. Examples include a conventional

wireline phone, a mobile phone, and an interconnected VoIP phone.

51. In a NG911 environment, however, end user devices are far more likely to be liberated from a particular transport network. This treatment acknowledges important industry trends, such as the increasing portability of devices among service providers, open access possibilities, and the increasing use of user-selected IP-based devices that may exploit widely-available sources of Internet access. As such, the number of participants in an NG911 environment will increase dramatically. The table below lists the potential NG911 participants and their possible roles in an NG911 environment.

Participant/Affected by	Media transport and encodings	Call/Message identification	Location provisioning	Call/Message routing
PSAPs	X	X	X	X
VSP and application service providers		X		X
Residential ISP			X	
Non-traditional ISP (hotels, coffee shops, community networks, etc.)			X	
Enterprise IP-PBX	X	X	X	X
UE vendors	X	X	X	X
Communication software developers	X	X	X	X
Home gateway manufacturers			X	

52. Currently, only devices that provide telephone services are capable of transmitting 911 calls. In the future, however, most electronic devices will have communication capabilities, ranging from televisions, in-car systems, portable music players, tablet computers, and game consoles. We seek comment on what devices can usefully provide emergency calling services. Should every consumer device with Internet or cellular connectivity and a suitable user interface have the ability to request emergency assistance? Should such devices be certified and labeled as 911-capable? How will a user of a device or software be able to tell whether a device or communication software is capable of placing 911 calls? If this capability is conditional, e.g., on properly-configured network connectivity, can the user or device test 911 reachability?

53. In the *E911 Scope Order*, the Commission established the following four criteria for determining which licensees should be subject to the wireless enhanced 911 obligations: Those licensees that (1) offer real-time, two-way switched voice service, interconnected with the PSTN, either on a stand-alone basis or packaged with other telecommunications services; (2) whose customers clearly expected

access to 911 and E911; (3) that competed with analog and broadband PCS providers; and (4) where it is technically and operationally feasible to provide enhanced 911 service. Should the Commission consider expanding or modifying the four criteria from the E911 911 Scope Order to apply to additional NG911 participants? For example, should hot-spot providers that are not traditional communications providers, such as coffee shops, hotels, bus lines, and public parks be expected to play a role in the deployment of NG911?

3. Interoperability and Standards

54. Many potential NG911 media types permit a range of encoding and performance parameters. For example, photos are typically compressed using the JPEG standard, but may also use other formats. Photos may also include meta data (EXIF), ranging from camera settings to embedded geographic location. Further, camera images can range from low-resolution web cam photos with less than one megapixel to professional-quality images with more than 15 megapixels and several megabytes in size. For text, accented and foreign language characters can be represented in a range of character encodings with Unicode in its UTF-8

encoding among the most popular. While a wide variety of digital formats are potentially available for encoding such information, NG911 will require use of compatible formats across the network, so that PSAPs can receive and process the text, photos, and other digital information that are sent by the public. We seek comment on how best to ensure such compatibility in the formatting and coding of text, photos, and other digital information. Should there be standards for media encodings? Should we specify minimal performance ranges, e.g., minimum file sizes for digital images, that NG911 networks must support and PSAPs be able to accept?

55. If there is a need to develop standards for digital information transported on NG911 networks, what entity should set and update these standards, or assist in their coordination? Should the standards be national or international? Are there standards efforts currently under way that could form the basis for future evolution in this regard? Should specific technical standards or architectures be mandated? How can the interoperability of end user devices and PSAP devices be ensured (e.g., through interoperability testing)? Should there be a certification process that indicates

whether a device or downloadable software application is compliant with certain standards? If so, what form of certification seems to be the most suitable, *e.g.*, self-certification or approved certification organizations? Should all devices of a certain class be required to meet the certification criteria? As more people—especially within the disability community—begin to make video-based telephone calls, are there steps needed to ensure that NG911 networks interoperate seamlessly with the video software and applications being utilized in smart phones, tablets, computers and other devices? Similarly, are there steps needed to ensure interoperability with the video communication services provided by all video relay service providers?

4. PSAP Functions in an NG911 Environment

56. As noted earlier, IP-based technology removes many of the location constraints of traditional circuit-switched technology. In particular, a PSAP no longer has to be in a single building at a fixed location. Call takers that are organizationally part of a single PSAP can be located virtually anywhere an Internet connection can be found, and a single call taker could be supporting multiple PSAPs. Such “virtual PSAP” arrangements may allow more flexible and efficient staffing and may allow PSAPs to better recover from major disasters by temporarily relocating operations. We seek comment on the potential for development of virtual PSAPs as part of the transition from legacy 911 to NG911. Are current technologies sufficient to support virtual PSAPs? Are there regulatory or legal barriers changes that are necessary to facilitate the development and operation of virtual PSAPs? Are there current PSAP databases that would need to be standardized to support a remote “virtual PSAP”? How could local data that is contained in current Computer Aided Dispatch Data Bases, MSAGs, and other repositories that are necessary for an efficient response by emergency personnel be distributed on a timely and reliable basis for use by non-local PSAPs?

57. While emergency service networks and PSAPs will continue to be operated and managed regionally, the deployment of NG911 may require a set of national infrastructure components. Based on the current NENA NG911 architecture, these may include: (1) A national PSAP and ESInet lookup directory, called the LoST “forest guide”; (2) a public-key cryptography certificate to ensure that other NG911 entities can authenticate PSAPs and to

ensure that PSAPs are capable of receiving access to sensitive information; and (3) interconnection to an IP-based national network to ensure that emergency calls can be routed amongst PSAPs without PSAPs losing information. The Commission seeks comment on whether it is necessary to establish a national set of infrastructure components to ensure the deployment of NG911. If it is necessary, what entity should operate this national set of infrastructure components?

C. Other Specialized NG911 Applications

58. Device-Initiated Services for Emergency Communications. In an IP-based network architecture, emergency calls can be placed not only by human beings, but by a variety of automatically triggered devices. Examples of such devices include environmental sensors capable of detecting chemicals, highway cameras, security cameras, alarms, personal medical devices, telematics, and consumer electronics in automobiles. We seek comment on how the deployment of NG911 will facilitate the ability of device-initiated emergency services to reach PSAPs. What steps are needed to facilitate such deployment? Is there a need to modify existing laws, regulations, or tariffs to ensure that device-initiated emergency services have access to the NG911 network?

59. Social Media for Emergency Communications. How have consumers used social media to report an emergency or contact public safety during an emergency? How will consumers expect to use social media for emergency purposes in the future? To what extent might State and local public safety jurisdictions employ social media tools as a way to interact with the public? How will these tools impact the deployment of NG911?

60. N11 Numbers and Other Services for Emergency Communications. The basic functionality of NG911 is similar to many other location-based information and assistance services, such as 211 (community information and referral), 311 (non-emergency city services), 511 (traffic information), poison control, call-before-you-dig, and other similar services. Since these services share much of the same technical functionality, it may be possible to reduce cost and improve service by integrating some of these services to use a common technology platform. Further, callers may need to be transferred from one service to another, *e.g.*, from 911 to 311 or 211. Can such coordination and integration be helpful and cut costs? How will the deployment of NG911 address N11

numbers, including N11 services such as 311, which is designated for non-emergencies? How will the deployment of NG911 impact other emergency services, such as poison control centers using 800 services? How will the deployment of NG911 affect TRS that use 711?

61. Auxiliary Data. NG911 offers the opportunity to provide additional data to PSAPs and first responders, such as the caller’s medical history, a description of the caller’s residence or business location, and related data, including building floor plans, information about hazardous materials, and building occupants with special needs. This data will often be maintained and provided by third parties, such as health care organizations that maintain electronic medical records or commercial landlords that maintain floor plans. How should the PSAP be informed about the availability of this data? What entity should associate this information with the call or message, such as the application service provider or a third party? Is there a need for regulations that require an application service provider to supply these services, *e.g.*, by providing the appropriate call signaling or lookup functionality? Is there a need for standards to ensure that PSAPs and first responders receive access to this data without every PSAP having to make individual arrangements with each data source? Since this auxiliary data may be considered part of the 911 call record and therefore subject to public disclosure, is there a need to protect the privacy of this data differently than the remainder of the call information?

62. Disaster Planning and Recovery. How will NG911 facilitate disaster planning and recovery? How will NG911 interact with existing and future public alerting systems? Can national security be enhanced by the consistent implementation of interoperable NG911 systems across the nation? What key NG911 elements should be the focus for consistent implementation and interoperability?

63. MLTS for Emergency Communications in an NG911 Environment. Currently, MLTS operators are not subject to the FCC’s E911 regulations. In 2003, the Commission found that economic and competitive factors existed that rendered it impracticable to adopt E911 requirements for MLTS. The Commission, however, sought comment on its “jurisdiction over MLTS operators, in light of the Commission’s earlier interpretations of its section 4(i) authority and its prior statement that

‘the reliability of 911 service is integrally related to our responsibilities under section 1 of the Act.’” In light of NG911’s potential impact on MLTS, we seek comment on whether the Commission has the jurisdiction to regulate MLTS operators. How will the deployment of NG911 improve emergency services for MLTS users? Will MLTS operators be able to provide improved location information in an NG911 environment?

D. Issues Related to NG911 Implementation/Transition

64. We seek comment on the potential operational, technical, and other challenges associated with the transition to NG911. As both the ICO Plan and the National Broadband Plan highlight, the transition to NG911 will be an evolutionary process, involving technological, economic, and institutional challenges. The ICO Plan also noted that “a timetable for national deployment of NG9–1–1 is difficult to estimate due to the lack of:

- Consistent funding for planning, training, deployment and implementation;
- Complete set of standards and time required to develop them; and
- Coordinated planning and implementation efforts by stakeholders at all levels (e.g., government, industry, OSPs, standards organizations).”

65. In light of these challenges, what actions should the Commission take to encourage the deployment of NG911? Have there been any recent developments that provide additional details on a potential timeline for NG911 deployment? Have there been any coordinated management efforts by State, Tribal, or local governments? Should there be a national set of milestones that provide a planning horizon? If so, what entity or entities should set those milestones, measure progress, and disseminate the measurement results? What are the milestones that will be useful to accelerate and measure NG911 deployment? What changes will need to take place in the emergency communications governance structures, at both the Federal and non-Federal levels, to facilitate NG911 planning and implementation? What policies can be established to enable and instigate the development and deployment of shared State-wide ESInet, and related cooperative working agreements between Federal, State, Tribal, and local agencies, as a fundamental 911 and emergency communications policy objective? Will waivers of certain rules and regulations be necessary during the transition to NG911? Should the FCC

provide certain criteria for consideration of waiver grants?

1. Disparate PSAP Capabilities in an NG911 Environment

66. Because the transition to NG911 is likely to be gradual rather than a large scale “flash cut,” what can be done to ensure that NG911 networks interoperate seamlessly with legacy networks? PSAPs will likely offer different capabilities for both primary and secondary media types during the transition to NG911; however, consumers in need of emergency services will also expect a uniform experience. For example, it may confuse consumers if they can use IP-based devices and applications to reach a PSAP in one county, but cannot use them to reach a PSAP in a neighboring county. Will the deployment of NG911 permit statewide or nationwide PSAPs to uniformly support new emergency communication capabilities? We seek comment on whether a timetable or deadline should be established for all PSAPs to support a minimal set of NG911 capabilities. Should we implement a timetable or deadline to ensure that all primary media types can be used to contact 911? Should certain media types, such as message-based text, only be permitted for emergency purposes when a threshold percentage of PSAPs across the country can accept these media types? Is fallback routing acceptable, where larger regional entities handle media types, such as SMS, when the local PSAP cannot? If this is not the best path forward, how should consumers determine what media types they can use to reach emergency services in their locality? Should NG911-enabled devices be able to automatically discover the local NG911 capabilities?

2. 911 Competition

67. In the current 911 system, incumbent local exchange carriers are the primary 911 System Service Providers (SSPs); however, in the NG911 environment, there are likely to be multiple SSPs offering a variety of service capabilities and options. Thus, NG911 systems will provide the opportunity for competitive services to emerge in the 911 marketplace. However, as NENA has pointed out, there are many State, local, and Federal regulations that may inadvertently inhibit the transition to NG911. We seek comment on both the potential benefits and potential drawbacks of competition in the 911 marketplace. If competition does provide a benefit, what steps should be taken at both the Federal and

non-Federal level to enable competition for the delivery of NG911 services?

68. Since many 911 laws and regulations were written in an era where the technological capabilities of NG911 did not exist, we seek comment on how legislative and regulatory bodies can modify their laws and regulations to ensure that they keep pace with the rapidly changing public safety marketplace. As NENA noted, “[d]uring the transition to NG9–1–1 * * * rights and obligations are unclear for those companies that are providers of IP services and seek to provide complete systems * * * [thus] * * * a clarification of rules impacting the delivery of 9–1–1 and emergency services is needed in the near term.” Given these new opportunities, what regulations should the Commission implement, or clarify, to facilitate an open and competitive NG911 environment?

69. How competitive is today’s 911 system in terms of call routing, switching, transport, and database management services? Are there current laws and regulations that would inhibit an interoperable environment for NG911? Can these laws and regulations be modified to enable the IP-based, software, and database controlled structure of NG911? How do State laws and local ordinances that currently exclude non-voice based communications, automated 911 access, and sensors affect the deployment of NG911? Are disparate cost recovery mechanisms for originating 911 traffic and data costs and varying interconnection requirements impeding the transition to NG911? Do incumbent 911 system service providers have sufficient incentives to upgrade their technology absent regulatory change? Specifically, will NG911 architecture encourage more competition in the provision of 911 services? Should the FCC encourage such competition, and if so, how? What actions are necessary to optimize 911 governing authority choices for competitive NG911 SSPs, including the ability of governing authorities to act directly as SSPs? Should existing regulations, laws, or tariffs be modified to ensure that 911 governing authorities or new 911 SSPs are entitled to receive relevant routing, location, and other related 911 information at reasonable rates and terms? Should laws, regulations, and tariffs be modified to account for the responsibility of cost distribution for the decreasing use of shared legacy resources, such as legacy selective routers?

70. NENA has also recommended that the Commission examine its use of the term “wireline E9-1-1 network” as defined in section 9.3 of the Commission’s rules. According to NENA, “[i]t could be argued that this definition would not allow for the routing of 9-1-1 calls via an IP-based NG9-1-1 system.” The Commission seeks comment on NENA’s recommendation. What other regulations need to be modified or expanded to enable data based services and other NG911 capabilities, including the expansion of call routing from a location-only basis to more effective forms, such as caller characteristics or needs (*e.g.*, hearing or speech impaired, preferred language, *etc.*)?

3. Liability Concerns

71. NG911 will promote a more complex service delivery environment, with more types of services able to connect to NG911 systems, more external data sources available to PSAPs, and increased information-sharing options among emergency response agencies. While this flexibility promises to provide benefits to the public and PSAPs, it is also likely to create more complex liability issues and may require new forms of liability protection for providers of NG911-related services.

72. Liability concerns may arise in a variety of contexts, based on the variability and complexity of NG911 services. For example, PSAPs may face differing liability scenarios depending on whether they choose to receive all possible information from all devices or to limit their systems to receipt of certain information or devices. Moreover, because NG911 can provide far more detailed information in real time than legacy 911, new liability issues may arise if errors occur in the transition of such data. For example, a 911 call could arrive at a PSAP from a telematics-equipped vehicle with information on the severity of a crash along with information from the vehicle occupants’ electronic health records. Based on this information, algorithms may be able to predict the probability of severe injury and suggest a certain type of response. These capabilities are intended to result in the appropriate level of care quickly being sent to victims in need of assistance; however, they may also result in unintentional errors and liability exposure. Liability issues may also arise from the transfer of emergency calls and data outside the NG911 system, such as among multiple national N11/800 numbers (*e.g.*, 211, 311, 811, 911, suicide hotline, poison control centers). The current ability to

transfer calls and data among the multiple N11 entities is limited, but will not be as NG911 systems are deployed and N11 calls are able to be routed over shared networks. As a result, these entities may be exposed to liability.

73. These examples illustrate that NG911 may raise liability concerns both for PSAPs and for commercial providers of NG911-related services, and that liability protections may therefore need to be modified in an NG911 environment. Some of the new communication services that have been proposed for inclusion in the NG911 ecosystem may offer benefits to the intended user. However, in their present implementation, these services may not provide the reliability and quality of service that is associated with an emergency service. We seek comment on whether and how liability protections should be modified to ensure that NG911 service providers and PSAPs are adequately protected in an NG911 environment. How should the benefits of these new modes of communication be balanced against the potential liabilities they may introduce? Are there actions that the FCC can take, consistent with its statutory authority, in regard to modifying liability protections? Should liability protection extend to all forms of information pushed to a PSAP or pulled from external sources by a PSAP, regardless of the platform over which information travels? Should liability protection extend beyond the PSAP to all entities appropriately involved in the emergency response? Should the FCC review its requirement that all 911 calls be routed to the “geographically appropriate” PSAP to ensure that 911 calls are not prevented from being intelligently routed to the appropriate PSAP, even if it is not the geographically closest PSAP? Does the possibility of 911 calls being answered by a “virtual” PSAP give rise to liability concerns that would need to be addressed?

4. Confidentiality and Privacy Concerns

74. The legacy 911 system is a dedicated, closed, single-purpose system. Since information associated with a 911 call in today’s system is generally stored in a single restricted location, preserving the confidentiality of the information and retaining appropriate records as required by law is relatively straightforward. Conversely, NG911 systems will be shared systems comprised of multiple entities. Indeed, the NG911 network may be only one part of a much larger system that will be shared with government, private sector, and other public safety entities. As

previously noted, the number of media types that may be received by PSAPs and shared with emergency response agencies will greatly surpass that of current E911 systems.

75. In light of the shared nature of NG911 architecture, we seek comment on whether privacy laws or regulations will need to be modified to adapt to the NG911 environment. What privacy concerns will be introduced with the deployment of NG911? What existing or new regulations might be necessary to ensure appropriate privacy controls? Will the definition of a “911 call” need to be modified in certain statutes and rules? How should we address concerns regarding private personal information that may be transmitted as part of an NG911 communication, for example, personal medical information that NG911 can provide to PSAPs and other third parties? How can 911 call takers at virtual PSAPs legally access 911 call data when necessary, while requiring adherence to appropriate confidentiality, disclosure, and retention statutes and rules?

5. Location Capabilities

76. As noted in the ICO Plan, new location-based technologies and applications have generated an increased demand for location services, yet the decoupling of originating service providers from network operators will make the delivery of real-time, automatic location information more challenging. To what degree should Federal regulations require that access providers provide call location data to end systems and/or voice service providers on reasonable and non-discriminatory terms, using standard protocol interfaces? How can stationary, nomadic, and mobile end systems in wireline and non-cellular wireless networks (including Wi-Fi) reliably discover their location information to ensure call routing and dispatch? What, if any, obligations need to be imposed on Internet service providers, residential and enterprise equipment vendors, and other parties to ensure that location information can be discovered, conveyed, and validated? Is there a need for a national or regional certification entity that will allow a provider of location information to cryptographically sign the location information?

6. Network and Data Security Concerns

77. The IP-based nature of NG911 architecture, and its complex relationship with other systems, gives rise to concerns about maintaining the security, integrity, and reliability of NG911 networks and information. We

seek comment on how to address these concerns. Will the deployment of NG911 allow increased security of information through role-based access control and data rights management that limits access to information only to authorized entities? What additional security concerns will be implicated by the transition to NG911 as compared to the legacy 911 security functionality? How can the NG911 network be protected against viruses, cyber attacks, fraudulent or harassing transmissions, and other unwarranted intrusions and interruptions?

7. Education

78. What role will public information campaigns play in the transition to NG911? How can the Commission ensure that public safety personnel, consumers, and carriers are aware of NG911 deployments? What entities should lead and contribute to consumer education? Should the Commission foster common terms and terminology to facilitate the deployment of NG911? How can we ensure that other relevant organizations are aware of NG911's benefits, such as mobile health and telemedicine? Beyond the EAAC, how can we ensure that the disability community is involved with and aware of the transition to NG911?

8. Unidentified Caller Access to NG911

79. Given the proliferation of services and devices that will be able to initiate emergency calls in an NG911 environment, there will likely be many more ways for callers to contact a PSAP, including those callers that do not have an active subscription with an application (voice) service provider, or do not have access privileges for the wireless network available at their current location.

80. We are concerned that unauthorized access to the NG911 network will increase the number of unintentional, prank, or malicious calls to a PSAP. However, there may be opportunities to reduce the risks by creating authorization models that are separate from traditional subscriber arrangements. As a hypothetical example, State motor vehicle authorities could provide, as part of their normal identity management operations, network and Application Service Provider (ASP) credentials that would be valid for emergency calls. We seek comment on whether such emergency-call-only credentials would be desirable and feasible? If so, how can they be implemented? What regulatory arrangements would be necessary to facilitate this emergency-call authentication?

81. Even if new authorization procedures can be developed, it may still be necessary for NG911 systems to support emergency communications in some circumstances where the caller cannot be identified. We seek comment on how this problem can be addressed. When would it be appropriate for the NG911 system to support emergency calls without authentication and/or authorization? Should ASPs be required to support emergency calls for zero-balance customers? Should providers of public and semi-public wireless data networks, such as 802.11 hot spots, be required to provide access for emergency calls?

9. International Issues

82. Currently, an international traveler can make a 911 call in the United States as long as the traveler's mobile phone can connect to the local wireless network. In an NG911 environment, an international traveler's home ASP can route an emergency call to the appropriate PSAP in the United States, even if the ASP is located in another country. However, regulatory arrangements may be needed to make this call routing feasible. Should these types of calls be supported by NG911? What kind of arrangements and regulatory changes will be needed to facilitate these calls?

E. Jurisdiction, Authority, and Regulatory Roles

83. State, Tribal, and local governments are the primary administrators of the legacy 911 system and are responsible for establishing and designating PSAPs or appropriate default answering points, purchasing customer premises equipment, retaining and training PSAP personnel, and purchasing 911 network services. Certain communications technologies, however, necessitated the adoption of a uniform national approach. For example, following the introduction of CMRS in the United States, the Commission established rules requiring CMRS carriers to implement basic 911 and E911 services. In addition, Congress adopted the 911 Act to promote and enhance public safety through the use of wireless communications services. The 911 Act directed the Commission to designate 911 as the universal emergency assistance number for wireless and wireline calls, which the Commission accomplished in 1999. The 911 Act also required the Commission to consult and cooperate with State and local officials in its role of encouraging and supporting the deployment of "comprehensive end-to-end emergency communications infrastructure and

programs." Similarly, in applying E911 rules to interconnected VoIP in 2005, the Commission noted that a uniform national approach was necessary to ensure that the quality and reliability of 911 service would not be damaged by the introduction of new communications technologies that posed technical and operational challenges to the 911 system. In 2008, Congress codified these rules in the NET 911 Act.

84. The level and manner of State-level coordination of 911 services varies widely. In some states, 911 service is strictly a local matter. Other states have centralized the 911 program function or have otherwise established a statewide coordination mechanism, although their circumstances and authority vary widely. Another factor that varies widely is the extent to which states have coordinated their 911 systems with those of Tribal governments. Although the staffing of PSAPs and handling of 911 calls will generally remain a local function, certain aspects of transitioning to NG911 will require State-level planning and implementation coordination. For example, according to NENA, "ESInets will be developed and managed locally or regionally, but will need strong State-level leadership and coordination to ensure both operability and interoperability of State, local, and regional ESInets." In light of the variation in State-level approaches to legacy 911, we seek comment on the ability of states to effectively coordinate the transition to NG911. Should each State designate an organization that will be responsible for planning, coordinating, and implementing the NG911 system in that particular State? Similarly, we seek comment on how coordination with Tribal governments is effectuated at the local level.

85. We also seek comment on whether there should be Federal oversight or governance of State deployment of NG911. The National Broadband Plan called on Congress to enact and the FCC to implement a Federal NG911 regulatory framework that confers Federal jurisdiction and oversight for the "development and transition to NG911 networks" while preserving "existing State authority for 911 services." We seek comment on the extent of the FCC's jurisdiction to oversee the transition to NG911, since PSAPs, service providers, consumer device manufacturers, and software developers will all be involved. We also seek comment on the role that other Federal agencies, such as ICO and those entities with responsibilities to Tribal lands, should play. Should a single Federal entity be established to oversee

the transition to NG911? Should there be a single Federal entity to ensure compliance with required standards, coordination, implementation, and policies? Should there be a national policy established by the Commission or another Federal entity to ensure consistent regulation? What entity should enable and instigate the development and deployment of shared State-wide ESInets and related cooperative working agreements between Federal, State, tribal, and local agencies? What functions and responsibilities should be performed at the Federal, regional, State, Tribal, and local levels in the implementation, transition to, and ongoing operation of NG911 in areas including networks, NG911 functional elements, databases, system operation, and PSAP operation? What statutory or regulatory changes, if any, would be necessary for the Commission, other Federal agencies, States, Tribes, or localities to facilitate and oversee NG911?

86. How should the FCC coordinate with other Federal agencies on issues related to the deployment of NG911, such as mobile health, telemedicine and disability access? How should the FCC and other Federal agencies coordinate with the states and Tribal governments? Should the FCC provide oversight to the states as they assume leadership roles in the transition to and implementation of NG911 systems within and between states?

V. Procedural Matters

A. Paperwork Reduction Act

87. This document does not contain proposed information collection(s) subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104-13. In addition, therefore, it does not contain any new or modified "information collection burden for small business concerns with fewer than 25 employees," pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107-198, see 47 U.S.C. 3506(c)(4).

B. Ex Parte Presentations

88. The inquiry this Notice initiates shall be treated as a "permit-but-disclose" proceeding in accordance with the Commission's ex parte rules. Persons making oral ex parte presentations are reminded that memoranda summarizing the presentations must contain summaries of the substance of the presentations and not merely a listing of the subjects discussed. More than a one or two sentence description of the views and arguments presented generally is

required. Other requirements pertaining to oral and written presentations are set forth in section 1.1206(b) of the Commission's rules.

C. Comment Filing Procedures

89. Pursuant to sections 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using: (1) the Commission's Electronic Comment Filing System (ECFS), (2) the Federal Government's eRulemaking Portal, or (3) by filing paper copies. See Electronic Filing of Documents in Rulemaking Proceedings, 63 FR 24121 (1998).

- *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the ECFS: <http://fjallfoss.fcc.gov/ecfs2/> or the Federal eRulemaking Portal: <http://www.regulations.gov>.

- *Paper Filers:* Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

- Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

- All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St., SW., Room TW-A325, Washington, DC 20554. The filing hours are 8 a.m. to 7 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building.

- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.

- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street, SW., Washington DC 20554.

90. *People with Disabilities:* To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an e-mail to fcc504@fcc.gov or call the Consumer & Governmental Affairs Bureau at 202-418-0530 (voice), 202-418-0432 (tty).

VI. Ordering Clause

91. Accordingly, *it is ordered* that, pursuant to the authority contained in sections 4(i), 4(j), 10, 218, 303(b), 303(r), and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 154(j), 160, 218, 303(b), 303(r), and 403, this Notice of Inquiry *is adopted*.

Federal Communications Commission
Marlene H. Dortch,
Secretary.

[FR Doc. 2011-565 Filed 1-12-11; 8:45 am]

BILLING CODE 6712-01-P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 575

[Docket No. NHTSA 2011-0005]

RIN 2127-AK06

Consumer Information Regulations; Fees for Use of Traction Skid Pads

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice of Proposed Rulemaking (NPRM).

SUMMARY: This NPRM proposes to amend NHTSA's consumer information regulations on uniform tire quality grading standards by updating the fees currently charged for use of the traction skid pads at NHTSA's San Angelo Test Facility, formerly called the Uniform Tire Quality Grading Test Facility, in San Angelo, Texas and by eliminating fees for course monitoring tires, which are no longer supplied by NHTSA. This NPRM updates the fees in accordance with Office of Management and Budget Circular A-25, which governs fees assessed for Government services and use of Government goods or resources.

DATES: Comments to this proposal must be received on or before March 14, 2011.

ADDRESSES: You may submit comments, identified by the docket number in the heading of this document, by any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the instructions for submitting comments on the electronic docket site by clicking on "Help" or "FAQ."

- *Mail:* Docket Management Facility, M-30, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Rm. W12-140, Washington, DC 20590.

- *Hand Delivery or Courier:* 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12-140, between 9 a.m. and 5 p.m. Eastern Time, Monday through Friday, except Federal holidays.
- *Fax:* (202) 493-2251.

Regardless of how you submit your comments, you should mention the docket number of this document.

You may call the Docket Management Facility at 202-366-9826.

Instructions: For detailed instructions on submitting comments and additional information on the rulemaking process, see the Public Participation heading of the Supplementary Information section of this document. Note that all comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477-78) or you may visit <http://www.dot.gov/privacy.html>.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>, or the street address listed above. Follow the online instructions for accessing the dockets.

FOR FURTHER INFORMATION CONTACT: *For program issues:* Mr. George Gillespie, Office of Vehicle Safety Compliance, National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590. Telephone: (202) 366-5299.

For legal issues: Ms. Carrie Gage, Office of the Chief Counsel, National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590. Telephone: (202) 366-6051.

SUPPLEMENTARY INFORMATION:

I. Background

Section 203 of the National Traffic and Motor Vehicle Safety Act of 1966 directs the Secretary of Transportation to prescribe standards establishing "a uniform quality grading system for motor vehicle tires." 49 U.S.C. 30123. Those standards are found at 49 CFR 575.104. To aid consumers in making an informed choice in the purchase of passenger car tires, the standards require motor vehicle and tire manufacturers and tire brand owners to label such tires with information

indicating their relative performance in the areas of treadwear, traction and temperature resistance. See 49 CFR 575.104(a).

The Uniform Tire Quality Grading Standards (UTQGS), 49 CFR 575.104, state that tire traction is "evaluated on skid pads that are established, and whose severity is monitored, by the NHTSA both for its compliance testing and for that of regulated persons." 49 CFR 575.104(f)(1). As further described in the standards, the test pads are paved with asphalt and concrete surfaces that have specified locked wheel traction coefficients when evaluated in a manner prescribed in the standards. The traction skid pads are located at NHTSA's San Angelo Test Facility. 49 CFR 575.104, App. B. In addition to this government test facility, traction skid pads have been constructed at several commercial facilities.

The current fees charged for use of the traction skid pads at the San Angelo Test Facility, as well as fees charged for course monitoring tires, were established by final rule published in the **Federal Register** on August 2, 1995. See 60 FR 39269 (Aug. 2, 1995).¹ Pursuant to Appendix D to 49 CFR 575.104, the fees charged to manufacturers for use of the Government traction skid pads continue in effect until adjusted by the Administrator of NHTSA.

II. Proposal

This NPRM proposes to update, in accordance with Office of Management and Budget (OMB) Circular A-25, the fee charged to manufacturers for use of the agency's traction skid pads at the San Angelo Test Facility. It also proposes to remove provisions concerning the fees charged for course monitoring tires, as NHTSA no longer supplies these tires for purchase by manufacturers. Based on a current assessment using a "market price" analysis as outlined below, NHTSA proposes to update the fees for use of the facility from \$34.00 an hour, established in 1995, to \$125 an hour. As discussed below, NHTSA believes that this proposed fee reflects the current market price for use of traction skid pads.

OMB Circular A-25 establishes Federal policy regarding fees assessed

¹The August 2, 1995 final rule responded to a Department of Transportation Office of Inspector General (OIG) audit of NHTSA's facility in San Angelo in which the OIG concluded that NHTSA was not charging a user fee for the use of the traction skid pads at the facility and was not recovering the full cost of the course monitoring tires that it sold at San Angelo, contrary to OMB Circular A-25. See 60 FR 39269.

for Government services and for sale or use of Government goods or resources. The Circular expresses the general policy that "[a] user charge * * * will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public." According to the Circular, a "special benefit" accrues and a user charge is assessed when a Government service "is performed at the request of or for the convenience of the recipient, and is beyond the services regularly received by other members of the same industry or group or by the general public." Manufacturer use of NHTSA's testing facility is a special benefit because use of the facility is beyond the services regularly received by the industry or the general public.² Accordingly, NHTSA assesses a user charge for the use of the traction track.

For the purposes of assessing user charges, the Circular requires that, when the Government is acting in its capacity as sovereign, user charges be sufficient to recover the full cost to the Government of providing the good or service. When the Government is not acting as sovereign, however, user charges are to be based on market prices. The Government acts in its capacity as sovereign when it uses powers over which it has a monopoly. See e.g., *U.S. v. Reyes*, 87 F.3d 676, 681 (5th Cir. 1996). The Government may act in a sovereign capacity, for example, when it is the only source of a good or service, such as where the Government issues a license. See *National Park Service—Special Park Use Fees*, B-307319, *6 (Aug. 23, 2007).

The agency is not acting in its capacity as sovereign in making the San Angelo Test Facility available for traction testing by manufacturers. That facility serves primarily for NHTSA's own compliance testing of manufacturers' tires. As we recently stated with regard to the UTQGS regulations, manufacturers are not restricted to the use of the traction skid pads at the government facility in San Angelo. Rather, manufacturers may test their tires wherever they choose. See 75 FR 15894, 15913 (March 30, 2010).³

²While there is a public benefit in making available a standardized tire grading facility for manufacturer use, the public benefits are incidental to the special benefits derived by the manufacturers. According to Circular A-25, when the public obtains a benefit as a necessary consequence of an agency's provision of special benefits to an identifiable recipient, an agency should seek to recover the applicable fee from the identifiable recipient.

³It is the responsibility of each tire manufacturer to certify that its tires comply with applicable Federal safety standards.

Because NHTSA's own compliance tests are conducted at the San Angelo Test Facility, tire manufacturers often choose to do so as well.

III. Proposed Fee Update Based on Market Price

Pursuant to Circular A-25, "Market price' means the price for a good, resource, or service that is based on competition in open markets, and creates neither a shortage nor a surplus of the good, resource, or service." Where there is substantial competitive demand for a good, resource, or service, the market price is determined by commercial practice, for example, by competitive bidding, or by reference to the prevailing price of the same or similar good, resources, or services, adjusted to reflect demand, level of service and quality of the good or service.

To determine the appropriate market price for use of the San Angelo Test Facility, NHTSA surveyed several commercial facilities with traction skid pads available for public use. Prices for the hourly use of traction skid pads ranged from approximately \$115 per hour to approximately \$200 per hour. From its own experience, NHTSA believes that discounted rates may be available based on volume use or advance planning. Accordingly, NHTSA believes it is appropriate to take the availability of discounts into account in arriving at a determination of market rate. Taking a conservative approach, we propose to set the rate for use of the traction skid pads at the lower end of this range—\$125 per hour. NHTSA welcomes comments regarding whether our proposed rate for hourly use of the traction skid pads at the San Angelo Test Facility accurately reflects the market price for such services.

IV. Public Participation

Interested persons are invited to comment on this notice of proposed rulemaking. The procedure for submitting comments is noted below.

How do I prepare and submit written comments?

Your comments must be written and in English. To ensure that your comments are correctly filed in the Docket, please include the docket number at the beginning of this NPRM in your comments. Your primary comments cannot exceed 15 pages. See 49 CFR 553.21. We established this limit to encourage you to write your primary comments in a concise fashion. However, you may attach additional documents to your primary comments.

There is no limit to the length of the attachments.

Please submit your comments by any of the following methods:

- *Federal eRulemaking Portal*: go to <http://www.regulations.gov>. Follow the instructions for submitting comments to the electronic docket site by clicking on "Help" or "FAQ."
- *Mail*: Docket Management Facility, M-30, U.S. Department of Transportation, West Building, Ground Floor, Rm. W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- *Hand Delivery or Courier*: West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., between 9 am and 5 pm Eastern Time, Monday through Friday, except Federal holidays.
- *Fax*: (202) 493-2251.
- If you are submitting comments electronically as a PDF (Adobe) file, we ask that the documents submitted be scanned using Optical Character Recognition (OCR) process, thus allowing the agency to search and copy certain portions of your submissions.⁴
- Please note that pursuant to the Data Quality Act, in order for substantive data to be relied upon and used by the agency, it must meet the information quality standards set forth in the OMB and DOT Data Quality Act guidelines. Accordingly, we encourage you to consult the guidelines in preparing your comments. OMB's guidelines may be accessed at <http://www.whitehouse.gov/omb/fedreg/reproducible.html>.

How can I be sure that my comments were received?

If you submit your comments by mail and wish Docket Management to notify you upon its receipt of your comments, enclose a self-addressed, stamped postcard in the envelope containing your comments. Upon receiving your comments, Docket Management will return the postcard by mail.

How do I submit confidential business information?

If you wish to submit any information under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Chief Counsel, NHTSA, at the address given above under **FOR FURTHER INFORMATION CONTACT**. When you send a comment containing information claimed to be confidential business information, you should include a cover letter setting

⁴ Optical character recognition (OCR) is the process of converting an image of text, such as a scanned paper document or electronic fax file, into computer-editable text.

forth the information specified in our confidential business information regulation. See 49 CFR 512.

In addition, you should submit a copy, from which you have deleted the claimed confidential business information, to the Docket by one of the methods set forth above.

Will the agency consider late comments?

We will consider all comments received before the close of business on the comment closing date indicated above under DATES. To the extent possible, we will also consider comments received after that date. Therefore, if interested persons believe that any new information the agency places in the docket affects their comments, they may submit comments after the closing date concerning how the agency should consider that information for the final rule.

How can I read the comments submitted by other people?

You may read the materials placed in the docket for this document (e.g., the comments submitted in response to this document by other interested persons) at any time by going to <http://www.regulations.gov>. Follow the online instructions for accessing the dockets. You may also read the materials at the Docket Management Facility by going to the street address given above under **ADDRESSES**. The Docket Management Facility is open between 9 am and 5 pm Eastern Time, Monday through Friday, except Federal holidays.

V. Rulemaking Analyses and Notices

A. Executive Order 12866 and DOT Regulatory Policies and Procedures

Executive Order 12866, "Regulatory Planning and Review," 58 FR 51735 (Oct. 4, 1993), provides for making determinations whether a regulatory action is "significant" and therefore subject to Office of Management and Budget (OMB) review and to the requirements of the Executive Order. The Order defines a "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees,

or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities or the principles set forth in the Executive Order.

NHTSA has considered the impact of this rulemaking action under Executive Order 12866 and the Department of Transportation's regulatory policies and procedures. This rulemaking is not significant as it does not implicate any of the above-enumerated concerns. Accordingly, the Office of Management and Budget has not reviewed this rulemaking document under Executive Order 12886. Further, NHTSA has determined that the rulemaking is not significant under the Department of Transportation's regulatory policies and procedures.

Based on the type of fees and the anticipated use of the test track, NHTSA believes that the costs of the final rule would be minimal and would not warrant preparation of a regulatory evaluation. The proposed rule would increase fees charged to private manufacturers for use of a government facility to prevailing market rates. Manufacturers have a choice as to whether to use this government facility or a private commercial facility. As a result, this action does not involve any substantial public interest or controversy. Furthermore, NHTSA anticipates that any impact on the sale price of tires would be minimal, because an increase in testing fees would likely be distributed across a manufacturer's sales volume. There would be no substantial effect upon State and local governments. There would be no substantial impact upon a major transportation safety program.

B. National Environmental Policy Act

NHTSA has evaluated this proposed action for purposes of the National Environmental Policy Act and has determined that it would not have a significant effect on the quality of the human environment.

C. Regulatory Flexibility Act

NHTSA has considered the impact of this proposed rulemaking under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996). NHTSA believes that the proposed rule would not have a significant economic impact on a substantial number of small entities.

The following is NHTSA's statement providing the factual basis for the certification (5 U.S.C. 605(b)). Tire manufacturers are not small entities.

The proposed amendments would affect businesses that conduct contract traction testing, some of which are small businesses within the meaning of the Regulatory Flexibility Act; however, the agency does not believe that this proposed rule would result in a significant economic impact on these entities. Under the proposed standards, the fees paid for use of the government facility would be essentially equivalent to those paid to a commercial testing facility—the market rate. The agency believes that small governmental jurisdictions would be only minimally affected by the proposed rule since they are generally not large scale purchasers of vehicles tires. Furthermore, even in the case of substantial purchases, as noted above, costs passed on to consumers are expected to be minimal since testing fees would likely be distributed across a manufacturer's sales volume.

D. Executive Order 13132 (Federalism)

Executive Order 13132 on "Federalism," 64 FR 43255 (Aug. 10, 1999), requires NHTSA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have Federalism implications." Executive Order 13132 defines the term "policies that have federalism implications" to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." Under Executive Order 13132, NHTSA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal Government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or NHTSA consults with State and local officials early in the process of developing the proposed regulation.

The proposed rule would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government as specified in Executive Order 13132. Accordingly, Section 6 of the Executive Order does not apply to this rulemaking action.

E. Executive Order 12988 (Civil Justice Reform)

Pursuant to Executive Order 12988 "Civil Justice Reform," 61 FR 4729 (Feb.

7, 1996), NHTSA has considered whether this rulemaking would have any retroactive effect. The proposed rule would not have any retroactive effect.

F. Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104-4, requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or Tribal governments, in the aggregate, or by the private sector, of more than \$100 million annually (adjusted for inflation with the base year of 2005). Adjusting this amount by the implicit gross domestic product price deflator for 2009 results in \$135 million (109.770/81.536 = 1.35).

This proposed rule will not result in the expenditure by State, local, or Tribal governments, in the aggregate, of more than \$135 million annually, and will not result in an expenditure of that magnitude by private entities. Because a final rule based on this proposal would not require expenditures exceeding \$135 million annually, this action is not subject to the requirements of Sections 202 and 205 of the UMRA.

G. Paperwork Reduction Act

Under the procedures established by the Paperwork Reduction Act of 1995 (PRA), a person is not required to respond to a collection of information by a Federal agency unless the collection displays a valid OMB control number. The proposed rule does not require the collection of information by a Federal agency. Accordingly, the PRA is not applicable to this action.

H. Regulation Identifier Number (RIN)

The Department of Transportation assigns a regulation identifier number (RIN) to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. You may use the RIN that appears in the heading on the first page of this document to find this action in the Unified Agenda.

I. Plain Language

Executive Order 12866 requires each agency to write all rules in plain language. Application of the principles of plain language includes consideration of the following questions:

- Have we organized the material to suit the public's needs?

- Are the requirements in the rule clearly stated?
 - Does the rule contain technical language or jargon that isn't clear?
 - Would a different format (grouping and order of sections, use of headings, paragraphing) make the rule easier to understand?
 - Would more (but shorter) sections be better?
 - Could we improve clarity by adding tables, lists, or diagrams?
 - What else could we do to make the rule easier to understand?
- If you have any responses to these questions, please include them in your comments on this proposal.

J. Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an organization, business, labor union, *etc.*). You may review DOT's complete Privacy Act statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit <http://www.dot.gov/privacy.html>.

List of Subjects in 49 CFR Part 575

Consumer protection, Incorporation by reference, Motor vehicle safety, Reporting and recordkeeping requirements, Tires.

In consideration of the foregoing, NHTSA proposes to amend 49 CFR Part 575 as follows:

PART 575—CONSUMER INFORMATION

1. The authority citation for part 575 continues to read as follows:

Authority: 49 U.S.C. 32302, 32304A, 30111, 30115, 30117, 30123, 30166, and 30168, Pub. L. 104–414, 114 Stat. 1800, Pub. L. 109–59, 119 Stat. 1144, Pub. L. 110–140, 121 Stat. 1492, 15 U.S.C. 1232(g); delegation of authority at 49 CFR 1.50.

2. Revise Appendix D to § 575.104 to read as follows:

§ 575.104 Uniform tire quality grading standards.

* * * * *

Appendix D—User Fees

1. *Use of Government Traction Skid Pads:* A fee of \$125 will be assessed for each hour, or fraction thereof, that the traction skid pads at Goodfellow Air Force Base, San Angelo, Texas are used. This fee is based upon the market price of the use of the traction skid pads.

2. Fee payments shall be by check, draft, money order, or Electronic Funds Transfer

System made payable to the Treasurer of the United States.

3. The fee set forth in this Appendix continues in effect until adjusted by the Administrator of NHTSA. The Administrator reviews the fee set forth in this Appendix and, if appropriate, adjusts it by rule at least every 2 years.

Issued on: January 10, 2011.

Claude Harris,

Acting Associate Administrator for Enforcement.

[FR Doc. 2011–643 Filed 1–12–11; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 101029546–0547–01]

RIN 0648–BA39

Atlantic Highly Migratory Species; Bluefin Tuna Bycatch Reduction in the Gulf of Mexico Pelagic Longline Fishery

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to require the use of “weak hooks” in the Gulf of Mexico (GOM) pelagic longline (PLL) fishery. A weak hook is a circle hook that meets NMFS’ current size and offset restrictions for the GOM PLL fishery, but is constructed of round stock wire that is thinner-gauge than the circle hooks currently used, *i.e.*, no larger than 3.65 mm in diameter. Weak hooks can allow incidentally hooked bluefin tuna (BFT) to escape capture because the hooks are more likely to straighten when a large fish is hooked. Requiring weak hooks in the GOM will reduce bycatch of BFT, allow the long-term beneficial socio-economic benefits of normal operation of directed fisheries in the GOM with minimal short-term negative socio-economic impacts, and have both short- and long-term beneficial impacts on the stock status of Atlantic BFT, an overfished species. Since 2007, NMFS has conducted research on weak hooks used on PLL vessels operating in the GOM to reduce the incidental catch of large BFT during directed PLL fishing for other species. Preliminary results show that the use of a weak hook can significantly reduce the amount of BFT caught incidentally

by PLL vessels in the GOM. The purpose of the proposed action is to reduce PLL catch of Atlantic BFT in the GOM, which is the only known BFT spawning area for the western Atlantic stock of BFT. This action would be consistent with the advice of the International Commission for the Conservation of Atlantic Tunas (ICCAT) Standing Committee for Research and Statistics (SCRS) that ICCAT may wish to protect the strong 2003 year class until it reaches maturity and can contribute to spawning. The purpose is also to allow directed fishing for other species to continue within allocated BFT sub-quota limits. This measure would be consistent with the 2006 Consolidated Highly Migratory Species (HMS) Fishery Management Plan (FMP), including the BFT rebuilding program.

DATES: Written comments will be accepted until February 12, 2011. NMFS will hold three public hearings on this proposed rule on February 7, 2011, in Silver Spring, MD; February 9, 2011, in Panama City, FL; and February 10, 2011, in Kenner, LA to receive comments from fishery participants and other members of the public regarding this proposed rule. An operator-assisted conference call will be held to receive comments, only on this proposed rulemaking, from HMS Advisory Panel members on February 8, 2011. This is not an HMS Advisory Panel meeting, and the conference call will be open to members of the public, who may observe and comment to the extent time permits. Please see the **SUPPLEMENTARY INFORMATION** section of this proposed rule for specific dates, times, and locations.

ADDRESSES: The public hearings will be held in Maryland, Florida, and Louisiana. Please see the **SUPPLEMENTARY INFORMATION** section of this ANPR for specific dates, times, and locations.

You may submit comments, identified by 0648–BA39, by any one of the following methods:

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

- Fax: 301–713–1917, Attn: Margo Schulte-Haugen

- Mail: 1315 East-West Highway, Silver Spring, MD 20910. Please mark the outside of the envelope “Comments on the Proposed Rule to Reduce Bluefin Tuna Bycatch in the Gulf of Mexico.”

- Instructions: No comments will be posted for public viewing until after the comment period has closed. All comments received are a part of the public record and generally will be

posted to <http://www.regulations.gov> without change. All Personal Identifying Information (e.g., name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

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

FOR FURTHER INFORMATION CONTACT: Dianne Stephan by phone at 978-281-9260 or Randy Blankinship by phone at 727-824-5399.

SUPPLEMENTARY INFORMATION: Atlantic tunas are managed under the dual authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) and the Atlantic Tuna Conventions Act (ATCA), which authorizes the Secretary of Commerce (Secretary) to promulgate regulations as may be necessary and appropriate to implement recommendations of ICCAT. The authority to issue regulations under the Magnuson-Stevens Act and ATCA has been delegated from the Secretary to the Assistant Administrator for Fisheries, NOAA (AA). On May 28, 1999, NMFS published in the **Federal Register** (64 FR 29090) final regulations, effective July 1, 1999, implementing the Fishery Management Plan for Atlantic Tunas, Swordfish, and Sharks (1999 FMP). On October 2, 2006, NMFS published in the **Federal Register** (71 FR 58058) final regulations, effective November 1, 2006, implementing the 2006 Consolidated HMS FMP, which details the management measures for Atlantic HMS fisheries including the PLL fishery.

Background

NMFS is issuing a proposed rule that would require the use of “weak hooks” by PLL vessels fishing in the GOM. A weak hook is a circle hook that meets NMFS’ current size and offset restrictions but is constructed of round wire stock that is thinner-gauge (*i.e.*, no larger than 3.65 mm in diameter) than the circle hooks currently used in the PLL fishery. The purpose of the proposed action is to reduce PLL catch of Atlantic BFT in the GOM, which is the only known BFT spawning area for the western Atlantic stock of BFT. This measure would also be consistent with the ICCAT SCRS advice that ICCAT may wish to protect the strong 2003 year class until it reaches maturity and can contribute to spawning. Implementation

of weak hooks in the GOM PLL fishery by spring 2011 is important because the strong 2003 year class is beginning to enter adulthood, and it is likely that some of them will begin to spawn in the GOM this spring. Also, reducing the incidental BFT catch in the GOM may enable the PLL fishery to continue to operate year-round by increasing the likelihood that landings and dead discards will remain below the quota. The proposed rule would require a new gear technology that could allow the GOM PLL fleet to continue routine directed fishing operations (*e.g.*, yellowfin tuna (YFT) and swordfish) while decreasing the numbers of incidentally caught BFT. Weak hooks can allow incidentally hooked BFT to escape capture because the hooks are more likely to straighten when a large fish is hooked, thus releasing the fish.

This action is necessary to achieve domestic management objectives under the Magnuson-Stevens Act, and to implement the 2006 Consolidated HMS FMP, including goals to rebuild stocks and end overfishing. Atlantic BFT has historically been documented as overfished with overfishing occurring. Since 1998, an ICCAT rebuilding plan, which was implemented in the Consolidated HMS FMP, has been in place with the goal of rebuilding the western BFT stock by 2019. Strict quotas and domestic regulations have been in place to achieve this goal, including a prohibition on all directed fishing on BFT in the GOM in recognition that is the sole known spawning area for the western BFT stock. Although directed fishing for BFT is prohibited in the GOM, the incidental catch of BFT has become an area of heightened concern due to the status of the stock and mortality of incidentally caught spawning BFT in the directed PLL fishery that targets YFT and swordfish. Furthermore, a recent stock assessment conducted by ICCAT’s SCRS in October 2010, shows that a strong 2003 year class is expected to begin to contribute to an increase in spawning biomass after several years. In particular, the SCRS notes “that the 2010 assessment is the first time that this strong 2003 year-class has been clearly demonstrated, likely as a result of age assignment refinements resulting from the growth curve and additional years of data; more observations from the fishery are required to confirm its relative strength. A further concern is that subsequent year-classes, although even less well estimated, are the lowest observed values in the time series. The Commission may wish to protect the 2003 year class until it reaches maturity

and can contribute to spawning.” While the increased presence of spawning BFT in the GOM could provide a positive impact on the stock, PLL interactions with spawning BFT could also be expected to increase with the higher number of fish in this year class. This could lead to increased incidental catches (and discards) of BFT, potentially diminishing the reproductive impact of this large year class to the western BFT stock.

Several other factors have also heightened concern about BFT recently, such as the April 2010 Deepwater Horizon/BP oil spill in the GOM and potential impacts on BFT, particularly in the GOM. In addition, some environmental groups have called for the suspension of the entire Atlantic BFT fishery and the creation of a permanent BFT sanctuary in the GOM spawning area. In May 2010, the Center for Biological Diversity petitioned NMFS to list BFT as threatened or endangered under the Endangered Species Act and to designate critical habitat for the species. NMFS published a 90-Day Finding on the Petition to List Atlantic Bluefin Tuna as Threatened or Endangered under the Endangered Species Act on Sept. 21, 2010 (75 FR 57431). The analysis of that petition is ongoing.

Tuna researchers working on tagging projects in the GOM have noted that almost all BFT caught by PLL vessels are dead due to the high metabolic stress endured during capture from the warm water. Promising research results, from an experiment (the weak hook study) conducted by the NMFS Harvesting Systems and Engineering Branch, Pascagoula, MS, have found over the past 3 years that the weak hook, which is designed to bend under pre-determined loads, could potentially result in the quick release of large BFT, as well as some large pelagic sharks in PLL fisheries. The PLL vessel operators and owners involved in the study have shown support for use of weak hooks. Initial results show the potential for increasing the biomass of the western BFT stock in the short- and long-term with some potential adverse impacts to directed fisheries (*i.e.*, approximately a 7 percent reduction in YFT and 41 percent reduction in swordfish retained for sale).

On an annual basis, ICAAT issues the United States its BFT quota, which is further divided among fisheries under the Consolidated HMS FMP. Under the Consolidated HMS FMP, PLL vessels are currently allocated 8.1 percent of the available landings quota for the incidental retention (and dead discards) of BFT while directing on other target

species such as YFT and swordfish in the GOM and swordfish in the North Atlantic. In the last few years however, the total PLL landings and dead discards, all of which must be reported to ICCAT, have exceeded the Consolidated HMS FMP-based PLL allocation (*i.e.*, landings and dead discards comprised 23 percent of the U.S. catch in 2009, substantially more than the 8 percent allocation of the U.S. quota assigned for the PLL fishery). Beginning in 2007, to provide quota sufficient for the PLL fleet to operate for the entire fishing year (based on the best available estimates of discards and landings), NMFS has added to the Longline category sub-quota a substantial portion of quota unharvested by other categories in the prior year. In 2008 and 2009, NMFS provided 54 mt and 83 mt, respectively, during the annual quota specification process to cover the Longline category sub-quota overages. After 2010, the amount of unharvested ICCAT-issued quota that the United States may carry forward to the subsequent year will be substantially reduced (from 50 percent of the total U.S. quota to 10 percent). In addition, if U.S. quota for 2011 and beyond remains at current levels, or less, there is the potential that other directed BFT fisheries (*e.g.*, commercial and recreational handgear fisheries) may fully utilize their sub-quotas. Under these types of quota constraints, NMFS may, in future years, have to consider closing the PLL target fisheries to avoid further incidental catch of BFT or consider closing directed BFT fisheries in order to manage the fishery within the available U.S. quota and FMP-based quota allocations.

The objectives of this proposed rulemaking are to: (1) Enhance stock rebuilding by increasing BFT spawning potential and subsequent recruitment into the fishery, (*i.e.*, rapidly implement the proposed action to increase the survival of spawning BFT in 2011 in the GOM particularly the 2003 year class); (2) constrain PLL BFT catch to the incidental BFT quota allocation; (3) allow the PLL fleet to continue to participate in their directed fisheries (*e.g.*, YFT and swordfish) year-round with less risk of fishery interruption due to insufficient incidental quota availability (*i.e.*, minimize negative social and economic impacts to the PLL directed fisheries); (4) reduce the need for BFT quota reallocation from directed fisheries or the Reserve to cover PLL BFT bycatch (*i.e.*, minimize negative and social impacts to BFT directed fisheries); and (5) minimize negative

ecological impacts on non-target or protected species.

As required by current regulation under the authority of ATCA, the retention of BFT in the PLL fishery is allowed incidentally to the targeted catch of YFT and swordfish. This incidental catch of BFT must be within the target catch retention limits of one BFT per 2,000 lbs of target catch, two BFT per 6,000 lbs, and three BFT per 30,000 lbs. BFT that are caught in excess of these existing target catch retention limits must be discarded and, for purposes of the discussion in this proposed rule, may be considered bycatch. Bluefin tuna that are discarded dead are counted against the quota along with landed BFT. In this proposed rule and related to BFT in the PLL fishery, the terms "incidental catch" and "bycatch" are used within this context.

Background and History

A brief history on the management of the PLL fishery is provided below as it pertains to this proposed action. A more complete summary of Atlantic HMS management can be found in the 2006 Consolidated HMS FMP, in the annual HMS SAFE Reports, and online at <http://www.nmfs.noaa.gov/sfa/hms/>.

NMFS has implemented a series of management measures designed to regulate the incidental catch of BFT in non-directed Atlantic fisheries. In 1981, NMFS prohibited the use of longlines for any directed BFT fishery, implemented incidental catch limits, and established northern and southern management areas where different catch limits applied (46 FR 8012, January 26, 1981). PLL fishermen were restricted to two BFT per vessel per trip in the southern region and 2 percent by weight of all other fish on board in the northern region. In 1982, ICCAT recommended a ban on directed fishing for BFT in the GOM. Over the following decade, the value of BFT increased dramatically and fishing practices evolved with respect to incidental catch of BFT. In response, NMFS established various management measures to discourage PLL vessels from developing a directed fishery for this valuable species while allowing for the retention of some incidentally caught BFT, which included altering target catch requirements and adjusting geographic management areas (57 FR 365, January 6, 1992).

Despite these efforts, incidental catch of BFT by U.S. PLL vessels continued. NMFS continued to evaluate management alternatives to achieve a balance between allowing the retention of true incidentally-caught BFT while preventing a directed fishery and reducing discards.

On May 28, 1999, NMFS published in the **Federal Register** (64 FR 29090) final regulations, effective July 1, 1999, implementing the Fishery Management Plan for Atlantic Tunas, Swordfish, and Sharks (1999 FMP). As part of the 1999 FMP, the regulations for all Atlantic HMS, including billfish, were consolidated into one part of the Code of Federal Regulations, 50 CFR Part 635. The 1999 FMP was the first FMP for Atlantic tunas and included numerous management measures governing all HMS fisheries including the sub-allocation of 8.1 percent of the United States' overall ICCAT allocated quota for BFT landed by PLL vessels incidental to directed fishing operations targeting other species. Other highlights from the 1999 FMP included a measure to close an area of ocean off the Mid-Atlantic Bight to PLL fishing during the month of June in an attempt to minimize bycatch of BFT and ensure compliance with ICCAT recommendations. The HMS FMP also considered, but did not implement, further modifications to target catch requirements because of the difficulty in determining catch levels and landings allowances that would likely reduce dead discards.

NMFS also stated that a comprehensive approach to time/area closures would be undertaken as part of a bycatch reduction strategy after further analysis of the data and consultation with the HMS and Billfish advisory panels. This led to the development of a draft Technical Memorandum, which was made available to the public on November 2, 1999 (64 FR 59162).

Subsequent to the release of the Technical Memorandum, NMFS considered three alternative actions to reduce bycatch and/or bycatch mortality in the Atlantic HMS PLL fishery: status quo, gear modifications that would decrease hook-ups and/or increase survival of bycatch species, and the prohibition of PLL fishing (closures) in areas where rates of bycatch are higher. A proposed rule was published December 15, 1999 (64 FR 69982), for which alternatives were identified and analyzed in a draft Supplemental Environmental Impact Statement (64 FR 73550, December 30, 1999), that included proposed closed areas for PLL gear in the western GOM and off the southeast coast of the United States.

During the comment period on the proposed rule, NMFS received comments on many issues related to the proposed time/area closures. In particular, commenters asserted that a proposed closure in the western GOM would not adequately address juvenile swordfish bycatch in the DeSoto Canyon area of the eastern portion of the Gulf.

Additionally, commenters noted the significant economic impacts associated with large scale area closures on vessel operators and shoreside support services that would need considerable time for adjustment and relocation. Given these comments, NMFS analyzed the potential impacts of an additional closed area in the DeSoto Canyon area. Subsequently, NMFS published supplementary information regarding the potential impacts of closing the DeSoto Canyon Area together with a revised summary of the IRFA prepared for the proposed rule (65 FR 24440, April 26, 2000). The comment period for the proposed rule was reopened through May 12, 2000, and NMFS specifically requested comments on the extent to which delayed effectiveness of the closure could mitigate the economic impacts of area closures.

On August 1, 2000, NMFS published a final rule that prohibited live bait longlining in the GOM and prohibited PLL fishing at any time in the DeSoto Canyon area (beginning November 2000) and East Florida Coast (beginning February 2001), and from February through April of each year in the Charleston Bump area (beginning February 2001) (65 FR 47214, August 1, 2000). In the PLL fishery, some species of sea turtles are sometimes caught or become entangled in the fishing gear. Because sea turtle species are listed as threatened or endangered under the Endangered Species Act (ESA), provisions of the ESA, such as Section 7 Consultation apply to the PLL fishery. During the course of the August 1, 2000, rulemaking, the PLL fleet exceeded the incidental take statement for sea turtles established during the ESA Section 7 Consultation for the 1999 FMP. That, combined with new information on sea turtles and the uncertainty regarding the effect of the closures on sea turtles, resulted in reinitiation of consultation and issuance of a new Biological Opinion (BiOp) (June 30, 2000), which concluded that the continuation of the PLL fishery as proposed was likely to jeopardize the continued existence of leatherback and loggerhead sea turtles.

As a result of the June 2000 BiOp jeopardy finding, NMFS needed to implement certain measures to reduce sea turtle bycatch in the PLL fishery. NMFS decided that further analyses of observer data and additional population modeling of loggerhead sea turtles would be needed to determine more precisely the impact of the PLL fishery on sea turtles. Because of this, NMFS reinitiated consultation on the HMS fisheries on September 7, 2000. In the interim, NMFS implemented emergency regulations, based on historical data on

sea turtle interactions, to reduce the short-term effects of the PLL fishery on sea turtles, including the closure of a portion of the Northeast Distant Statistical Area (NED) and a requirement that dipnets and line clippers be carried and used on PLL vessels to aid in the release of any captured sea turtle. These regulations published on October 13, 2000 (65 FR 60889).

NMFS issued a BiOp on June 8, 2001 (revised on June 14, 2001), which again concluded that the continued operation of the Atlantic PLL fishery was likely to jeopardize the continued existence of loggerhead and leatherback sea turtles. Accordingly, the BiOp provided a reasonable and prudent alternative (RPA) to avoid jeopardy. The RPA included the following elements: Closing the NED area effective July 15, 2001, and conducting a research experiment in this area on various PLL gear modifications to reduce sea turtle bycatch and bycatch mortality in the PLL fishery. The BiOp also included a requirement that all vessels permitted for HMS fisheries post sea turtle handling and release guidelines. This requirement was modified to specify its application only to bottom and PLL vessels by an August 31, 2001, memorandum from the Office of Protected Resources.

On July 13, 2001, NMFS published an emergency rule (66 FR 36711) to implement several of the June 2001 BiOp requirements. NMFS published an amendment to the emergency rule to incorporate the change in requirements for the handling and release guidelines that were published in the **Federal Register** on September 24, 2001 (66 FR 48812).

On July 9, 2002, NMFS published the final rule (67 FR 45393) implementing measures required under the June 14, 2001 BiOp on Atlantic HMS to reduce the incidental catch and post-release mortality of sea turtles and other protected species in HMS fisheries, with the exception of the gangion placement measure. The rule implemented the NED closure, required the length of any gangion to be 10 percent longer than the length of any floatline if the total length of any gangion plus the total length of any floatline is less than 100 meters, and prohibited vessels from having hooks on board other than corrodible, non-stainless steel hooks. The final rule also required all HMS bottom and PLL vessels to post sea turtle handling and release guidelines in the wheelhouse. NMFS did not implement the gangion placement requirement because it appeared to result in an unchanged number of interactions with loggerhead

sea turtles and an apparent increase in interactions with leatherback sea turtles.

During this time frame, NMFS again proposed changes to the PLL BFT target catch requirements and other modifications to the Longline category regulations in December 2002 (67 FR 78404, December 24, 2002). The May 2003 final rule set the incidental retention/target catch requirements as follows: One large medium or giant BFT per vessel per trip may be landed, provided that at least 2,000 lb (907 kg) of species other than BFT are legally caught, retained, and offloaded from the same trip and are recorded on the dealer weighout slip as sold; two large medium or giant BFT may be landed incidentally to at least 6,000 lb (2,727 kg) of species other than BFT; and three large medium or giant BFT may be landed incidentally to at least 30,000 lb (13,620 kg) of species other than BFT (68 FR 32414 May 30, 2003). The final rule also set Longline category allocations at no more than 60 percent of the Longline category quota for landing in the area south of 31 degrees north latitude. Twenty-five mt are allocated for incidental catch by PLL vessels fishing in the Northeast Distant gear restricted area. The required advance notice for any inseason adjustment to target catch requirements was set at 21 days. These target catch requirements and subquota allocations remain in effect today.

On November 28, 2003, based on the conclusion of the NED experiment and based on preliminary data indicating that the Atlantic PLL fishery may have exceeded the ITS established in the June 14, 2001 BiOp, NMFS published a Notice of Intent (NOI) to prepare a Supplemental Environmental Impact Statement (SEIS) to assess the potential effects on the human environment of proposed alternatives and actions under a proposed rule to reduce sea turtle bycatch (68 FR 66783).

In January 2004, NMFS reinitiated consultation after receiving data that indicated the Atlantic PLL fishery exceeded the ITS for leatherback sea turtles in 2001–2002 and for loggerhead sea turtles in 2002. In the spring of 2004, NMFS released a proposed rule to require PLL fishermen to use certain hook and bait types, and take other measures to reduce sea turtle takes and mortality. The resulting June 1, 2004 BiOp considered these measures and concluded that the PLL fishery as proposed was not likely to jeopardize the continued existence of loggerhead sea turtles, but was still likely to jeopardize the continued existence of leatherback sea turtles.

On July 6, 2004, NMFS published a final rule (69 FR 40734) pursuant to the

2004 PLL BiOp implementing many gear and bait restrictions and requiring certain sea turtle handling and release tools and methods. Specifically, the 2004 final rule required vessel operators participating in the PLL fishery for Atlantic HMS operating outside of the NED, at all times, to possess onboard and/or use only 16/0 or larger non-offset circle hooks and/or 18/0 or larger circle hooks with an offset not to exceed 10 degrees. Only whole finfish and squid baits could be possessed and/or utilized with the allowable hooks outside of the NED. The 2004 rule also re-opened the NED to PLL fishing for Atlantic HMS, but required vessels with PLL gear onboard in that area, at all times, to possess and/or use only 18/0 or larger circle hooks with an offset not to exceed 10 degrees. Within the NED, only whole mackerel and squid baits may be possessed and/or utilized with allowable hooks. Finally, NMFS required specific sea turtle release equipment to be possessed on board PLL vessels and adherence to specific handling and release techniques for sea turtles. The sea turtle handling and release placards and protocols were revised, and a video showing proper sea turtle handling techniques was mailed to all PLL vessel owners. The placards, protocols, and video were made available in English, Spanish, and Vietnamese.

In 2006, NMFS merged the FMP for Atlantic Tunas, Swordfish, and Sharks and the Atlantic Billfish FMP into one Consolidated HMS FMP. The final rule implementing the 2006 Consolidated HMS FMP (71 FR 58058, Oct. 2, 2006) contained several management measures applicable to the PLL fishery. These included: (1) Mandatory workshops for the safe release, disentanglement, and identification of protected resources for PLL vessel owners and operators; (2) implementation of the Madison-Swanson and Steamboat Lumps Marine Reserves to complement Gulf of Mexico Fishery Management Council regulations; and, (3) a clarification of the definitions of bottom longline and PLL gear based upon the species composition of the catch onboard or offloaded.

NMFS also thoroughly considered and analyzed time/area closures as a means to minimize bycatch and bycatch mortality in HMS fisheries in the Environmental Impact Statement that supported the Consolidated HMS FMP. The EIS analyzed the ecological, economic, and social impacts of 12 alternatives and subalternatives for potential PLL closures in the Atlantic and GOM on blue and white marlin,

sailfish, spearfish, BFT, pelagic and large coastal sharks, and leatherback, loggerhead, and other sea turtles as part of the management measures considered to reduce bycatch. To evaluate the potential overall conservation benefits of each closure scenario, NMFS analyzed the impacts of the redistribution of fishing effort under various redistribution schemes (e.g., fleet-wide redistribution of effort into all open areas or redistribution of effort only to open areas of the GOM). Redistribution of effort refers to fishing effort that is, or may be, applied in another location due to a closure. Previous research and requests for closures of portions of the GOM to protect BFT did not consider redistribution of effort when proposing a closure. These requests included research that presumed fishermen would simply stop fishing altogether if they could not fish in the closed areas. NMFS analyses were the only analyses at the time that modeled the potential for redistribution of effort related to closures in the GOM.

NMFS found that with some level of redistributed effort, no one closure, or combination of closures, would have reduced bycatch of all of the species considered. In addition to implementing complementary HMS management measures in the Madison-Swanson and Steamboat Lumps Marine Reserves, the final 2006 Consolidated HMS FMP established criteria to consider when assessing possible new time/area closures or making modifications to existing time/area closures. Criteria that would be considered may include, but are not limited to, the following: Any ESA-related issues, concerns, recommendations, or requirements including those in applicable Biological Opinions; bycatch rates of protected species, prohibited HMS, or non-target species both within the specified or potential closure area(s) and throughout the fishery; bycatch rates and post-release mortality rates of bycatch species associated with different gear types; applicable research; new or updated landings; bycatch and fishing effort data; social and economic impacts; and the practicability of implementing new or modified closures, including consistency with the FMP, Magnuson-Stevens Act, ATCA, and other applicable law. If the species is an ICCAT-managed species, NMFS would consider the effects of domestic and international fisheries on that species before implementing time/area closures. Other factors that NMFS would consider before implementing time/area closures include, but are not limited to, gear

types and the location and timing of a closed area. NMFS would attempt to balance the ecological benefits with economic and social impacts. NMFS would also consider alternatives to closed areas, such as reducing quotas, mandatory gear modifications, or alternative fishing practices such as designated fishing days. Thus, before the implementation of a time/area closure, NMFS would determine that such a closure would be the best option for a given set of management goals, consistent with the FMP, the Magnuson-Stevens Act, and applicable law. Although NMFS decided at the time to not move forward with an HMS PLL closure in the GOM given the implications associated with redistribution of fishing effort, it stated its intent to continue to pursue other alternatives to reduce bycatch in the GOM, especially for BFT.

Since 2006, there have been additional regulatory and management actions potentially affecting PLL vessels in the GOM. These include Amendment 1 to the Consolidated HMS FMP (74 FR 28018, June 12, 2009), which revised HMS Essential Fish Habitat and designated a new Habitat Area of Particular Concern (HAPC) for BFT spawning areas in the GOM, and implementation of a small closure to protect reef species in the GOM named the "Edges 40 Fathom Closure" (74 FR 66585, December 16, 2009). There has also been a positive 90-Day Finding on a Petition to List Atlantic Bluefin Tuna as Threatened or Endangered Under the ESA (75 FR 57431, September 21, 2010), although this is a preliminary step in any listing process. With regard to sea turtles, NMFS has recently proposed to list the Northwest Atlantic loggerhead sea turtle as "endangered" under the ESA (75 FR 12598, March 16, 2010).

In the spring of 2007, observer coverage in the GOM was increased to better characterize the interaction of the PLL fleet with BFT on the spawning ground with coverage approaching 100 percent during the spawning season (April to mid-June). In 2010, approximately 50 percent of trips during the BFT spawning season were observed, which provides a reliable estimate of bluefin tuna bycatch. Starting in 2007, the NMFS Engineering and Harvesting Branch of the Southeast Fisheries Science Center (SEFSC), Mississippi Laboratories, began conducting scientific research in consultation and cooperation with the domestic PLL fleet in the GOM to develop and assess the efficacy of new technologies for reducing the bycatch mortality of BFT in the directed YFT fishery. During the first year of the

research, experiments were conducted aboard the NOAA research vessel R/V Gandy to collect data on the relative force exerted by BFT and YFT when captured on PLL gear. Treatments of three different breaking strengths of monofilament leader were tested to determine which leader strength would effectively release BFT yet retain YFT. Based on promising results that indicated certain monofilament leaders were capable of releasing BFT of the sizes captured, NOAA researchers began working with hook manufacturers to develop a hook design that has less tensile strength than standard hook designs. Research conducted since has continued to evaluate the efficacy of a weaker 16/0 circle hook in reducing the bycatch of BFT by comparing it to a standard 16/0 circle hook used in the PLL fishery during targeted fishing operations. (See Research Experiment section below.)

Since January 1, 2007, shark limited access and swordfish limited access permit holders who fish with longline or gillnet gear have been required to attend a Protected Species Safe Handling, Release, and Identification Workshop and submit a certificate to NMFS indicating that they have attended a workshop in order to renew their shark and swordfish permits. These mandatory workshops teach longline and gillnet fishermen the required techniques for the safe handling and release of entangled and/or hooked protected species, such as sea turtles, marine mammals, and smalltooth sawfish. The overall goal of the workshops is to provide fishermen with the skills needed to reduce the mortality of protected species to meet the requirements of the 2004 PLL BiOp. Approximately two workshops are held monthly in locations along the Atlantic coast and the GOM. Over 100 workshops have been conducted since 2006.

On April 20, 2010, an explosion and subsequent fire damaged the Deepwater Horizon MC252 oil rig, which capsized and sank approximately 50 miles southeast of Venice, LA. Oil flowed for 86 days into the GOM from a damaged well head on the sea floor. In response to the Deepwater Horizon/BP oil spill, NMFS issued a series of emergency rules (75 FR 24822, May 6, 2010; 75 FR 26679, May 12, 2010; 75 FR 27217, May 14, 2010) closing a portion of the GOM exclusive economic zone (EEZ) to all fishing. The fishery closures ranged in size from 6,817 sq. mi. (<4 percent of the U.S. GOM) on May 2, 2010, to 88,522 sq. mi. (approx. 37 percent of the U.S. GOM) on June 2, 2010. NMFS continues to adjust the spatial

dimensions of the fishery closed area as new information becomes available regarding areas affected by oil. Information regarding the current status of the oil spill related fishery closed area may be found at <http://sero.nmfs.noaa.gov/>.

Status of BFT and Primary Target Species

Western Atlantic BFT Stock Assessment

ICCAT's SCRS conducted their latest BFT stock assessments in September 2010. The text below (under the headings of "State of the Stock" through "Management Recommendations") is quoted from the executive summary of the western BFT stock assessment found in the Report of the SCRS, Madrid, Spain, October 4–8, 2010. It is important to note that in its summary text, the SCRS made reference to only a few specific TAC levels and associated probabilities of success for purposes of illustrating the chances of rebuilding the stock (maintaining B above B_{MSY}) through the rebuilding period and preventing overfishing (maintaining F below F_{MSY}) around certain thresholds, under the low and high recruitment scenarios. However, SCRS considered and presented a broad range of TACs under the low recruitment, high recruitment, and combined scenarios in "Kobe II matrix" tables that were part of the SCRS report. Note that the SCRS uses the abbreviation "t" for tons; it is equivalent to mt.

"State of the Stock"

"A new assessment was conducted this year, including information through 2009. The most influential change since the 2008 assessment was the use of a new growth curve that assigns fish above 120 cm to older ages than did the previous growth curve. As a result, the base model estimates lower fishing mortality rates and higher biomasses for spawners, but also less potential in terms of the maximum sustainable yield. The trends estimated during the 2010 assessment are consistent with previous analyses in that spawning stock biomass (SSB) declined steadily from 1970 to 1992 and has since fluctuated between 21 percent and 29 percent of the 1970 level. In recent years, however, there appears to have been a gradual increase in SSB from the low of 21 percent in 2003 to an estimated 29 percent in 2009. The stock has experienced different levels of fishing mortality (F) over time, depending on the size of fish targeted by various fleets. Fishing mortality on spawners (ages 9 and older) declined markedly after 2003.

"Estimates of recruitment were very high in the early 1970s, and additional analyses involving longer catch and index series suggest that recruitment was also high during the 1960s. Since 1977, recruitment has varied from year to year without trend with the exception of a strong year-class in 2003. The 2003 year-class is estimated to be the largest

since 1974, but not quite as large as those prior to 1974. The 2003 year class is expected to begin to contribute to an increase in spawning biomass after several years. The Committee expressed concern that the year-class estimates subsequent to 2003, while less reliable, are the lowest on record.

"A key factor in estimating maximum sustainable yield (MSY)-related benchmarks is the highest level of recruitment that can be achieved in the long term. Assuming that average recruitment cannot reach the high levels from the early 1970s, recent F (2006–2008) is 70 percent of the MSY level and SSB_{2009} is about 10 percent higher than the MSY level. Estimates of stock status are more pessimistic if a high recruitment scenario is considered ($F/F_{MSY}=1.9$, $B/B_{MSY}=0.15$).

"One important factor in the recent decline of fishing mortality on large BFT is that the TAC had not been taken during this time period until 2009, due primarily to a shortfall by the United States fisheries (until 2009). Two plausible explanations for the shortfall were put forward previously by the Committee: (1) That availability of fish to the United States fishery has been abnormally low, and/or (2) the overall size of the population in the Western Atlantic declined substantially from the level of recent years. While there is no overwhelming evidence to favor either explanation over the other, the base case assessment implicitly favors the first hypothesis (regional changes in availability) by virtue of the estimated increase in SSB. The decrease indicated by the U.S. catch rate of large fish is matched by an increase in several other large fish indices. Nevertheless, the Committee notes that there remains substantial uncertainty on this issue and more research needs to be done.

"The SCRS cautions that the conclusions of this assessment do not capture the full degree of uncertainty in the assessments and projections. An important factor contributing to uncertainty is mixing between fish of eastern and western origin. Limited analyses were conducted of the two stocks with mixing in 2008, but little new information was available in 2010. Based on earlier work, the estimates of stock status can be expected to vary considerably depending on the type of data used to estimate mixing (conventional tagging or isotope signature samples) and modeling assumptions made. More research needs to be done before mixing models can be used operationally for management advice. Another important source of uncertainty is recruitment, both in terms of recent levels (which are estimated with low precision in the assessment), and potential future levels (the "low" vs. "high" recruitment hypotheses which affect management benchmarks). Improved knowledge of maturity at age will also affect the perception of changes in stock size. Finally, the lack of representative samples of otoliths requires determining the catch at age from length samples, which is imprecise for larger BFT.

"Outlook
 "A medium-term (10-year) outlook evaluation of changes in spawning stock size and yield over the remaining rebuilding period under various management options was conducted. Future recruitment was

assumed to fluctuate around two alternative scenarios: (i) Average levels observed for 1976–2006 (85,000 recruits, the low recruitment scenario) and (ii) levels that increase as the stock rebuilds (MSY level of 270,000 recruits, the high recruitment scenario). The Committee has no strong evidence to favor either scenario over the other and notes that both are reasonable (but not extreme) lower and upper bounds on rebuilding potential.

“The outlook for BFT in the West Atlantic with the low recruitment scenario (is more optimistic with respect to current stock status than that from the 2008 assessment (owing to the use of improved information on the growth of BFT). A total catch of 2,500 t is predicted to have at least a 50 percent chance of achieving the convention objectives of preventing overfishing and maintaining the stock above the MSY level. The outlook under the high recruitment scenario is more pessimistic than the low recruitment scenario since the rebuilding target would be higher; a total catch of less than 1,250 t is predicted to maintain F below F_{MSY} , but the stock would not be expected to rebuild by 2019 even with no fishing.

“[The Kobe II matrices] summarize the estimated chance that various constant catch policies will allow rebuilding under the high and low recruitment scenarios for the base-case. The low recruitment scenario suggests the stock is above the MSY level with greater than 60 percent probability and catches of 2,500 t or lower will maintain it above the MSY level. If the high recruitment scenario is correct, then the western stock will not rebuild by 2019 even with no catch, although catches of 1,100 t or less are predicted to have a 60 percent chance to immediately end overfishing and initiate rebuilding. The Committee notes that considerable uncertainties remain for the outlook of the western stock, including the effects of mixing and management measures on the eastern stock.

“Effects of current regulations

“The Committee previously noted that Recommendation 06–06 was expected to result in a rebuilding of the stock towards the convention objective, but also noted that there has not yet been enough time to detect with confidence the population response to the measure. This statement is also true for Recommendation 08–04, which was implemented in 2009. Some of the available fishery indicators as well as the current assessment suggest the spawning biomass of western BFT may be slowly rebuilding.

“Management recommendations

“In 1998, the Commission initiated a 20-year rebuilding plan designed to achieve B_{MSY} with at least 50 percent probability. In response to recent assessments, in 2008 the Commission recommended a total allowable catch (TAC) of 1,900 t in 2009 and 1,800 t in 2010 [Rec. 08–04].

“The current (2010) assessment indicates similar historical trends in abundance as in previous assessments. The strong 2003 year class has contributed to stock productivity such that biomass has been increasing in recent years.

“Future stock productivity, as with prior assessments, is based upon two hypotheses

about future recruitment: A ‘high recruitment scenario’ in which future recruitment has the potential to achieve levels that occurred in the early 1970’s and a ‘low recruitment scenario’ in which future recruitment is expected to remain near present levels. Results in previous assessments have shown that long term implications of future biomass are different between the two hypotheses and this research question remains unresolved. However, the current (2010) assessment is also based on new information on western BFT growth rates that has modified the Committee’s perception of the ages at which spawning and maturity occur. Maturity schedules remain very uncertain, and, thus, the application of the new information in the current (2010) assessment accentuates the differences between the two recruitment hypotheses.

“Probabilities of achieving B_{MSY} within the Commission rebuilding period were projected for alternative catch levels. The ‘low recruitment scenario’ suggests that biomass is currently sufficient to produce MSY, whereas the ‘high recruitment scenario’ suggests that B_{MSY} has a very low probability of being achieved within the rebuilding period. Despite this large uncertainty about the long term future productivity of the stock, under either recruitment scenario current catches (1,800 t) should allow the biomass to continue to increase. Also, catches in excess of 2,500 t will prevent the possibility of the 2003 year class elevating the productivity potential of the stock in the future.

“The SCRS notes that the 2010 assessment is the first time that this strong 2003 year-class has been clearly demonstrated, likely as a result of age assignment refinements resulting from the growth curve and additional years of data; more observations from the fishery are required to confirm its relative strength. A further concern is that subsequent year-classes, although even less well estimated, are the lowest observed values in the time series. The Commission may wish to protect the 2003 year class until it reaches maturity and can contribute to spawning. Maintaining catch at current levels (1,800 t) may offer some protection.

“As noted previously by the Committee, both the productivity of western Atlantic BFT and western Atlantic BFT fisheries are linked to the eastern Atlantic and Mediterranean stock. Therefore, management actions taken in the eastern Atlantic and Mediterranean are likely to influence the recovery in the western Atlantic, because even small rates of mixing from East to West can have significant effects on the West due to the fact that Eastern plus Mediterranean resource is much larger than that of the West.”

ICCAT’s 2010 Western Atlantic BFT Recommendation

At its November 2010 meeting, ICCAT adopted a measure for western Atlantic BFT that, among other things, reduced the TAC from 1,800 mt to 1,750 mt for both the 2011 and 2012 fishing seasons—a 2.8 percent reduction overall. The Kobe II matrices show that,

under the low recruitment scenario, the new TAC has a 99 percent probability of maintaining the fishing mortality of western bluefin tuna for 2011 and 2012 below the fishing mortality associated with MSY and a 95 percent probability of maintaining the stock above the biomass that will support MSY (B_{MSY}) through the end of the rebuilding period, i.e., by 2019. Under the combined scenario, the TAC has a 54 percent probability of ending overfishing within 2 years and a 48 percent probability of rebuilding the stock to the B_{MSY} level by the end of the rebuilding period. Under the high recruitment scenario, the TAC has an 8 percent probability of ending overfishing within two years and a zero chance of rebuilding the stock to the B_{MSY} level by the end of the rebuilding period. Under any scenario, the agreed TAC is expected to support continued stock growth if compliance with agreed rules remains strong.

The 2010 ICCAT western Atlantic BFT recommendation is scheduled to enter into force in June 2011. NMFS plans to implement the U.S. portion of the TAC in the spring of 2011 via proposed and final rulemaking to set quotas for the domestic fishing categories.

BFT and the Gulf Oil Spill

Data are not available, at this time, to demonstrate any specific effects of the Deepwater Horizon/BP oil spill on the BFT, YFT, swordfish, or other HMS resources. However, it is possible that the oil spill could have impacts on fish eggs and larval stages of species (including BFT, YFT, swordfish, and other highly migratory species that occur in the GOM). Oil from the spill has dispersed on the surface as well as deep within the water column, but in the time since the well head was capped, oil has disappeared from some areas. BFT spawn from April to mid-June. Oil that was present in surface waters could have affected the survival of eggs and larvae and affected recruitment. Effects on the physical environment such as low oxygen and the inter-related effects that culminate and magnify through the food web could lead to impacts on the ability of larvae and post-larvae to survive, even if they never encountered oil. In addition, effects of oil exposure may not always be lethal, but can create sub-lethal effects on the eggs, larva, and early life stages of fish. There is the potential that the stressors can be additive, and each stressor may increase the susceptibility to the harmful effects of the other. Conversely, juvenile BFT, YFT, swordfish, and most other HMS

are pelagic in nature, have a fast growth rate, and quickly gain the ability to swim over long distances. This capability may allow juvenile HMS to avoid areas of concentrated oil. In addition, there would be less potential impacts to HMS juveniles and adults if oil remains on the surface, continues to wash ashore, or continues to decompose to non-lethal levels.

Atlantic Yellowfin Tuna Stock Assessment

As described above, the GOM PLL fishery targets YFT and, to a lesser extent, swordfish. These species, along with BFT and others, are managed by ICCAT. The ICCAT SCRS conducted a full stock assessment for YFT in 2008, applying both an age-structured model and a non-equilibrium production model to the available catch data through 2006. In summary, 2006 catches were estimated to be well below MSY levels, stock biomass was estimated to be near the Convention Objective (near B_{MSY} or the level of biomass that can sustain MSY) and fishing mortality rates somewhat below F_{MSY} . Trends through 2006 indicate declining effective effort and some recovery of stock levels. However, when the uncertainty around the point estimates from both models is taken into account, there was still about a 60 percent chance that stock status was not consistent with Convention Objectives.

North Atlantic Swordfish Stock Assessment

The current SCRS results for swordfish indicate that the stock is at or above B_{MSY} . The estimated relative biomass trend shows a consistent increase since 2000. The relative trend in fishing mortality shows that the level of fishing peaked in 1995, followed by a decrease until 2002, followed by small increase in the 2003–2005 period and downward trend since then. Fishing mortality has been below F_{MSY} since 2005. The results suggest that there is a greater than 50 percent probability that the stock is at or above B_{MSY} , and thus ICCAT's rebuilding objective has been achieved. However, it is important to note that, since 2003, the catches have been below the TAC, greatly increasing the chances for a fast recovery. Overall, the stock was estimated to be somewhat less productive than the previous assessment, with the intrinsic rate of increase, r , estimated at 0.44 compared to 0.49 in 2006.

GOM PLL Fishery

The PLL fishery for Atlantic HMS primarily targets swordfish, YFT, and bigeye tuna in various areas and

seasons. Secondary target species include dolphin (fish), albacore tuna, and, to a lesser degree, sharks. Although PLL gear can be modified (e.g., depth of set, hook type, hook size, bait, *etc.*) to target swordfish, tunas, or sharks, it is generally a multi-species fishery. These vessel operators are opportunistic, switching gear style and making subtle changes to target the fish providing the most economic benefit for each individual trip. PLL gear sometimes attracts and hooks non-target finfish with little or no commercial value, as well as species that cannot be legally retained by commercial fishermen, such as billfish. PLL gear may also interact with protected species such as marine mammals, sea turtles, and seabirds. Thus, this gear has been classified as a Category I fishery with respect to the Marine Mammal Protection Act (MMPA). Any species (or undersized catch of permitted species) that cannot be legally landed is required to be released, regardless of whether the catch is dead or alive.

The U.S. PLL fishery has historically been comprised of five relatively distinct segments with different fishing practices and strategies. These segments are: (1) The GOM YFT fishery; (2) the South Atlantic-Florida east coast to Cape Hatteras swordfish fishery, although historical catches have decreased because of the Florida East Coast and Charleston Bump time/area closures; (3) the Mid-Atlantic and New England swordfish and bigeye tuna fishery; (4) the U.S. distant water swordfish fishery; and, (5) the Caribbean Islands tuna and swordfish fishery. In addition to geographical area, these segments have historically differed by percentage of various target and non-target species, gear characteristics, and deployment techniques. Some vessels fish in more than one fishery segment during the course of a year. Due to the various changes in the fishery (*i.e.*, regulations, operating costs, market conditions, species availability, *etc.*) the fishing practices and strategies of these different segments may change over time.

GOM vessels primarily target YFT year-round; however, a handful of these vessels directly target swordfish, either seasonally or year-round. Longline fishing vessels that target YFT in the GOM also catch and sell dolphin (fish), swordfish, other tunas, and sharks. During YFT fishing, few swordfish are captured incidentally. Many of these vessels participate in other GOM fisheries (targeting shrimp, shark, and snapper/grouper) during allowed seasons. Home ports for this fishery include, but are not limited to, Madiera

Beach, FL; Panama City, FL; Dulac, LA; and Venice, LA.

Research Experiment

NMFS, Engineering and Harvesting Branch of the Southeast Fisheries Science Center (SEFSC), Mississippi Laboratories, worked with the GOM PLL fleet from 2007–2010, to collaboratively develop technology to address a growing concern about bycatch mortality of spawning BFT. Research efforts focused on how to take advantage of the difference in the relative larger size of spawning bluefin as compared to the target species, YFT. NMFS researchers worked with hook manufacturers to develop a hook design that has less tensile strength than standard hook designs. Research conducted in 2008–2010 evaluated the efficacy of a weaker 16/0 circle hook in reducing the bycatch of BFT by comparing it to a standard 16/0 circle hook used in the PLL fishery.

The control treatment was an industry standard Mustad 16/0 circle hook (model 39960D) with 0° of offset, constructed of 4.0 mm steel wire with Duratin coating. The experimental treatment was a custom made Mustad 16/0 circle hook (model 39988D) with 0° of offset, constructed from 3.65 mm steel wire with Duratin coating. Experimental hooks and standard 16/0 circle hooks were alternated on the longline during sets. Other than the experimental design requirements, captains were allowed to fish normally and chose the location of fishing, length of trips, total number of hooks fished, *etc.* All vessels participating in the experiment carried NMFS trained observers who collected fishery data as described by the SEFSC PLL Observer Program. Over the course of the study from 2008–10, data was collected from six vessels completing 34 trips with 311 PLL sets deploying 198,606 total hooks (99,303 of each hook type).

A total of 33 BFT were caught during the experiment, of which 10 were caught on the experimental hook for a statistically significant reduction of 56.5 percent compared to the control hook (95 percent confidence interval (CI) = 8.7 percent to 79.3 percent). Vessels landed a total of 2,065 YFT, of which 1,016 were caught on the experimental hook for a reduction of 3.2 percent (95 percent CI = 11.2 percent to –5.6 percent; a negative number denotes an increase), which was not statistically significant. Not all YFT caught are retained for sale mainly due to some fish not meeting the minimum size limit. The difference in YFT retained for sale between the control and experimental hooks was analyzed and

showed a reduction of 7.0 percent (95 percent CI = 15.6 percent to -2.5 percent), which was not statistically significant.

The total swordfish catch per unit effort (CPUE) (number of fish per 1,000 hooks) for the control and experimental hooks (1.21 and 1.15, respectively) were not significantly different. The difference in the catch of swordfish retained for sale (0.34 control and 0.20 experimental) was not statistically significant. The difference in CPUEs for the control and experimental hooks for wahoo (1.48 and 1.09 respectively) was statically significant. The difference in CPUEs for dolphin fish (4.25 and 3.93 respectively) and escolar (1.81 and 1.78 respectively) were not significantly different. A total of 96 white marlin and roundscale spearfish combined were caught and discarded with 38 and 58 fish caught on the control and experimental hook, respectively, for an increase of 52.7 percent that was marginally significant.

The data presented suggest a weaker circle hook design may have the potential to mitigate bycatch mortality of BFT with minimal reduction in the retention of the YFT target catch and some potential reduction in swordfish retained. The evaluation of the condition of hooks that caught BFT shows that BFT interaction with control hooks (the currently required hook/industry standard) commonly results in deformation of the hook. These observations suggest some portion of the 53 straightened control hooks that resulted in fish escapement were likely due to BFT interactions.

There are several factors that contribute to the application of the level of force necessary to straighten a hook during the interactions with animals. It would be difficult to assess all of these factors. This research has shown that YFT weight is a contributing factor. It is reasonable to suspect the same is true for BFT. Other factors which may influence the level of force exerted on a hook by an animal during interaction include: Water temperature, currents, fishing depth, hooks between floats, distance to the nearest float, interaction with other animals on the longline, and vessel hauling practices.

The retention rate of YFT with the experimental hook was highly variable among the vessels participating in the experiment. The two vessels with the highest reduction of YFT also had the highest rate of fish escapement due to straightened experimental hooks. Attempts were made to standardize the gear configurations as much as possible during this fishery dependant research. Therefore, it is probable that variability

in YFT retention rates was a result of the variability in hauling practices. NMFS anticipates that this variability in the performance of the new hook design will be reduced over time as fishermen become more familiar with fishing with the weak hook. As with any new conservation technology, minor adjustments in fishing practices are often needed in order to optimize the gear performance. However, the majority of the vessels involved with the study continue to use the new hook design. Additional vessels, not involved in the study, have purchased the experimental hook for use. Additional research will improve the statistical precision and confidence of the results and, if conducted on a year round basis, will help evaluate possible temporal effects of the weak hook on the target catch.

Weak Hook Implementation in the PLL Fishery

In this proposed rule, NMFS proposes to require all PLL vessels fishing in the GOM to use weak hooks. This alternative would limit vessel operators participating in the Atlantic HMS PLL fishery in the GOM, at all times, to possess and/or use only weak hooks immediately upon the effective date of the action. A weak hook would be defined as a circle hook, meeting current size and offset restrictions, constructed of only round wire stock that is no larger than 3.65 mm in diameter. All other existing requirements for the GOM PLL fishery would remain in effect including, but not limited to: Existing hook size and shape requirements; existing bait requirements; existing time/area closures and live bait restrictions in the GOM PLL fishery; and existing possession and use requirements for bycatch mitigation gear, as well as sea turtle handling and release training and guidelines currently specified by NMFS. The fishery would continue to comply with all requirements of existing biological opinions.

The agency would conduct simultaneously an outreach program and work with dealers and vessel operators to educate and ensure the requirement is understood and implemented. Research programs would continue to determine the effect on bycatch and discard mortality of BFT and other bycatch, as well as target catches.

Assuming similar reductions from gear modifications as reflected in the GOM PLL BFT mitigation research, implementation of weak hooks could reduce the bycatch of BFT in the GOM PLL fishery by approximately 56.5

percent. This would likely result in a reduction in the number of BFT caught in the GOM from an annual average of 285 individual fish from 2006–2009 to approximately 124 individual fish. Reductions in interactions of this magnitude could have positive impacts on the BFT population by minimizing bycatch of spawning BFT, and thus bycatch mortality due to incidental interactions with PLL gear. Post-release mortality is expected to be reduced because BFT straighten the weak hooks relatively quickly after being caught and likely do not incur as high a level of metabolic stress as when the fish stay on the hook until being retrieved upon haul-back of the gear. Due to the fact that BFT have the highest level of energy available at the moment when they become hooked, NMFS suspects that escapement occurs soon after hook-up. Years of observer data and research fishing have shown that most BFT are dead upon haul-back of PLL gear set in the GOM. A reduction in the number of BFT captured incidentally by PLL operations in the GOM could possibly save 124 spawning BFT annually. Some positive ecological impacts may be realized in the near future if the weak hook is implemented prior to the 2011 spawning season. Rapid implementation could aid in the survival of the large 2003 year class identified by the ICCAT SCRS as warranting particular management attention. Enhanced survival of spawners from this year class may improve spawning success and size of subsequent year classes, ultimately increasing stock biomass.

While research results indicated a reduction in BFT bycatch, the results indicated a 52.7 percent increase in bycatch of white marlin and roundscale spearfish, combined, with the use of weak hooks as compared to the catch rate of the standard circle hook currently used by the GOM PLL fleet. The weak hook research indicated an increase of 52.7 percent in white marlin/roundscale spearfish catch, and this analysis assumes that the increase in catch would be proportionally the same for live discards and dead discards, thus representing a 52.7 percent increase in each. For the purposes of this analysis, NMFS assumes a 52.7 percent increase in dead discards. White marlin are considered to be overfished, although much uncertainty exists about the current population status due in part to confusion of white marlin with roundscale spearfish in various databases. Roundscale spearfish were recently recognized as a distinct, separate species (75 FR 57698;

September 22, 2010). The status of roundscale spearfish stocks is unknown. NMFS determined that listing white marlin as endangered or threatened under the ESA was not warranted in both 2002 and 2008.

According to logbook data, the average annual bycatch of white marlin in the GOM PLL fishery from 2006–2009 was 299 individual fish. With weak hook use in the GOM, the expected catch of white marlin in the GOM PLL fishery could increase by 158 to approximately 457 individual white marlin, annually. Due to the difficulty of distinguishing roundscale spearfish from white marlin, it is likely that some roundscale spearfish are included in the reporting of white marlin catches. Therefore, the estimate of additional white marlin catch would likely be a combination of white marlin and roundscale spearfish.

According to observer data, white marlin dead discards in the GOM PLL fishery in 2009 were 13,200 lbs, which equates to 275 individual fish (using the 2008 average white marlin dead discard weight of 48 lbs). NMFS fishery observers are trained to distinguish white marlin from roundscale spearfish; therefore, it is likely that roundscale spearfish are not included in the white marlin dead discard data for 2009. If white marlin dead discards increase by 52.7 percent (as found during research fishing), an additional 144 white marlin could be discarded dead. There may also be some additional roundscale spearfish dead discards that could occur with the use of weak hooks; however, NMFS is unable to provide an estimate at this time. NMFS found no significant difference in bycatch of blue marlin or sailfish while using industry standard circle hooks and the experimental weak hook on PLL gear in the GOM.

With regard to target species and other marketable catch, data from the GOM PLL BFT mitigation research indicate that the experimental weak hook facilitates the release of BFT but also decreases YFT and swordfish catch by 3.2 percent and 5.0 percent, respectively. The reduction in catch for YFT and swordfish was not statistically significant. Further, use of the weak hook may decrease the number of YFT and swordfish retained for sale (meaning fish equal to or larger than the minimum size) by 7.0 percent and 41.2 percent, respectively. The reductions in fish retained for sale were not statistically significant. With use of the weak hook, the number of wahoo caught may decrease by 26.6 percent. The results for pelagic and large coastal sharks were not significant; although, observations were mixed with reduction

in catch observed for some species and increases in catch for others. These uncertain results are likely due to low numbers of observations during the experiment. The results of the weak hook study for species with low sample size (<10 individuals) cannot be relied upon to determine the effects of using the experimental hook.

With the use of weak hooks in the GOM PLL fishery, potential decreases in YFT, swordfish, and wahoo catches, by number of fish, may have positive ecological benefits for all three species by leaving more sexually mature individuals in the ecosystem. Decreased YFT and swordfish catches may have negative ecological impacts for species known to interact with PLL gear if an increase in fishing effort occurs in order to offset reduced YFT catches. Increased effort may result in an increase in bycatch and bycatch mortality of non-target species, including billfish and protected resources. With the use of weak hooks, potential decreases in lancetfish bycatch by 14.8 percent (which was statistically significant) may have positive ecological benefits for lancetfish by leaving more fish in the ecosystem to reproduce.

A reduction in catch of some pelagic and large coastal sharks did occur with the experimental hook; although only a few observations were recorded and the reduction was not statistically significant. If some reduction in catch of pelagic or large coastal sharks actually occurs with the use of weak hooks, some unquantifiable positive ecological benefits for pelagic and large coastal sharks may occur due to the reduction in marketable sharks retained.

The use of weak hooks in the GOM PLL fishery would continue to provide positive ecological impacts, similar to the existing required standard circle hook, by facilitating the removal of fishing gear, which is expected to increase post-hooking survival of species caught incidentally to target fishing operations, including protected species. Additionally, anecdotal reports from scientists that conducted the weak hook study indicated that the weak hook was easier to dislodge from incidentally captured/foul hooked leatherback sea turtles than the currently required standard circle hook.

Magnuson-Stevens Act National Standard 9 was identified in the 2006 Consolidated HMS FMP along with National Standard 1 as priority management goals for HMS fisheries, particularly the Atlantic PLL fishery. National Standard 9 states that “conservation and management measures shall, to the extent practicable, (A) minimize bycatch and (B) to the

extent bycatch cannot be avoided minimize the mortality of such bycatch.” National Standard 9 applies to all species and fisheries. National Standard 1 states that “Conservation and management measures shall prevent overfishing while achieving, on a continuing basis, the optimum yield from each fishery for the United States fishing industry. The 2006 HMS FMP analysis of alternatives for time area closures and combinations of closures showed higher bycatch levels for some species and lower for others. NMFS did not prefer any new closures in the 2006 Consolidated HMS FMP, except the complementary measures in the Madison-Swanson and Steamboat Lumps Marine Reserves, and did not modify any closures at that time primarily because no closure alternative or combination of alternatives would substantially reduce the bycatch of all species considered, assuming redistribution of effort, and address other goals of the FMP, including minimizing any negative impacts.

This proposed action is expected to reduce BFT bycatch. The recent NMFS weak hook study was conducted in response to concerns for spawning age BFT PLL post release survivability in the GOM and provides information that may help to reduce bycatch and bycatch mortality of spawning age BFT. Preliminary results of the study showed a reduction, no change, or inconclusive results in the bycatch of species caught on PLL gear in the GOM except for an increase in bycatch of white marlin and roundscale spearfish. NMFS does not believe that this increase is likely to have population or ecosystem effects for those species because the predicted increase of 144 white marlin (or 1.05 mt in 2009 at 48 lb per fish) dead discards represents less than 0.8 percent of the total amount of international white marlin catch (which includes recreational landings and commercial dead discards) in the North Atlantic (406 mt in 2009). Due to misidentification of roundscale spearfish as white marlin, the total of white marlin international catch also includes some roundscale spearfish and, as such, indicates that any potential increase in roundscale spearfish that might occur in the GOM PLL fishery as a result of this proposed action should be very small in relation. In addition, NMFS already has comprehensive regulations in place to conserve these species in its domestic fisheries. Under current regulations, PLL vessels are not allowed to retain white marlin/ roundscale spearfish, and any that are captured must be released alive or

discarded if dead. Additionally, PLL vessels are currently required to possess and use protected species safe handling and release gears and techniques that aid in releasing hooked animals, including white marlin, and maximize post-release survival without removing the fish from the water. Most white marlin/roundscale spearfish that are hooked are released alive. Beyond PLL vessels, current regulations also include a ban on retention on all commercial fishing vessels, observer coverage and mandatory reporting on commercial fishing vessels, a recreational size limit, and an annual 250 marlin landings limit in recreational fisheries.

If this proposed action was finalized, NMFS would continue research with weak hook technology and closely monitor white marlin and roundscale spearfish catch through observer coverage in the fishery. Should the increased catches of white marlin and roundscale spearfish continue, NMFS would investigate potential mitigation measures that might be implemented if necessary to reduce the catches and/or reduce the bycatch mortality associated with the catches. Such measures could include adopting a seasonal application of the weak hook, modification or removal of the weak hook requirement or other measures as necessary and appropriate. NMFS would closely monitor fleet activities and catch statistics and consider making management measures adjustments, including use of inseason management authority, should the data warrant. Given the conservation and management measures in place and continued research and monitoring, and taking into account the National Standard 9 Guidelines, NMFS believes that this proposed rule minimizes bycatch and bycatch mortality to the extent practicable.

Implementation of weak hooks in the GOM PLL fishery would be expected to have moderate negative social and economic impacts in the short-term for those vessels able to successfully utilize the weak hook when fishing with PLL for YFT and other species in the GOM and greater temporary negative economic impacts for those vessels that are unable to quickly alter their fishing techniques to successfully utilize the weak hook technology. NMFS gear researchers have found that fishermen participating in research tend to work through a learning curve with new technology and generally improve their performance with a particular gear over time.

As mentioned above, a reduction in catch of some pelagic and large coastal sharks did occur with the experimental

hook; although only a few observations were recorded and the reduction was not statistically significant. If some reduction in catch of pelagic or large coastal sharks actually occurs with the weak hook, some unquantifiable negative economic impacts may occur due to the reduction in marketable sharks retained. Conversely, some unquantifiable economic benefits may result if fishing efficiency increases and fishermen lose less fishing time clearing lines and handling large unmarketable sharks. Additionally, fishermen may experience a reduction in economic losses due to damaged or lost fishing gear.

A probability analysis of the potential change in numbers of BFT incidentally caught, but allowed to be retained due to target catch tolerances, showed only a small reduction with the use of the weak hook. Because only a small portion of the BFT caught are available for landing, the 56.5 percent reduction in catch observed with the weak hook design will not likely result in a 56.5 percent reduction in landings. The majority of trips that landed BFT actually caught more than twice as many BFT as they landed. Therefore, for a majority of trips, the new hook design will not affect the opportunity for vessels to land the allowable number of BFT under existing regulations. The probability analysis used observer data from 2009 and 2010, and estimated any changes in landings that might have occurred if the weak hook had been used. There were 68 observed trips in 2009 and 34 trips observed in 2010 during the BFT tuna observer coverage period. The estimates are based on 2009 and 2010 non-experimental data where 320 BFT were caught with 47 landed during observed trips in 2009, and 115 BFT were caught with 12 landed during observed trips in 2010. The maximum number of BFT caught during a trip was 18 and the maximum number of BFT landed from a trip was two. Results show that use of the weak hook is predicted to decrease the number of BFT retained by only 14 percent (i.e., from 59 observed landings to 51 predicted) with the use of weak hooks. This minor reduction in landings would likely result in minimal negative economic impacts.

The use of weak hooks in the GOM PLL fishery is predicted to have indirect positive economic and social impacts to both the PLL fishery and on the targeted BFT fishery. In past years, the PLL fishery has landed and discarded dead BFT substantially in excess of its allocated quota. If landings and discards can be brought more into alignment with FMP sub-quotas, then management

actions with likely substantial negative impacts, such as closure of the PLL fishery, may not need to be considered for quota management purposes. Exceeding PLL allocated incidental quotas (landings and dead discards) has also meant that the BFT sub-quotas have had to be reallocated from prior year underage, the reserve, or directed categories with underharvest to ensure the United States does not exceed its total ICCAT allocated quota. In the near future, however, NMFS may not have the same ability to reallocate quota if ICCAT quotas decrease and directed BFT categories fully meet their own individual quota allocations. The anticipated increased availability of adult (and greater than or equal to the commercial minimum size limit of 73 inches curved fork length) BFT as the strong 2003 year class continues to mature increases the likelihood of, not only increased landings from directed fishing categories, but increased incidental interactions with PLL gear as well. Unless incidental BFT catch is brought into alignment with the available BFT incidental PLL quota, it is possible that quota may need to be transferred from directed quota categories resulting in early closures and negative social and economic impacts to these directed BFT fisheries or that the PLL fishery would have to be closed prior to the end of the fishing year.

Request for Comments

Comments on this proposed rule may be submitted via <http://www.regulations.gov>, mail, or fax. Comments may also be submitted at a public hearing (see Public Hearings and Special Accommodations below). NMFS solicits comments on this proposed rule by February 12, 2011 (see **DATES** and **ADDRESSES**).

NMFS will hold three public hearings for this proposed rule. The meeting times, dates, and locations follow. All meetings will begin with an opportunity for individuals to receive information and ask questions about the GOM PLL BFT Mitigation Research followed by a public hearing.

1. February 7, 2011, 2 p.m. to 5 p.m. Eastern Standard Time (EST), NOAA Science Center, 1301 East-West Highway, Silver Spring, MD, 20910.

2. February 9, 2011, 5 p.m. to 8 p.m. Central Standard Time (CST), NMFS Panama City Laboratory, 3500 Delwood Beach Road, Panama City, FL, 32408

3. February 10, 2011, 5 p.m. to 8 p.m. CST, Hilton New Orleans Airport Hotel, 901 Airline Drive, Kenner, LA, 70062

An operator-assisted conference call will be held to receive comments from

HMS Advisory Panel members on February 8, 2011, from 2 p.m. to 4 p.m. EST (phone number 888-989-6419; participant code 3557004). This will be a conference call to hear comments from HMS Advisory Panel members; however, the public is invited to participate, and this is not an HMS Advisory Panel meeting. Priority will be given to comments from the Advisory Panel and comments from the general public will be heard as time allows.

The hearings will be physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Peter Cooper at (301) 713-2347 at least 7 days prior to the hearing date. The public is reminded that NMFS expects participants at the public hearings to conduct themselves appropriately. At the beginning of each public hearing, a representative of NMFS will explain the ground rules (e.g., alcohol is prohibited from the hearing room; attendees will be called to give their comments in the order in which they registered to speak; each attendee will have an equal amount of time to speak; and attendees should not interrupt one another). The NMFS representative will attempt to structure the meeting so that all attending members of the public will be able to comment, if they so choose, regardless of the controversial nature of the subject(s). Attendees are expected to respect the ground rules, and, if they do not, they will be asked to leave the hearing.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that the proposed rule is consistent with the 2006 Consolidated HMS FMP and its amendments, other provisions of the MSA, ATCA, and other applicable law, subject to further consideration after public comment.

NMFS prepared an environmental assessment for this rule that discusses the impact on the environment as a result of this rule. In this proposed action, NMFS is considering requiring the use of weak hooks by PLL vessels fishing in the GOM. This measure is meant to provide a new gear technology for PLL vessels to continue routine fishing operations in the GOM on directed fisheries such as YFT while increasing the live release of incidentally caught Atlantic BFT to further stock recovery of this overfished species. A copy of the environmental assessment is available from NMFS (see ADDRESSES).

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

An initial regulatory flexibility analysis (IRFA) was prepared, as required by section 603 of the RFA (RFA). The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities. A description of the action, why it is being considered, and the legal basis for this action are contained at the beginning of this section in the preamble and in the **SUMMARY** section of the preamble. A summary of the analysis follows. A copy of this analysis is available from NMFS (see ADDRESSES).

In compliance with section 603(b)(1) of the Regulatory Flexibility Act, the purpose of this proposed rulemaking is, consistent with the Magnuson-Stevens Act and the 2006 Consolidated HMS FMP and its amendments, to further BFT stock recovery by increasing live releases of incidentally caught BFT and adding flexibility by providing a new gear technology for PLL vessels to continue routine fishing operations in the GOM.

In compliance with section 603(b)(2) of the Regulatory Flexibility Act, the objectives of this proposed rulemaking are to: (1) Enhance stock rebuilding by increasing BFT spawning potential and subsequent recruitment into the fishery, (i.e., rapidly implement the proposed action to increase the survival of spawning BFT in 2011 in the GOM particularly the 2003 year class); (2) constrain PLL BFT catch to the incidental BFT quota allocation; (3) allow the PLL fleet to continue to participate in their directed fisheries (e.g., YFT and swordfish) year-round with less risk of fishery interruption due to insufficient incidental quota availability (i.e., minimize negative social and economic impacts to the PLL directed fisheries); (4) reduce the need for BFT quota reallocation from directed fisheries or the Reserve to cover PLL BFT bycatch (i.e., minimize negative and social impacts to BFT directed fisheries); and (5) minimize negative ecological impacts on non-target or protected species.

Section 603(b)(3) requires Federal agencies to provide an estimate of the number of small entities to which the rule would apply. NMFS considers all HMS permit holders to be small entities because they either had average annual receipts less than \$4.0 million for fish-harvesting, average annual receipts less than \$6.5 million for charter/party boats, 100 or fewer employees for wholesale dealers, or 500 or fewer employees for seafood processors. These

are the Small Business Administration (SBA) size standards for defining a small versus large business entity in this industry.

The GOM PLL fishery is comprised of fishermen who hold an Atlantic Tunas Longline, a Swordfish Directed or Incidental Permit, and a Shark Directed or Incidental limited access permit and the related industries including processors, bait houses, and equipment suppliers, all of which NMFS considers to be small entities according to the size standards set by the SBA. The proposed rule would apply to PLL vessels that fish in the GOM. As of October 2010, there were 248 Atlantic tuna longline limited access permit holders. Of these, 136 were registered in states along the coast of the GOM (including all Florida vessels). However, based on logbook records from 2006 to 2009, on average, only 51 PLL vessels were actively operating in the GOM annually, with a high of 55 vessels in 2007 and a low of 47 in 2006 and 2009. During the summer of 2010, preliminary vessel monitoring system information indicated that the number of active PLL vessels in the GOM decreased by more than 79% due to the Deepwater Horizon/BP oil spill and associated fishery closures.

This proposed rule does not contain any new reporting or recordkeeping requirements, but would require a new compliance requirement (5 U.S.C. 603(b)(4)). Fishing vessels with PLL gear onboard would be required, at all times, in all areas of the GOM open to HMS PLL fishing, to possess onboard and/or use only circle hooks meeting current size and offset restrictions, as well as being constructed of only round wire stock that is no larger than 3.65 mm in diameter. This proposed rule would not conflict, duplicate, or overlap with other relevant Federal rules (5 U.S.C. 603(b)(5)). Fishermen, dealers, and managers in these fisheries must comply with a number of international agreements, domestic laws, and other FMPs. These include, but are not limited to, the Magnuson-Stevens Act, the Atlantic Tunas Convention Act, the High Seas Fishing Compliance Act, the Marine Mammal Protection Act, the Endangered Species Act, the National Environmental Policy Act, the Paperwork Reduction Act, and the Coastal Zone Management Act. NMFS does not believe that the new regulations proposed to be implemented would duplicate, overlap, or conflict with any relevant regulations, Federal or otherwise.

Under section 603(c), agencies are required to describe any alternatives to the proposed rule which accomplish the

stated objectives and which minimize any significant economic impacts. These impacts are discussed below and in the Environmental Assessment for the proposed action. Additionally, the Regulatory Flexibility Act (5 U.S.C. 603 (c) (1)–(4)) lists four general categories of significant alternatives that would assist an agency in the development of significant alternatives. These categories of alternatives are: (1) Establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities; (3) use of performance rather than design standards; and, (4) exemptions from coverage of the rule for small entities.

In order to meet the objectives of this proposed rule, consistent with legal obligations, NMFS cannot exempt small entities or change the reporting requirements only for small entities. Thus, there are no alternatives discussed that fall under the first and fourth categories described above. In addition, none of the alternatives considered would result in additional reporting requirements (category two above). Fishing vessels with PLL gear onboard would be required, at all times, in all areas of the GOM open to HMS PLL fishing, to possess onboard and/or use only circle hooks meeting current size and offset restrictions as well as being constructed of only round wire stock that is no larger than 3.65 mm in diameter. NMFS does not know of any performance or design standards that would satisfy the aforementioned objectives of this rulemaking while, concurrently, complying with the Magnuson-Stevens Act. Perhaps there are performance or design standards that could be designed for weak hooks and BFT bycatch reduction, but they are not practical given the current understanding of this new technology.

NMFS considered and analyzed three main alternatives for this proposed rule. The first alternative was the status quo, no action alternative. This alternative would maintain existing hook and bait requirements in the Atlantic PLL fishery in the GOM. The second alternative would require all PLL vessels fishing in GOM to use weak hooks and is the preferred alternative. Finally, the third alternative would consider establishing additional time/area closures in the GOM. Under this alternative, an area of the GOM would be closed to PLL fishing and could extend over the entire GOM or a subarea. Temporal extents of a closure could be timed to the spawning season for BFT in the GOM, April to

mid-June, or for shorter or longer time frames (*i.e.*, year round). Areal extents of a closure could be restricted to portions of the GOM where particularly high concentrations of spawning BFT have been observed while minimizing inclusion of areas with high directed YFT fishing operations. Adaptive management programs might also be considered with the temporal/spatial extent of the time/area changes based on real-time information on distribution and abundance of target and non-target species as well as the socio-economic needs of the fishery. In addition to these three alternatives, NMFS also considered other options such as prohibition on all retention of BFT in the GOM (*i.e.*, no incidental retention of BFT allowed) and adjustment of target catch retention limits (*i.e.*, modify current limits of one BFT per 2,000 lbs of target catch, two BFT per 6,000 lbs and three BFT per 30,000 lbs). As these alternatives either do not reduce mortality of BFT but rather convert discards to landings (or vice versa), or may have substantial negative social and economic impacts and cannot be implemented in short time frames, these alternatives were determined to not meet the objectives of the action and were not considered further.

Alternative 1, the status quo, no action alternative would not result in any additional economic impacts to small entities in the short-term. NMFS does not anticipate a significant change in landings, ex-vessel prices, or operating costs relative to the “status quo” for small entities under this alternative. However, adverse economic impacts in the medium and long-term could result if no action is taken to address the incidental catch of BFT in the GOM PLL fishery. Adverse economic impacts could occur if the longline quota for BFT is exceeded and a partial or total closure of the fishery is implemented.

The preferred alternative, Alternative 2, would require vessels with PLL gear onboard, at all times, in all areas of the GOM open to PLL fishing, to possess onboard and/or use only circle hooks meeting current size and offset restrictions as well as being constructed of only round wire stock that is no larger than 3.65 mm in diameter. This alternative would result in some minor increases in equipment costs for the new hooks, would likely impact vessel operations, and would also potentially impact catch rates and thus potentially reduce vessel revenues.

Alternative 2 would result in moderate positive social and economic benefits if this measure is able to reduce the bycatch of BFT in the GOM

sufficiently to allow the PLL fishery to continue operating in the GOM. However, there would likely be some increased economic costs associated with switching to the weak hook.

This alternative would result in some minor increases in equipment costs associated with acquiring the new weak hooks. Direct cost of purchasing weak hooks is anticipated to increase expenses by \$.02 per hook. An informal telephone survey of hook suppliers provides a price of approximately \$0.34 per hook for 16/0 commercial grade circle hooks and approximately \$0.36 per hook for 16/0 circle hooks constructed of 3.65 mm diameter round wire stock. Assuming that an average of 1,600 hooks per vessel are needed initially to equip vessels with enough required hooks for one trip, the compliance cost, on a per vessel basis, would be approximately \$576. NMFS intends to explore opportunities to mitigate costs for PLL fishermen with their initial purchase of the required supply of weak hooks once the weak hook gear is finalized as a requirement. Opportunities might include third party sponsorship of a voucher program where eligible PLL vessels that actively fish in the GOM would be eligible for their initial supply of weak hooks. NMFS specifically requests comments about such a potential voucher program.

Hook replacement rates are anticipated to increase with use of the weak hook. Researchers during the GOM PLL BFT mitigation research estimated that requiring the weak hook would result in a 4.41 hooks per 1,000 hooks increase in the rate of hook replacement due to straightened hooks and YFT hook deformation. The researchers anticipated that this rate was an underestimate; however, they estimated the cost of additional hook replacement with the weak hook to be less than \$3.00 per 1,000 hooks set. The standard 16/0 circle hooks currently in use will continue to be used in the U.S. Atlantic and inventories of unused standard 16/0 hooks could be sold to vessels fishing Atlantic outside of the GOM.

With regard to PLL vessels fishing in the Atlantic, but outside the GOM, NMFS solicits specific comment on gear stowage procedures that could allow vessels entering or exiting the GOM with hooks not meeting the weak hook requirement. Such stowage procedures would need to allow vessels to transit the GOM while ensuring the enforceability of weak hook requirements.

Alternative 2 would also potentially impact vessel catch rates, and thus potentially reduce vessel revenues.

Based on the GOM PLL BFT mitigation research results, catch rates for several commercially important species were found to be lower using the new weak hooks versus the standard 16/0 circle hooks. The researchers found a statistically significant (at the 5 percent level) reduction in the total catch of BFT and wahoo when weak hooks were used compared to conventional circle hooks. The total catch of BFT was reduced 56.5 percent when weak hooks were used in the experiment. This reduction includes both discards and BFT retained for sale. Based on observer reports of the number of BFT discarded versus retained in the GOM, the researchers estimate that the experimental results indicate that the use of weak hooks would result in approximately a 14 percent reduction in BFT retained for sale given the BFT incidental retention limits. The total catch of wahoo using the weak hook was reduced by 26.6 percent.

The research also observed reduction in the number of YFT and swordfish retained for sale. While these results were not statistically significant at the 5 percent level, the reductions in YFT and swordfish retained did have p-values ≤ 0.15 . Weak hooks in the experiment resulted in a 7 percent reduction in YFT retained for sale and 41.2 percent reduction in swordfish retained for sale. No other commercially targeted species observed during the research exhibited catch rate differences between weak hooks and conventional circle hooks with p-values of ≤ 0.15 . Therefore, given that YFT is often the target catch for PLL trip in the GOM and the heterogeneous nature of fishing vessel operations, this analysis conservatively includes the observed reductions in YFT and swordfish. In addition, NMFS also ran the analysis with just BFT and wahoo which exhibited statistically significant differences in catch at the 5 percent level to help illustrate the range of possible outcomes.

Using vessel logbook catch data, NMFS translated the reductions in catch observed in the research experiment into potential fishery revenue impacts that may result from requiring the use of weak hooks in the GOM. The calculations are detailed in the EA for this proposed rule which is available on request. Based on the research results, the estimated per trip reduction in revenues that would potentially result from requiring the use of weak hooks in the GOM is approximately \$2,265.

Based on HMS logbook reports from 2006 to 2009, the average number of PLL trips taken per vessel per year in the GOM is 9.7. Multiplying 9.7 trips per vessel by the estimated \$2,265 per trip reduction in catch revenues results

in an estimated reduction of \$21,974 in commercial fishing revenues per vessel per year in the GOM resulting from switching to weak hooks. Alternatively, if the analysis only considers the statistically significant reductions in catch at the 5 percent level, as used in the research study, the estimated reduction in annual catch revenues per vessel in the GOM for Alternative 2 would be \$1,351 (9.7 trips \times \$139). This lower estimate may also represent the potential improvements in catch rates that may occur over time as fishermen adapt to the new weak hook technology. NMFS does not foresee that the national net benefits and costs would change significantly in the long term as a result of implementation of the proposed action.

Alternative 3 may cause some fishermen to shift effort to fishing areas outside the GOM and there could be changes in the distribution of the fleet with some fishermen possibly exiting the fishery. Predicting fishermen's behavior is difficult, especially as some factors that may determine whether to stay in the fishery, relocate, or leave the fishery are beyond NMFS' control (fuel prices, infrastructure, hurricanes, etc.). While some fishermen will continue to fish in the remaining open areas of the Atlantic, Caribbean, and Gulf of Mexico, others may be forced to leave the fishery entirely, such as selling their permits and going out of business, as a result of the closure. Changes in fishing patterns may result in fishermen having to travel greater distances to reach more favorable grounds, which would likely result in increased fuel, bait, ice, and crew costs. While there may be a potential increase in travel, this is unlikely to raise significant safety concerns because the fleet is highly mobile. The potential shift in fishing grounds, should it occur, could result in fishermen selecting new ports for offloading. This would likely have negative social and economic consequences for traditional ports of offloading, including processors, dealers, and supply houses, and positive social and economic consequences for any new selected ports of offloading. NMFS conducted a detailed, comprehensive socio-economic analysis for the time/area alternatives considered in the 2006 Consolidated HMS FMP and found that the economic impacts of each of the closures considered may be substantial, ranging in losses of up to several million dollars annually, depending upon the closure and displacement of a significant number of fishing vessels. Since the data analysis conducted in the 2006 Consolidated

HMS FMP, several events have affected the GOM including Hurricane Katrina, Hurricane Rita, and the DWH/BP oil spill among other events. These events resulted in negative economic impacts. While these further impacts have occurred, NMFS believes the closure analysis in 2006 still reflects the substantial impacts of the alternatives that are likely to occur. Cumulatively, the impacts of the closures would likely be adverse and greater than in 2006. Additionally, Alternative 3 in this proposed rule doesn't meet all of the objectives of this proposed rule because it doesn't rapidly enhance BFT stock rebuilding by increasing BFT spawning potential and subsequent recruitment into the fishery (*i.e.* rapidly implement the proposed action to increase the survival of spawning BFT by spring 2011 in the GOM).

List of Subjects in 50 CFR Part 635

Fisheries, Fishing, Fishing vessels, Foreign relations, Imports, Penalties, Reporting and recordkeeping requirements, Treaties.

Dated: January 10, 2011.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 635 is proposed to be amended as follows:

PART 635—ATLANTIC HIGHLY MIGRATORY SPECIES

1. The authority citation for part 635 continues to read as follows:

Authority: 16 U.S.C. 971 *et seq.*; 16 U.S.C. 1801 *et seq.*

2. In § 635.2, the definition of "round wire stock" is added to read as follows:

§ 635.2 Definitions.

* * * * *

Round wire stock means round metal wire, typically used in the manufacturing of fishing hooks, that has not been forged, or otherwise treated in any way to increase the original factory tensile strength set by the hook manufacturer.

* * * * *

3. In § 635.21, paragraph (c)(5)(iii)(C)(2)(i) is revised to read as follows:

§ 635.21 Gear operation and deployment restrictions.

* * * * *

- (c) * * *
- (5) * * *
- (iii) * * *
- (C) * * *

(2) * * *

(i) For purposes of paragraphs (c)(5)(iii)(C)(1), and (c)(5)(iii)(C)(2) of this section, the outer diameter of an 18/0 circle hook at its widest point must be no smaller than 2.16 inches (55 mm), and the outer diameter of a 16/0 circle hook at its widest point must be no smaller than 1.74 inches (44.3 mm), when measured with the eye of the hook on the vertical axis (y-axis) and perpendicular to the horizontal axis (x-axis). The distance between the hook point and the shank (*i.e.*, the gap) on an 18/0 circle hook must be no larger than 1.13 inches (28.8 mm), and the gap on

a 16/0 circle hook must be no larger than 1.01 inches (25.8 mm). The allowable offset is measured from the barbed end of the hook, and is relative to the parallel plane of the eyed-end, or shank, of the hook when laid on its side. The only allowable offset circle hooks are those that are offset by the hook manufacturer. In the Gulf of Mexico, as described at 600.105(c), circle hooks also must be constructed of corrodible round wire stock that is no larger than 3.65 mm in diameter.

* * * * *
4. In § 635.71, add paragraph (a)(54) to read as follows:

§ 635.71 Prohibitions.

* * * * *

(a) * * *

(54) Possess, use, or deploy, in the Gulf of Mexico, any circle hook, other than as described at § 635.21(c). Vessels in the Gulf of Mexico, with pelagic gear onboard, are prohibited from possessing, using, or deploying circle hooks that are constructed of round wire stock which is larger than 3.65 mm in diameter.

* * * * *

[FR Doc. 2011-689 Filed 1-12-11; 8:45 am]

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Notices

Federal Register

Vol. 76, No. 9

Thursday, January 13, 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

January 7, 2011.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), OIRA_Submission@OMB.EOP.GOV or fax (202) 395-5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250-7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720-8958.

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

the collection of information unless it displays a currently valid OMB control number.

Animal and Plant Health Inspection Service

Title: Dairy Heifer Raiser 2010 Study.
OMB Control Number: 0579-NEW.

Summary of Collection: Collection and dissemination of animal health data and information is mandated by 7 U.S.C. 391, the Animal Industry Act of 1884, which established the precursor of the Animal and Plant Health Inspection Service (APHIS), Veterinary Service, and the Bureau of Animal Industry. Legal requirements for examining and reporting on animal disease control methods were further mandated by 7 U.S.C. 8308 of the Animal Health Protection Act, "Detection, Control, and Eradication of Diseases and Pests," May 13, 2002. This submission is a request for approval to initiate the National Animal Health Monitoring Systems (NAHMS) Dairy Heifer Raiser 2010 Study, an information collection by the Animal and Plant Health Inspection Service (APHIS). The study will be conducted with the assistance of State Animal Health Officials using NAHMS-242, "Dairy Heifer Raiser Questionnaire." The Dairy Heifer Raiser 2010 Study is a part of an ongoing series of NAHMS studies on the U.S. dairy population.

Need and Use of the Information: The information collected through the Dairy Heifer Raiser 2010 Study will be analyzed and organized into descriptive reports. APHIS will use the data collected to: (1) Provide the first comprehensive information on animal health and management practices for heifer-raising operations; (2) Evaluate the biosecurity risks associated with heifer-raising operations (e.g., commingling cattle from multiple operations, exposing young cattle to Mexican cattle); and (3) Assist in the development of a biosecurity assessment that can be used to evaluate the risk of disease transmission (e.g., Tuberculosis, Bovine Viral diarrhea, etc.). Without this type of data, the ability to detect trends in management, production, and health status, either directly or indirectly, would be reduced or nonexistent.

Description of Respondents: Business or other for-profit.

Number of Respondents: 800.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 752.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2011-571 Filed 1-12-11; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No. AMS-NOP-10-0045; NOP-10-03]

National Organic Program: Notice of Draft Guidance Concerning "Made With Organic (Specified Ingredients or Food Groups)" Products: Product Composition and Use of Percentage Statements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice with request for comments.

SUMMARY: This notice announces draft guidance for the organic industry to address the labeling, composition of and use of percentage statements in "made with organic (specified ingredients or food groups)." Specifically, the draft guidance addresses (1) the use of non-organic ingredients in "made with organic (specified ingredients or food groups)" products, and (2) the use of statements about the percentage of organic ingredients within the "made with organic (specified ingredients or food groups)" labeling category.

The guidance explains the policy of the National Organic Program (NOP) concerning the portions of the regulations in question, referenced herein. The NOP invites organic producers, handlers, certifying agents, consumers and other interested parties to submit comments about these guidance provisions. A notice of availability of final guidance on this topic will be issued upon its final approval. Once finalized, this guidance document will be available from the NOP through "The Program Handbook: Guidance and Instructions for Accredited Certifying Agents (ACAs) and Certified Operations." This Handbook provides those who own, manage, or certify organic operations with guidance and instructions that can assist them in complying with the

National Organic Program (NOP) regulations. The current edition of the Program Handbook is available online at <http://www.ams.usda.gov/nop> or in print upon request.

DATES: Comments must be submitted on or before March 14, 2011.

ADDRESSES: NOP invites interested persons to submit comments pertaining to guidance on “made with organic (specified ingredients or food groups)” labeling and composition addressed herein using the following procedures:

- *Internet:* <http://www.regulations.gov>.
- *Mail:* Comments may be submitted to Toni Strother, Agricultural Marketing Specialist, National Organic Program, USDA-AMS-NOP, Room 2646-So., Ag Stop 0268, 1400 Independence Ave., SW., Washington, DC 20250-0268.

Written comments responding to this request should be identified with the document number AMS-NOP-10-0045; NOP-10-03. Clearly indicate the provision you are addressing and your support for or opposition to it and the reason for your position. Please include only relevant information and data to support your position.

USDA intends to make available all comments, including names and addresses when provided, regardless of submission procedure used, on <http://www.regulations.gov> and at USDA, AMS, NOP, Room 2646-South building, 1400 Independence Ave., SW., Washington, DC, from 9 a.m. to noon and from 1 to 4 p.m., Monday through Friday (except official Federal holidays). Persons wanting to visit the USDA South building to view comments from the public to this notice are request to make an appointment by calling (202) 720-3252.

FOR FURTHER INFORMATION CONTACT: Melissa Bailey, Director, Standards Division, National Organic Program, USDA-AMS-NOP, 1400 Independence

Ave., SW., Room 2646-So., Ag Stop 0268, Washington, DC 20250. Telephone: (202) 720-3252; Fax: (202) 205-7808.

SUPPLEMENTARY INFORMATION:

Purpose & Applicability

The Organic Foods Production Act of 1990 (OFPA), 7 U.S.C. Section 6501, *et seq.*, as amended, and the NOP regulations implemented in 7 CFR part 205, National Organic Program (NOP) Final Rule, regulate the production, handling, processing, and labeling of all raw or processed agricultural products to be sold, labeled, or represented as organic in the United States.

This guidance describes the policies for certified operations, certifying agents accredited by the U.S. Department of Agriculture (USDA), and approved State Organic Programs with respect to “made with organic (specified ingredients or food group(s))” products in the following two areas:

1. Restrictions on the use of non-organic ingredients; and
2. Statements about the percentage of organic ingredients.

I. Product Composition

Background

The NOP regulations describe the composition requirements for products to be labeled as “100% organic,” “organic,” and “made with organic (specified ingredients or food group(s)).” The purpose of this section is to explain the allowances and restrictions on the use of non-organic ingredients that may comprise up to 30 percent of a “made with organic (specified ingredients or food group(s))” product.

According to § 205.301(c) products within the “made with organic (specified ingredients or food group(s))” labeling category must contain at least 70 percent certified organic agricultural products. None of the ingredients in the

final product may be produced using excluded methods (*i.e.*, genetically modified organisms), sewage sludge or ionizing radiation.

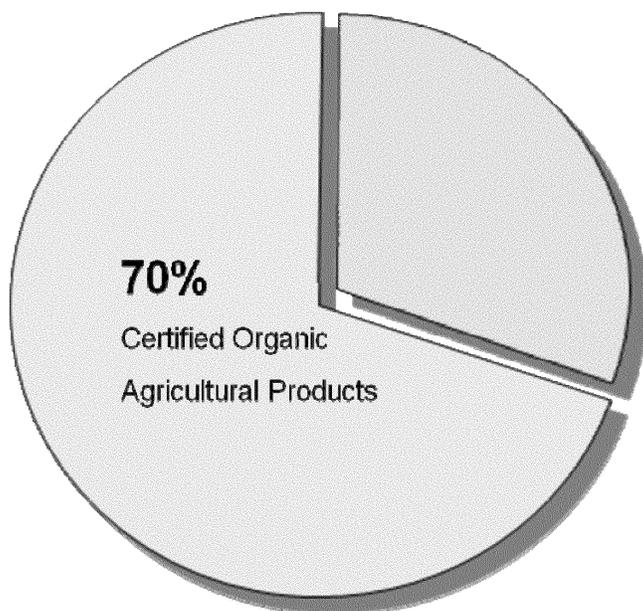
Multi-ingredient products labeled as “made with organic (specified ingredients or food group(s))” may contain up to 30 percent of the following: (1) Conventionally produced (non-organic) agricultural products such as fruits, spices and grains regardless of the synthetic substances which may have been used in their production or processing; and (2) natural and synthetic ingredients or processing aids listed in § 205.605 *Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food groups).”* Any synthetic substance may be used to manufacture a substance on § 205.605; however, if the synthetic is present in the final § 205.605 substance, the synthetic must also be on the National List and allowed for the intended use.

Policy Statement

Products within the “made with organic (specified ingredients or food group(s))” labeling category must contain at least 70 percent certified organic agricultural products. The remaining 30 percent may include:

1. Agricultural ingredients which are conventionally produced. These ingredients must not have been produced using excluded methods (genetically modified organisms), sewage sludge, or ionizing radiation, but may be produced using synthetic substances not appearing on the National List at § 205.605.

2. Natural and synthetic ingredients or processing aids that are listed within § 205.605.



- 30% may be
 - Substances from 205.605
 - Any non-organic agricultural product produced without GMO, sewage sludge, or irradiation

II. Statement of Percentage of Organic Ingredients

Background

The NOP regulations (§§ 205.303(a) and 205.304(a)) state that products in packages described in §§ 205.301(a), (b), and (c), *may* display the terms, “100 percent organic,” “organic,” and “made with organic (specified ingredients or food group(s)),” respectively, as applicable. These provisions also state these products *may* display the percentage of organic ingredients in the product.

Accordingly, the NOP has received questions about whether a percentage statement may appear without a product composition statement (“100% organic,” “organic,” “made with organic (specified ingredients or food groups)” on a product package. For example, may a soup label state, “75 percent organic ingredients” on the principal display panel without a “made with organic vegetables” statement?

The purpose of this section is to clarify (a) the display of product composition and percentage statements on packaged products, and (b) whether percentage statements can be used when the percent of the organic ingredients exceeds the product composition category. For example, may a soup label state “95 percent organic ingredients” when the soup qualifies only for a “made with organic vegetables” claim?

Policy Statement

The “made with organic (specified ingredients or food group(s))” statement is essential to clarify the product category and may be used without the percentage statement. The statements,

“made with organic ingredients,” or “made with (insert number)% organic ingredients,” do not comply with §§ 205.304(a)(1)(i) or (ii) and are not acceptable variations of a “made with organic” statement. The correct formats for “made with organic” statements are: “made with organic (*specified* ingredients); or (*specified* food groups),” provided that the statement does not list more than three organically produced ingredients or food groups.

A percentage statement must be accompanied by the statement, “made with organic (specified ingredients or food group(s))” when displayed on packages of products in this category, which are described in § 205.301(c). As written in the NOP regulations, the section heading for § 205.304, “Packaged products labeled “made with organic (specified ingredients or food group(s)),” implies that a “made with organic (specified ingredients or food group(s))” statement is present on the product, and, therefore, the product must contain at least 70 percent certified organic agricultural products. The “made with (specified ingredients or food group(s))” statement is particularly important when the product contains 95 percent or more organic ingredients; without it, a consumer cannot determine the appropriate product category and could be misled to assume that the product qualifies for the “organic” labeling category.

A claim of “100% organic” should only be used for products that qualify under § 205.301(a). The “100% organic” claim refers to a particular labeling category within the NOP regulations and should not be used in combination

with other NOP labeling categories. For example, a “made with 100% organic (specified ingredients or foods groups)” label may lead consumers into thinking that the “made with” product qualifies for the “100% organic” category.

Acceptable variations of percentage statements include: “X% Organic,” “X% Organic Ingredients,” “Contains X% Organic Ingredients,” “Made with X% Organic Ingredients.” Each of the above versions of a percentage statement need to appear with a proper “made with organic” statement. Additional versions of percentage claim statements may be acceptable as long as they are not misleading. Percentage statements must appear without highlighting and in the same type size, font and color in its entirety. The size of a percentage statement must not exceed one-half of the largest type size on the display panel, in accordance with § 205.304(a)(2).

III. Significance of Guidance

This draft guidance document is being issued in accordance with the Office of Management and Budget (OMB) Bulletin on Agency Good Guidance Practices (GGPs) (January 25, 2007, 72 FR 3432–3440).

The purpose of GGPs is to ensure that program guidance documents are developed with adequate public participation, are readily available to the public, and are not applied as binding requirements. The draft guidance, when finalized, will represent the NOP’s current thinking on these topics. It does not create or confer any rights for, or on, any person and does not operate to bind the NOP or the public. Guidance documents are intended to provide a

uniform method for operations to comply that can reduce the burden of developing their own methods and simplify audits and inspections. Alternative approaches that can demonstrate compliance with the Organic Foods Production Act (OFPA), as amended (7 U.S.C. 6501–6522), and its implementing regulations are also acceptable.

The NOP strongly encourages the industry to discuss alternative approaches with the NOP before implementing them to avoid unnecessary or wasteful expenditures of resources and to ensure the proposed alternative approach complies with the Act and its implementing regulations.

Authority: 7 U.S.C. 6501, *et seq.*; 7 CFR part 205.

Dated: January 7, 2011.

David R. Shipman,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2011–573 Filed 1–12–11; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Forest Service

Bridger-Teton National Forest Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of Meeting.

SUMMARY: The Bridger-Teton Resource Advisory Committee will meet in Kemmerer, Wyoming. The committee is meeting as authorized under the Secure Rural Schools and Community Self-Determination Act (Pub. L. 110–343) and in compliance with the Federal Advisory Committee Act. The purpose is to review project applications.

DATES: The meeting will be held on February 14, 2011, and will begin at 5 p.m.

ADDRESSES: The meeting will be held at the Kemmerer Ranger District Office, 308 U.S. Highway 189 North, Kemmerer, WY. Written comments should be sent to Tracy Hollingshead, Bridger-Teton National Forest, 308 Hwy 189 North, Kemmerer, WY 83101. Comments may also be sent via e-mail to thollingshead@fs.fed.us, or via facsimile to 307–828–5135.

All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at Bridger-Teton National Forest, Hwy 189 North, Kemmerer, WY 83101. Visitors are encouraged to call ahead to 307–877–4415 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT:

Tracy Hollingshead, DFO, USDA, Bridger-Teton National Forest, Hwy 189 North, Kemmerer, WY 83101; (307) 877–4415; E-mail thollingshead@fs.fed.us.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The meeting is open to the public. The following business will be conducted: (1) Approve minutes from November 29, 2010 meeting. (2) Review and discuss project applications. (3) Update on potential additional Resource Advisory Committee applicants; and (4) Public Comment. Persons who wish to bring related matters to the attention of the Committee may file written statements with the Committee staff before or after the meeting.

Dated: January 7, 2011.

Tracy Hollingshead,

Designated Federal Officer.

[FR Doc. 2011–662 Filed 1–12–11; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Pike & San Isabel Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Pike & San Isabel Resource Advisory Committee will meet in Pueblo, Colorado. The committee is meeting as authorized under the Secure Rural Schools and Community Self-Determination Act (Pub. L. 110–343) and in compliance with the Federal Advisory Committee Act. The purpose of the conference call is for project coordination and understanding.

DATES: The meeting will be held on February 10, 2011, and will begin at 9 a.m.

ADDRESSES: The conference call will be held at the Supervisor's Office of the Pike & San Isabel National Forests, Cimarron and Comanche National Grasslands (PSICC) at 2840 Kachina Dr., Pueblo, Colorado. Written comments should be sent to Barbara Timock, PSICC, 2840 Kachina Dr., Pueblo, CO 81008. Comments may also be sent via e-mail to btimock@fs.fed.us, or via facsimile to 719–553–1416.

All comments, including names and addresses when provided, are placed in

the record and are available for public inspection and copying. The public may inspect comments received at PSICC, 2840 Kachina Dr., Pueblo, CO 81008. Visitors are encouraged to call ahead to 719–553–1415 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT:

Barbara Timock, RAC coordinator, USDA, Pike & San Isabel National Forests, 2840 Kachina Dr., Pueblo, CO 81008; (719) 553–1415; E-mail btimock@fs.fed.us.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: To understand project proposals and coordination efforts, the PSI–RAC will convene a conference call. No decisions will be made during this call and the RAC will report out at the next meeting. The February 10 conference call is open to the public. The following business will be conducted: (1) Review projects submitted to the Web site, (2) Discuss RAC member liaison efforts, (3) Public Comment. Persons who wish to bring related matters to the attention of the Committee may file written statements with the Committee staff before or after the meeting. Public input sessions will be provided and individuals who made written requests by February 7, 2011 will have the opportunity to address the Committee at those sessions.

Dated: January 7, 2011.

John F. Peterson,

Designated Federal Official.

[FR Doc. 2011–670 Filed 1–12–11; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Notice of Idaho Panhandle Resource Advisory Committee Meeting

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the authorities in the Federal Advisory Committee Act (Pub. L. 92–463) and under the Secure Rural Schools and Community Self-Determination Act of 2000 (Pub. L. 110–343) the Idaho Panhandle Resource Advisory Committee will meet Friday, January 21, 2011, at 9 a.m. in Coeur d'Alene, Idaho for a business meeting. The business meeting is open to the public.

DATES: January 21, 2011.

ADDRESSES: The meeting location is the Idaho Panhandle National Forests' Supervisor's Office, located at 3815 Schreiber Way, Coeur d'Alene, Idaho 83815.

FOR FURTHER INFORMATION CONTACT: Ranotta K. McNair, Forest Supervisor and Designated Federal Official, at (208) 765-7369.

SUPPLEMENTARY INFORMATION: The meeting agenda will focus on reviewing proposals for forest projects and recommending funding during the business meeting. The public forum begins at 11 a.m.

Dated: January 6, 2011.

Ranotta K. McNair,
Forest Supervisor.

[FR Doc. 2011-466 Filed 1-12-11; 8:45 am]

BILLING CODE 3410-11-M

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Florida Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a meeting of the Florida Advisory Committee (Committee) to the Commission will convene on Wednesday, February 2, 2011, at 1:30 p.m. and adjourn at approximately 4 p.m. at Brevard Community College, Building 13, Room 203, 1519 Clearlake Road, Cocoa, Florida. The purpose of the meeting is member orientation and to discuss the Committee's report on migrant education.

The meeting is open to the public and members of the public are entitled to submit written comments. Comments must be received in the regional office by Friday, March 4, 2011. The address is Southern Regional Office, U.S. Commission on Civil Rights, 61 Forsyth St., SW., Suite 18T40, Atlanta, GA 30303. Persons wishing to e-mail their comments may do so to: pminarik@usccr.gov. Persons who desire additional information should contact the Southern Regional Office at (404) 562-7000 or 800-877-8339 for individuals who are deaf, hearing impaired, and/or have speech disabilities. Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Southern Regional Office at least ten (10) working days before the scheduled date of the meeting.

Records generated from this meeting may be inspected and reproduced at the

Southern Regional Office as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission's Web site, <http://www.usccr.gov>, or to contact the Southern Regional Office at the above e-mail or street address.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission and FACA.

Dated in Washington, DC, January 10, 2011.

Peter Minarik,

Acting Chief, Regional Programs
Coordination Unit.

[FR Doc. 2011-587 Filed 1-12-11; 8:45 am]

BILLING CODE 6335-01-P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Comprehensive Socioeconomic Data Collection from Alaskan Communities.

OMB Control Number: None.

Form Number(s): NA.

Type of Request: Regular submission (new information collection).

Number of Respondents: 500.

Average Hours per Response: Survey, 1 hour. Initial and follow-up telephone calls, 6 minutes.

Burden Hours: 521.

Needs and Uses: This request is for a new information collection.

The purpose of this data collection program is to improve commercial fisheries socioeconomic data for North Pacific fisheries, using the community as the unit of reporting and analysis. The North Pacific Fishery Management Council (NPFMC), the Alaska Fisheries Science Center (AFSC), and community stakeholder organizations, have identified ongoing collection of community level economic and socioeconomic information, specifically related to commercial fisheries, as a priority. The proposed data collection will include information on community revenues based in the fisheries economy, population fluctuations, vessel expenditures in ports, fisheries infrastructure available in the community, support sector business

operations in the community, community participation in fisheries management, effects of fisheries management decisions on the community, and demographic information on commercial fisheries participants from the community. The information collected in this program will capture the most relevant and pressing types of data needed for socioeconomic analyses of communities.

Affected Public: State, local or tribal government.

Frequency: Annually.

Respondent's Obligation: Voluntary.

OMB Desk Officer:

OIRA_Submission@omb.eop.gov.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482-0266, Department of Commerce, Room 6616, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at dHynek@doc.gov).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to

OIRA_Submission@omb.eop.gov.

Dated: January 10, 2011.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2011-589 Filed 1-12-11; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-201-822]

Stainless Steel Sheet and Strip in Coils From Mexico; Final Results of Antidumping Duty Administrative Review

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

SUMMARY: On August 9, 2010, the Department of Commerce (the Department) published the preliminary results of the administrative review of the antidumping duty order on stainless steel sheet and strip (S4) in coils from Mexico. *See Stainless Steel Sheet and Strip in Coils From Mexico; Preliminary Results of Antidumping Duty Administrative Review*, 75 FR 47780 (August 9, 2010) (*Preliminary Results*). This review covers sales of subject merchandise made by ThyssenKrupp Mexinox S.A. de C.V. (Mexinox) for the

period July 1, 2008, to June 30, 2009. Based on our analysis of the comments received, we have made changes to the margin calculation; therefore, the final results differ from the preliminary results. The final weighted-average dumping margin for the reviewed firm is listed below in the section entitled "Final Results of Review."

DATES: *Effective Date:* January 13, 2011.

FOR FURTHER INFORMATION CONTACT: Patrick Edwards, Brian Davis, or Angelica Mendoza, AD/CVD Operations, Office 7, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482-8029, (202) 482-7924, and (202) 482-3019, respectively.

SUPPLEMENTARY INFORMATION:

Background

On August 9, 2010, the Department published in the **Federal Register** the preliminary results of the administrative review of the antidumping duty order on S4 in coils from Mexico for the period July 1, 2008, to June 30, 2009. See *Preliminary Results*. In response to the Department's invitation to comment on the preliminary results of this review, Mexinox submitted (1) a request for a public hearing and (2) a case brief on September 8, 2010. See "Stainless Steel Sheet and Strip in Coils from Mexico—Case Brief," dated September 8, 2010 (Mexinox's Case Brief). Also on September 8, 2010, Allegheny Ludlum Corporation, AK Steel Corporation, and North American Stainless (collectively, petitioners), submitted a case brief. See "Stainless Steel Sheet and Strip in Coils from Mexico—Petitioner's Case Brief," dated September 8, 2010 (Petitioners' Case Brief). On September 9, 2010, the Department received a request from petitioners to extend the deadline to submit rebuttal briefs. On September 13, 2010, the Department granted this request. Petitioners timely submitted their rebuttal brief on September 15, 2010. See "Stainless Steel Sheet and Strip in Coils from Mexico—Petitioners' Rebuttal Brief," dated September 15, 2010 (Petitioners' Rebuttal Brief). Also on September 15, 2010, Mexinox submitted its rebuttal brief. See "Stainless Steel Sheet and Strip in Coils from Mexico—Rebuttal Brief," dated September 15, 2010 (Mexinox's Rebuttal Brief). On September 17, 2010, Mexinox withdrew its request for a hearing. See "Stainless Steel Sheet and Strip in Coils from Mexico—Withdrawal of Hearing Request," dated September 17, 2010.

On November 17, 2010, we issued a letter to petitioners notifying them that

we were rejecting their case brief because it contained new information regarding the U.S. entities that petitioners believe are purchasers of certain merchandise. Also on November 17, 2010, we issued a letter to Mexinox stating that we were rejecting its rebuttal brief because it also contained new information regarding the U.S. entities that petitioners believe are purchasers of certain merchandise. The deadline for submitting any factual information in the ongoing administrative review was December 18, 2009. Therefore, we requested that both petitioners and Mexinox re-file their respective briefs to exclude all references to the U.S. entities that petitioners believe are purchasers of the certain merchandise (and the relevant attachments). On November 22, 2010, Mexinox submitted its revised rebuttal brief and on November 23, 2010, petitioners submitted its revised case brief. On December 7, 2010, the Department issued a letter (1) notifying Mexinox of our intent to reclassify certain information as "public" rather than "business proprietary" and (2) requesting justification from Mexinox as to why certain information should be considered proprietary. On December 8, 2010, the Department published in the **Federal Register** our notice extending the time limit for this review until January 6, 2011. See *Stainless Steel Sheet and Strip in Coils from Mexico: Extension of Time Limit for Final Results of Antidumping Duty Administrative Review*, 75 FR 76396 (December 8, 2010). On Friday, December 10, 2010, Mexinox submitted its response to the Department's December 7, 2010, request.

Period of Review

The period of review (POR) is July 1, 2008, to June 30, 2009.

Scope of the Order

For purposes of the order, the products covered are stainless steel sheet and strip in coils. Stainless steel is alloy steel containing, by weight, 1.2 percent or less of carbon and 10.5 percent or more of chromium, with or without other elements. The subject sheet and strip is a flat-rolled product in coils that is greater than 9.5 mm in width and less than 4.75 mm in thickness, and that is annealed or otherwise heat treated and pickled or otherwise descaled. The subject sheet and strip may also be further processed (e.g., cold-rolled, polished, aluminized, coated, etc.) provided that it maintains the specific dimensions of sheet and strip following such processing.

The merchandise subject to this order is currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) at subheadings: 7219.13.00.31, 7219.13.00.51, 7219.13.00.71, 7219.13.00.81, 7219.14.00.30, 7219.14.00.65, 7219.14.00.90, 7219.32.00.05, 7219.32.00.20, 7219.32.00.25, 7219.32.00.35, 7219.32.00.36, 7219.32.00.38, 7219.32.00.42, 7219.32.00.44, 7219.33.00.05, 7219.33.00.20, 7219.33.00.25, 7219.33.00.35, 7219.33.00.36, 7219.33.00.38, 7219.33.00.42, 7219.33.00.44, 7219.34.00.05, 7219.34.00.20, 7219.34.00.25, 7219.34.00.30, 7219.34.00.35, 7219.35.00.05, 7219.35.00.15, 7219.35.00.30, 7219.35.00.35, 7219.90.00.10, 7219.90.00.20, 7219.90.00.25, 7219.90.00.60, 7219.90.00.80, 7220.12.10.00, 7220.12.50.00, 7220.20.10.10, 7220.20.10.15, 7220.20.10.60, 7220.20.10.80, 7220.20.60.05, 7220.20.60.10, 7220.20.60.15, 7220.20.60.60, 7220.20.60.80, 7220.20.70.05, 7220.20.70.10, 7220.20.70.15, 7220.20.70.60, 7220.20.70.80, 7220.20.80.00, 7220.20.90.30, 7220.20.90.60, 7220.90.00.10, 7220.90.00.15, 7220.90.00.60, and 7220.90.00.80. Although the HTSUS subheadings are provided for convenience and customs purposes, the Department's written description of the merchandise subject to the order is dispositive.

Excluded from the scope of the order are the following: (1) Sheet and strip that is not annealed or otherwise heat treated and pickled or otherwise descaled; (2) sheet and strip that is cut to length; (3) plate (*i.e.*, flat-rolled stainless steel products of a thickness of 4.75 mm or more); (4) flat wire (*i.e.*, cold-rolled sections, with a prepared edge, rectangular in shape, of a width of not more than 9.5 mm); and (5) razor blade steel. Razor blade steel is a flat-rolled product of stainless steel, not further worked than cold-rolled (cold-reduced), in coils, of a width of not more than 23 mm and a thickness of 0.266 mm or less, containing, by weight, 12.5 to 14.5 percent chromium, and certified at the time of entry to be used in the manufacture of razor blades. See Chapter 72 of the HTSUS, "Additional U.S. Note" 1(d).

In response to comments by interested parties, the Department has determined that certain specialty stainless steel products are also excluded from the scope of the order. These excluded products are described below.

Flapper valve steel is defined as stainless steel strip in coils containing,

by weight, between 0.37 and 0.43 percent carbon, between 1.15 and 1.35 percent molybdenum, and between 0.20 and 0.80 percent manganese. This steel also contains, by weight, phosphorus of 0.025 percent or less, silicon of between 0.20 and 0.50 percent, and sulfur of 0.020 percent or less. The product is manufactured by means of vacuum arc remelting, with inclusion controls for sulphide of no more than 0.04 percent and for oxide of no more than 0.05 percent. Flapper valve steel has a tensile strength of between 210 and 300 ksi, yield strength of between 170 and 270 ksi, plus or minus 8 ksi, and a hardness (Hv) of between 460 and 590. Flapper valve steel is most commonly used to produce specialty flapper valves for compressors.

Also excluded is a product referred to as suspension foil, a specialty steel product used in the manufacture of suspension assemblies for computer disk drives. Suspension foil is described as 302/304 grade or 202 grade stainless steel of a thickness between 14 and 127 microns, with a thickness tolerance of plus-or-minus 2.01 microns, and surface glossiness of 200 to 700 percent Gs. Suspension foil must be supplied in coil widths of not more than 407 mm, and with a mass of 225 kg or less. Roll marks may only be visible on one side, with no scratches of measurable depth. The material must exhibit residual stresses of 2 mm maximum deflection, and flatness of 1.6 mm over 685 mm length.

Certain stainless steel foil for automotive catalytic converters is also excluded from the scope of the order. This stainless steel strip in coils is a specialty foil with a thickness of between 20 and 110 microns used to produce a metallic substrate with a honeycomb structure for use in automotive catalytic converters. The steel contains, by weight, carbon of no more than 0.030 percent, silicon of no more than 1.0 percent, manganese of no more than 1.0 percent, chromium of between 19 and 22 percent, aluminum of no less than 5.0 percent, phosphorus of no more than 0.045 percent, sulfur of no more than 0.03 percent, lanthanum of between 0.002 and 0.05 percent, and total rare earth elements of more than 0.06 percent, with the balance iron.

Permanent magnet iron-chromium-cobalt alloy stainless strip is also excluded from the scope of the order. This ductile stainless steel strip contains, by weight, 26 to 30 percent chromium, and 7 to 10 percent cobalt, with the remainder of iron, in widths 228.6 mm or less, and a thickness between 0.127 and 1.270 mm. It exhibits magnetic remanence between 9,000 and 12,000 gauss, and a coercivity of

between 50 and 300 oersteds. This product is most commonly used in electronic sensors and is currently available under proprietary trade names such as "Arnokrome III."¹

Certain electrical resistance alloy steel is also excluded from the scope of the order. This product is defined as a non-magnetic stainless steel manufactured to American Society of Testing and Materials (ASTM) specification B344 and containing, by weight, 36 percent nickel, 18 percent chromium, and 46 percent iron, and is most notable for its resistance to high temperature corrosion. It has a melting point of 1390 degrees Celsius and displays a creep rupture limit of 4 kilograms per square millimeter at 1000 degrees Celsius. This steel is most commonly used in the production of heating ribbons for circuit breakers and industrial furnaces, and in rheostats for railway locomotives. The product is currently available under proprietary trade names such as "Gilphy 36."²

Certain martensitic precipitation-hardenable stainless steel is also excluded from the scope of the order. This high-strength, ductile stainless steel product is designated under the Unified Numbering System (UNS) as S45500-grade steel, and contains, by weight, 11 to 13 percent chromium, and 7 to 10 percent nickel. Carbon, manganese, silicon and molybdenum each comprise, by weight, 0.05 percent or less, with phosphorus and sulfur each comprising, by weight, 0.03 percent or less. This steel has copper, niobium, and titanium added to achieve aging, and will exhibit yield strengths as high as 1700 Mpa and ultimate tensile strengths as high as 1750 Mpa after aging, with elongation percentages of 3 percent or less in 50 mm. It is generally provided in thicknesses between 0.635 and 0.787 mm, and in widths of 25.4 mm. This product is most commonly used in the manufacture of television tubes and is currently available under proprietary trade names such as "Durphynox 17."³

Finally, three specialty stainless steels typically used in certain industrial blades and surgical and medical instruments are also excluded from the scope of the order. These include stainless steel strip in coils used in the production of textile cutting tools (*e.g.*, carpet knives).⁴ This steel is similar to ASTM grade 440F, but containing, by

weight, 0.5 to 0.7 percent of molybdenum. The steel also contains, by weight, carbon of between 1.0 and 1.1 percent, sulfur of 0.020 percent or less, and includes between 0.20 and 0.30 percent copper and between 0.20 and 0.50 percent cobalt. This steel is sold under proprietary names such as "GIN4 Mo." The second excluded stainless steel strip in coils is similar to AISI 420-J2 and contains, by weight, carbon of between 0.62 and 0.70 percent, silicon of between 0.20 and 0.50 percent, manganese of between 0.45 and 0.80 percent, phosphorus of no more than 0.025 percent and sulfur of no more than 0.020 percent. This steel has a carbide density on average of 100 carbide particles per square micron. An example of this product is "GIN5" steel. The third specialty steel has a chemical composition similar to AISI 420 F, with carbon of between 0.37 and 0.43 percent, molybdenum of between 1.15 and 1.35 percent, but lower manganese of between 0.20 and 0.80 percent, phosphorus of no more than 0.025 percent, silicon of between 0.20 and 0.50 percent, and sulfur of no more than 0.020 percent. This product is supplied with a hardness of more than Hv 500 guaranteed after customer processing, and is supplied as, for example, "GIN6."⁵

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by interested parties in this administrative review are addressed in the Issues and Decision Memorandum, "Issues and Decision Memorandum for the Final Results of the Antidumping Duty Administrative Review of Stainless Steel Sheet and Strip in Coils from Mexico" (Issues and Decision Memorandum), from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Ronald K. Lorentzen, Deputy Assistant Secretary for Import Administration, dated January 5, 2011, which is hereby adopted by this notice.⁶ A list of all issues, which parties have raised and to which we have responded, in the Issues and Decision Memorandum is attached to this notice as an appendix. Parties can find a complete discussion of all issues raised

⁵ "GIN4 Mo," "GIN5" and "GIN6" are the proprietary grades of Hitachi Metals America, Ltd.

⁶ See also Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Ronald K. Lorentzen, Deputy Assistant Secretary for Import Administration, dated January 5, 2011, titled, "Proprietary Arguments from the Issues and Decision Memorandum for the Final Results of the Antidumping Duty Administrative Review of Stainless Steel Sheet and Strip in Coils from Mexico."

¹ "Arnokrome III" is a trademark of the Arnold Engineering Company.

² "Gilphy 36" is a trademark of Imphy, S.A.

³ "Durphynox 17" is a trademark of Imphy, S.A.

⁴ This list of uses is illustrative and provided for descriptive purposes only.

in this review and the corresponding recommendations in this public memorandum, which is on file in the Central Records Unit in room 7046 of the main Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly via the Internet at www.ia.ita.doc.gov/fm/index.html. The paper copy and electronic version of the Issues and Decision Memorandum are identical in content.

Changes Since the Preliminary Results

The Department has revised its indirect selling expense calculation since the *Preliminary Results*. For these final results, we included the total POR indirect selling expenses incurred by all three companies (Mexinox USA, TKNNA, and TKAST USA) on sales of finished goods in the ratio's numerator (while excluding expenses attributable to raw material transfers to Mexinox), and total sales revenue made on all finished goods by all three companies (while excluding net raw material transfers for the POR and reserves/adjustments) in the denominator.

Because the denominator of the revised ratio includes the total net sales of finished goods for all three companies (*i.e.*, both subject and non-subject) and the revised numerator includes total indirect selling expenses relating to all three companies (*i.e.*, both sales of subject and non-subject merchandise), this methodology properly accounts for the fact that in selling German and Italian steel as purchased from ThyssenKrupp Nirosta GmbH and ThyssenKrupp Acciai Speciali Terni S.p.A. (TKNNA and TKAST USA's German and Italian affiliates, respectively)⁷ to their U.S. affiliates, some selling functions were performed and indirect selling expenses were incurred by entities other than Mexinox USA (*i.e.*, TKNNA and TKAST USA).⁸ In this way, we have ensured that all of Mexinox USAs, TKNNA's and TKAST USA's indirect selling expenses are captured and allocated over all of their U.S. sales.

See (1) Memorandum to the File, from Patrick Edwards and Brian Davis, Case Analysts, through Angelica Mendoza, Program Manager, titled "Analysis of Data Submitted by ThyssenKrupp

Mexinox S.A. de C.V. for the Final Results of the Antidumping Duty Administrative Review of Stainless Steel Sheet and Strip in Coils from Mexico (A-201-822)," dated January 5, 2011 (Final Analysis Memorandum) at pages 6 through 7 and (2) the Department's Issues and Decision Memorandum at pages 18 through 24 for further information regarding the Department's revised indirect selling expense calculation.

Furthermore, based on our analysis of the comments received, we have made the following changes to the margin calculation:

(1) We revised the Comparison Market Program to utilize cost data for all control numbers that Mexinox produced in the POR.

(2) We corrected the U.S. Margin Program to extend the cost of production (COP) and packing expenses on U.S. sales by quantity sold.

(3) We included sales by Ken-Mac Metals in our margin analysis.

(4) We removed all sample transactions from our margin analysis.

(5) We have adjusted our programming in order to include the value and quantity of merchandise that first entered but was subsequently exported to a third-country in our calculation of the assessment rate.

These changes are discussed in the relevant sections of the Issues and Decision Memorandum and Final Analysis Memorandum.

Final Results of Review

We determine the following weighted-average percentage margin exists for the period July 1, 2008, to June 30, 2009:

Manufacturer/Exporter	Weighted average margin (percentage)
ThyssenKrupp Mexinox S.A. de C.V.	21.16

Assessment

The Department will determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries, pursuant to section 751(a)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.212(b). The Department calculated an assessment rate for each importer of the subject merchandise covered by the review. Upon issuance of the final results of this review, for any importer-specific assessment rates calculated in the final results that are above *de minimis* (*i.e.*, at or above 0.50 percent), we will issue appraisal instructions directly to CBP to assess antidumping

duties on appropriate entries by applying the assessment rate to the entered value of the merchandise. Pursuant to 19 CFR 356.8(a), the Department intends to issue assessment instructions to CBP 41 days after the date of publication of these final results of review.

The Department clarified its "automatic assessment" regulation on May 6, 2003. See *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003). This clarification will apply to entries of subject merchandise during the POR produced by Mexinox for which Mexinox did not know the merchandise was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the 30.69 percent all-others rate if there is no company-specific rate for an intermediary involved in the transaction.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of these final results for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of these final results of administrative review, consistent with section 751(a)(1) of the Act: (1) The cash deposit rate for the reviewed company will be the rate listed above; (2) if the exporter is not a firm covered in this review, but was covered in a previous review or the original less-than-fair-value (LTFV) investigation, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original LTFV investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 30.69 percent, the all-others rate established in the LTFV investigation (*see Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order; Stainless Steel Sheet and Strip in Coils From Mexico*, 64 FR 40560 (July 27, 1999)) and modified during the section 129 determination (*see Implementation of the Findings of the WTO Dispute Settlement Panel and Appellate Body in United States—Final Anti-Dumping Measures on Stainless Steel from Mexico: Notice of Determination Under Section 129 of the Uruguay Round*

⁷ See Mexinox's AQR at 10.

⁸ See Mexinox's AQR at pages A-9 (and footnote 5) through A-14 for additional information regarding TKNNA and TKAST USA. The Department notes that TKNNA and TKAST USA are German and Italian affiliates, respectively, that sell German and Italian steel, respectively. See also Mexinox's July 21, 2010, supplemental questionnaire at attachments C-37 and C-38 for schedules of all TKNNA's and TKAST USA's U.S. indirect selling expenses, respectively.

Agreements Act, 74 FR 19527 (April 29, 2009)). These deposit requirements, when imposed, shall remain in effect until further notice.

Notifications to Interested Parties

This notice also serves as a final 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 Department's presumption that reimbursement of the antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective orders (APOs) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: January 5, 2011.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

Appendix—List of Issues in Issues and Decision Memorandum

- Comment 1: Ministerial Errors
- Comment 2: Offsetting for U.S. Sales that Exceed Normal Value
- Comment 3: Contemporaneous Model Matching
- Comment 4: Date of Sale
- Comment 5: U.S. Indirect Selling Expenses
- Comment 6: Circumstance of Sale Adjustment
- Comment 7: The Use of Quarterly Costs for the Cost Recovery Test
- Comment 8: TKSI SG&A Ratio for Purchases from Affiliates
- Comment 9: Profit Sharing Expenses Included in G&A
- Comment 10: G&A ratio includes Offsets for Other Income
- Comment 11: The COP Database

[FR Doc. 2011-626 Filed 1-12-11; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[C-580-851]

Dynamic Random Access Memory Semiconductors From the Republic of Korea: Final Results of Countervailing Duty Administrative Review

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

SUMMARY: On September 14, 2010, the Department of Commerce published in the *Federal Register* its preliminary results of administrative review of the countervailing duty order on dynamic random access memory semiconductors from the Republic of Korea for the period January 1, 2008, through August 10, 2008. We provided interested parties with an opportunity to comment on the preliminary results. Our analysis of the comments submitted led to a change in the net subsidy rate. The final net subsidy rate for Hynix Semiconductor, Inc. is listed below in the section entitled "Final Results of Review."

DATES: *Effective Date:* January 13, 2011.

FOR FURTHER INFORMATION CONTACT: Shane Subler or Jennifer Meek, AD/CVD Operations, Office 1, Import Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482-0189 or (202) 482-2778, respectively.

SUPPLEMENTARY INFORMATION:

Background

The following events have occurred since the publication of the preliminary results of this review. *See Dynamic Random Access Memory Semiconductors From the Republic of Korea: Preliminary Results of Countervailing Duty Administrative Review*, 75 FR 55764 (September 14, 2010) ("*Preliminary Results*").

On October 14, 2010, we received a case brief from the petitioner, Micron Technology, Inc. ("Micron"), and a joint case brief from Hynix Semiconductor, Inc. ("Hynix") and the Government of the Republic of Korea ("GOK"). On October 19, 2010, Micron submitted a rebuttal brief. Hynix and the GOK also submitted a joint rebuttal brief on this date.

Scope of the Order

The products covered by the order are dynamic random access memory semiconductors ("DRAMs") from the Republic of Korea ("ROK"), whether assembled or unassembled. Assembled DRAMs include all package types.

Unassembled DRAMs include processed wafers, uncut die, and cut die. Processed wafers fabricated in the ROK, but assembled into finished semiconductors outside the ROK are also included in the scope. Processed wafers fabricated outside the ROK and assembled into finished semiconductors in the ROK are not included in the scope.

The scope of the order additionally includes memory modules containing DRAMs from the ROK. A memory module is a collection of DRAMs, the sole function of which is memory. Memory modules include single in-line processing modules, single in-line memory modules, dual in-line memory modules, small outline dual in-line memory modules, Rambus in-line memory modules, and memory cards or other collections of DRAMs, whether unmounted or mounted on a circuit board. Modules that contain other parts that are needed to support the function of memory are covered. Only those modules that contain additional items which alter the function of the module to something other than memory, such as video graphics adapter boards and cards, are not included in the scope. The scope also covers future DRAMs module types.

The scope of the order additionally includes, but is not limited to, video random access memory and synchronous graphics random access memory, as well as various types of DRAMs, including fast page-mode, extended data-out, burst extended data-out, synchronous dynamic RAM, Rambus DRAM, and Double Data Rate DRAM. The scope also includes any future density, packaging, or assembling of DRAMs. Also included in the scope of the order are removable memory modules placed on motherboards, with or without a central processing unit, unless the importer of the motherboards certifies with U.S. Customs and Border Protection ("CBP") that neither it, nor a party related to it or under contract to it, will remove the modules from the motherboards after importation. The scope of the order does not include DRAMs or memory modules that are re-imported for repair or replacement.

The DRAMs subject to the order are currently classifiable under subheadings 8542.21.8005, 8542.21.8020 through 8542.21.8030, and 8542.32.0001 through 8542.32.0023 of the Harmonized Tariff Schedule of the United States ("HTSUS"). The memory modules containing DRAMs from the ROK, described above, are currently classifiable under subheadings 8473.30.1040, 8473.30.1080, 8473.30.1140, and 8473.30.1180 of the

HTSUS. Removable memory modules placed on motherboards are classifiable under subheadings 8443.99.2500, 8443.99.2550, 8471.50.0085, 8471.50.0150, 8517.30.5000, 8517.50.1000, 8517.50.5000, 8517.50.9000, 8517.61.0000, 8517.62.0010, 8517.62.0050, 8517.69.0000, 8517.70.0000, 8517.90.3400, 8517.90.3600, 8517.90.3800, 8517.90.4400, 8542.21.8005, 8542.21.8020, 8542.21.8021, 8542.21.8022, 8542.21.8023, 8542.21.8024, 8542.21.8025, 8542.21.8026, 8542.21.8027, 8542.21.8028, 8542.21.8029, 8542.21.8030, 8542.31.0000, 8542.33.0000, 8542.39.0000, 8543.89.9300, and 8543.89.9600 of the HTSUS. However, the product description, and not the HTSUS classification, is dispositive of whether merchandise imported into the United States falls within the scope.

Scope Rulings

On December 29, 2004, the Department of Commerce ("Department") received a request from Cisco Systems, Inc., to determine whether removable memory modules placed on motherboards that are imported for repair or refurbishment are within the scope of the *CVD Order*. See *Notice of Countervailing Duty Order: Dynamic Random Access Memory Semiconductors from the Republic of Korea*, 68 FR 47546 (August 11, 2003) ("*CVD Order*"). The Department initiated a scope inquiry pursuant to 19 CFR 351.225(e) on February 4, 2005. On January 12, 2006, the Department issued a final scope ruling, finding that removable memory modules placed on motherboards that are imported for repair or refurbishment are not within the scope of the *CVD Order* provided that the importer certifies that it will destroy any memory modules that are removed for repair or refurbishment. See Memorandum from Stephen J. Claeys to David M. Spooner, regarding Final Scope Ruling, Countervailing Duty Order on DRAMs from the Republic of Korea (January 12, 2006).

Period of Review

The period for which we are measuring subsidies, *i.e.*, the period of review ("POR"), is January 1, 2008, through August 10, 2008.

Analysis of Comments Received

We have addressed all issues raised in the case and rebuttal briefs in the January 5, 2011, Issues and Decision Memorandum for the Final Results in the Sixth Administrative Review of the Countervailing Duty Order on Dynamic

Random Access Memory Semiconductors from the Republic of Korea from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Ronald K. Lorentzen, Deputy Assistant Secretary for Import Administration ("Decision Memorandum"), which is hereby adopted by this notice. Attached to this notice as an appendix is a list of the issues which parties have raised and to which we have responded in the Decision Memorandum. Parties can find a complete discussion of all issues raised in this review and the corresponding recommendations in this public memorandum, which is on file in the Department's Central Records Unit, Room 7046 of the main Department building. In addition, a complete version of the public Decision Memorandum can be accessed directly on the Internet at <http://www.ia.ita.doc.gov/frn>. The paper copy and electronic version of the Decision Memorandum are identical in content.

Final Results of Review

In accordance with 19 CFR 351.221(b)(5), we calculated an individual subsidy rate for the producer, Hynix. For the period January 1, 2008, through August 10, 2008, we find that the *ad valorem* net subsidy rate for Hynix is 1.93 percent.

Assessment Rates

The Department intends to issue assessment instructions to CBP fifteen days after the date of publication of these final results of this review. The Department will instruct CBP to liquidate shipments of DRAMS by Hynix entered or withdrawn from warehouse, for consumption from January 1, 2008, through August 10, 2008, at 1.93 percent *ad valorem* of the F.O.B. invoice price, or 0.0033 U.S. dollars per megabit, as appropriate.¹

Cash Deposits

On October 3, 2008, the Department published a **Federal Register** notice that, *inter alia*, revoked this order, effective August 11, 2008. See *Dynamic Random Access Memory Semiconductors From the Republic of Korea: Final Results of Sunset Review and Revocation of Order*, 73 FR 57594 (October 3, 2008). As a result, CBP is no longer suspending liquidation for entries of subject merchandise occurring after the revocation. Therefore, there is no need to issue new cash deposit

¹ For the calculation of the per-megabit rate, see Memorandum to the File from Shane Subler and Jennifer Meek, "Final Results Calculations for Hynix Semiconductor, Inc." (January 5, 2010).

instructions pursuant to the final results of this administrative review.

This notice also serves as a reminder to parties subject to administrative protective order ("APO") of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This administrative review and notice are issued and published in accordance with section 751(a)(1) of the Tariff Act of 1930, as amended.

Dated: January 5, 2011.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

Appendix I—Comments in the Decision Memorandum

Comment 1: Income Tax Treatment of Hynix's Debt Restructuring

Comment 2: Allocation Method for Tax Benefit

Comment 3: Clerical Error Allegations

Comment 4: Circumvention of the Order

[FR Doc. 2011-615 Filed 1-12-11; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-827]

Certain Cased Pencils From the People's Republic of China: Preliminary Results and Partial Rescission of Antidumping Duty Administrative Review

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

DATES: *Effective Date:* January 13, 2011.

SUMMARY: The Department of Commerce ("the Department") has preliminarily determined that the respondents in this review, for the period December 1, 2008, through November 30, 2009, have made sales of subject merchandise at less than normal value. If these preliminary results are adopted in the final results of this review, we will instruct U.S. Customs and Border Protection ("CBP") to assess antidumping duties on all appropriate entries.

The Department is also rescinding this review for those foreign producers/exporters for which requests for review were timely withdrawn. For the

companies for which this review is rescinded, antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption.

The Department invites interested parties to comment on these preliminary results. The Department intends to issue the final results no later than 120 days from the publication date of this notice, pursuant to section 751(a)(3)(A) of the Tariff Act of 1930, as amended (“the Act”).

FOR FURTHER INFORMATION CONTACT:

Patricia Tran, Mahnaz Khan or David Layton, 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) 482-1503, (202) 482-0914 or (202) 482-0371, respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 28, 1994, the Department published in the **Federal Register** an antidumping duty order on certain cased pencils (“pencils”) from the People’s Republic of China (“PRC”). See *Antidumping Duty Order: Certain Cased Pencils from the People’s Republic of China*, 59 FR 66909 (December 28, 1994). On December 1, 2009, the Department published a notice of opportunity to request an administrative review of this order covering the period December 1, 2008, through November 30, 2009. See *Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review*, 74 FR 62743 (December 1, 2009). On December 4, 2009, in accordance with 19 CFR 351.213(b), Shandong Rongxin Import and Export Co., Ltd. (“Rongxin”), a foreign exporter/producer, requested that the Department review its sales of subject merchandise. On December 28, 2009, in accordance with 19 CFR 351.213(b), Beijing Fila Dixon Stationery Company Ltd. (“Beijing Dixon”), a foreign exporter, requested that the Department review its sales of subject merchandise. On December 31, 2009, the following exporters/producers requested reviews of themselves, in accordance with 19 CFR 351.213(b): Shanghai Three Star Stationery Industry Co., Ltd. (“Three Star”), Orient International Holding Shanghai Foreign Trade Corporation (“SFTC”), and China First Pencil Co., Ltd. (“China First”) and its affiliated companies including

Shanghai First Writing Instrument Co., Ltd. (“FST”), Fang Zheng Ltd. (“Fang Zheng”), Shanghai Great Wall Pencil Co. Ltd. (“Great Wall”) and China First Pencil Huadian Co., Ltd. (“Huadian”).¹

On January 29, 2010, the Department published a notice of initiation for this administrative review covering the companies listed in the requests received from the interested parties named above. See *Initiation of Antidumping and Countervailing Duty Administrative Reviews, Request for Revocation in Part, and Deferral of Initiation of Administrative Review*, 75 FR 4770, 4772 (January 29, 2010). On March 29, 2010, China First and its affiliated companies, and Three Star withdrew their December 31, 2009 requests for a review.

The Department issued antidumping duty questionnaires to Rongxin and Beijing Dixon on April 6, 2010. Rongxin submitted its Section A Questionnaire Response on May 6, 2010, and its Section C and Section D Questionnaire Responses on May 28, 2010. Beijing Dixon submitted its Section A Questionnaire Response on April 23, 2010, its Section C Questionnaire Response on May 12, 2010, and its Section D Questionnaire Response on May 12, 2010. The Department issued supplemental questionnaires to Rongxin and Beijing Dixon between June 2010 and December 2010. Both companies timely filed their responses to those supplemental questionnaires.

On September 3, 2010, we extended the time limit for the preliminary results in this review until January 7, 2011. See *Certain Cased Pencils From the People’s Republic of China: Extension of Time Limit for Preliminary Results of the Antidumping Duty Administrative Review*, 75 FR 54089 (September 3, 2010).

Scope of the Order

Imports covered by the order are shipments of certain cased pencils of any shape or dimension (except as described below) which are writing and/or drawing instruments that feature cores of graphite or other materials, encased in wood and/or man-made materials, whether or not decorated and whether or not tipped (e.g., with erasers, etc.) in any fashion, and either sharpened or unsharpened. The pencils subject to the order are currently

classifiable under subheading 9609.10.00 of the Harmonized Tariff Schedule of the United States (“HTSUS”). Specifically excluded from the scope of the order are mechanical pencils, cosmetic pencils, pens, non-cased crayons (wax), pastels, charcoals, chalks, and pencils produced under U.S. patent number 6,217,242, from paper infused with scents by the means covered in the above-referenced patent, thereby having odors distinct from those that may emanate from pencils lacking the scent infusion. Also excluded from the scope of the order are pencils with all of the following physical characteristics: (1) Length: 13.5 or more inches; (2) sheath diameter: not less than one-and-one quarter inches at any point (before sharpening); and (3) core length: not more than 15 percent of the length of the pencil.

In addition, pencils with all of the following physical characteristics are excluded from the scope of the order: novelty jumbo pencils that are octagonal in shape, approximately ten inches long, one inch in diameter before sharpening, and three-and-one eighth inches in circumference, composed of turned wood encasing one-and-one half inches of sharpened lead on one end and a rubber eraser on the other end.

Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the scope of the order is dispositive.

Partial Rescission of Review

The Department’s regulations at 19 CFR 351.213(d)(1) provide that the Department will rescind an administrative review, in part, if a party that requested a review withdraws the request within 90 days of the date of publication of the notice of initiation of the requested review. As explained above, SFTC withdrew its request for a review on March 1, 2010. On March 29, 2010, China First and its affiliated companies, and Three Star withdrew their requests for a review. These withdrawals occurred within the 90-day deadline, and no other party requested a review with respect to these companies. Therefore, the Department is rescinding this administrative review with regard to SFTC, China First and its affiliated companies, and Three Star.

Non-Market Economy Country Status

In every case conducted by the Department involving the PRC, the PRC has been treated as a non-market economy (“NME”) country. In accordance with section 771(18)(C)(i) of the Act, any determination that a foreign country is an NME country shall remain in effect until revoked by the

¹ The Department sent a letter to China First on January 13, 2010, asking China First to provide a complete list of its affiliated companies. China First responded on January 15, 2010, stating that its affiliated companies subject to the review are FST, Fang Zheng, Great Wall and Huadian. On March 1, 2010, SFTC withdrew its December 31, 2009 request for a review.

administering authority. *See, e.g., Brake Rotors From the People's Republic of China: Final Results and Partial Rescission of the 2004/2005 Administrative Review and Notice of Rescission of 2004/2005 New Shipper Review*, 71 FR 66304 (November 14, 2006). None of the parties to this proceeding has contested such treatment. Accordingly, we calculated normal value ("NV") in accordance with section 773(c) of the Act, which applies to NME countries.

Surrogate Country and Surrogate Values

When the Department investigates imports from an NME country and available information does not permit the Department to determine NV pursuant to section 773(a) of the Act, then, pursuant to section 773(c)(4) of the Act, the Department bases NV on an NME producer's factors of production ("FOPs"), to the extent possible, valued in one or more market-economy countries ("ME") that (1) are at a level of economic development comparable to that of the NME country, and (2) are significant producers of comparable merchandise. The Department determined that India, Indonesia, the Philippines, Ukraine, Thailand, and Peru are countries comparable to the PRC in terms of economic development. *See Memorandum from Carole Showers, Director, Office of Policy, to Brandon Farlander, Program Manager, Office 1, entitled "Request for a List of Surrogate Countries for Administrative Review of the Antidumping Duty Order on Certain Cased Pencils from the People's Republic of China ("PRC")," dated April 14, 2010. On April 15, 2010, the Department invited the interested parties to comment on surrogate country selection and to submit surrogate value data. On September 1 and on September 27, 2010, the Department extended the deadline for submission of publicly available information to value factors. *See the Department's Letters to All Interested Parties, "Certain Cased Pencils from the People's Republic of China: Deadlines for Surrogate Country and Surrogate Value Comments," dated April 15, 2010 and September 1, 2010, and Memorandum to the File from David Layton, "2008/2009 Administrative Review of Certain Cased Pencils from the People's Republic of China: Extension Request from Rongxin Import & Export Co., Ltd. Regarding the Submission of Surrogate Values," dated September 27, 2010. Beijing Dixon submitted publicly available information to value factors on October 15, 2010, and November 22, 2010. Rongxin submitted publicly available**

information on June 25, 2010, and October 18, 2010. Both respondents also provided certain surrogate value information in their supplemental responses.

As explained above, we determined that India is comparable to the PRC. Furthermore, India is a significant producer of comparable merchandise. *See Memorandum from Mahnaz Khan to the File, "2008–2009 Antidumping Duty Administrative Review on Certain Cased Pencils from the People's Republic of China: Selection of a Surrogate Country," dated January 7, 2011. Finally, it is the Department's practice to select an appropriate surrogate country based on the availability and reliability of data from those countries. In this instance, India has publicly available, reliable data. *See Department Policy Bulletin No. 04.1: Non-Market Economy Surrogate Country Selection Process, March 1, 2004.**

Therefore, because India is at a comparable level of economic development to the PRC, is a significant producer of comparable merchandise, and has publicly available and reliable data, we have selected India as the primary surrogate country for this review. The Department notes that India has been the primary surrogate country in past segments of this proceeding.

Separate Rates Determination

A designation as an NME remains in effect until it is revoked by the Department. *See section 771(18)(C) of the Act. Accordingly, the Department begins with a rebuttable presumption that all companies within the country are subject to government control and, thus, should be assessed a single antidumping duty deposit rate (i.e., a country-wide rate). *See, e.g., Department Policy Bulletin 05.1: Separate-Rates Practice and Application of Combination Rates in Antidumping Investigations involving Non-Market Economy Countries, April 5, 2005; see also Notice of Final Determination of Sales at Less Than Fair Value, and Affirmative Critical Circumstances, In Part: Certain Lined Paper Products From the People's Republic of China, 71 FR 53079 (September 8, 2006); Final Determination of Sales at Less Than Fair Value and Final Partial Affirmative Determination of Critical Circumstances: Diamond Sawblades and Parts Thereof from the People's Republic of China, 71 FR 29303, 29307 (May 22, 2006) ("Diamond Sawblades").**

It is the Department's policy to assign all exporters of 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. *See, e.g., Diamond Sawblades*, 71 FR at 29307. Exporters can demonstrate this independence through the absence of both *de jure* and *de facto* government control over export activities. *Id.* The Department analyzes each entity exporting the subject merchandise under a test arising from the *Final Determination of Sales at Less Than Fair Value: Sparklers From the People's Republic of China*, 56 FR 20588, 20589 (May 6, 1991) ("*Sparklers*"), as further developed in *Notice of Final Determination of Sales at Less Than Fair Value: Silicon Carbide From the People's Republic of China*, 59 FR 22585, 22586–87 (May 2, 1994) ("*Silicon Carbide*"). However, if the Department determines that a company is wholly foreign-owned or located in an ME, then a separate rate analysis is not necessary to determine whether it is independent from government control. *See, e.g., Final Results of Antidumping Duty Administrative Review: Petroleum Wax Candles from the People's Republic of China*, 72 FR 52355, 52356 (September 13, 2007).

The Department received a separate rate certification from Rongxin on February 26, 2010, and a separate rate certification from Beijing Dixon on March 5, 2010. China First, Three Star, and SFTC requested an extension until March 29, 2010, to file a separate rate certification before withdrawing their respective requests for a review. Consequently, SFTC, China First, and Three Star never filed separate rate certifications before the March 29, 2010 deadline.

In its separate rate application, Beijing Dixon reported that it is owned wholly by an entity located and registered in an ME country (*i.e.*, the United States). Thus, because we have no evidence indicating that Beijing Dixon is under the control of the PRC government, a separate-rate analysis is not necessary to determine whether it is independent from government control, and we determine Beijing Dixon has met the criteria for the application of a separate rate. *See Brake Rotors From the People's Republic of China: Preliminary Results and Partial Rescission of Fifth New Shipper Review*, 66 FR 29080, 29081 (May 29, 2001) (where the respondent was wholly owned by a U.S. registered company), unchanged in *Brake Rotors From the People's Republic of China: Final Results and Partial Rescission of Fifth New Shipper Review*, 66 FR 44331 (August 23, 2001); *Brake Rotors From the People's Republic of China: Preliminary Results and Partial Rescission of the Fourth New Shipper*

Review and Rescission of the Third Antidumping Duty Administrative Review, 66 FR 1303, 1306 (January 8, 2001) (where the respondent was wholly owned by a company located in Hong Kong), unchanged in *Brake Rotors From the People's Republic of China: Final Results and Partial Rescission of Fourth New Shipper Review and Rescission of Third Antidumping Duty Administrative Review*, 66 FR 27063 (May 16, 2001); and *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 owned by persons located in Hong Kong).

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 the individual exporter's business and export licenses; (2) any legislative enactments decentralizing control of companies; and (3) any other formal measures by the government decentralizing control of companies. See *Sparklers*, 56 FR at 20589. The evidence provided by Rongxin supports a preliminary finding of *de jure* absence of government control.

Rongxin has placed on the administrative record a copy of its business license and articles of association.² Neither of these documents contains restrictions with respect to export activities.

In its separate rates certification, Rongxin certified that during the POR: (1) As with the segment of the proceeding in which the firm was previously granted a separate rate ("previous Granting Period"), there were no government laws or regulations that controlled the firm's export activities; (2) the ownership under which the firm registered itself with the official government business license issuing authority remains the same as for the previous Granting Period; (3) the firm had a valid PRC Export Certificate of Approval, now referred to and labeled as a Registration Form for Foreign Trade Operator; (4) as in the previous Granting Period, in order to conduct export activities, the firm was not required by law or regulation at any level of government to possess additional certificates or other documents related to the legal status and/or operation of its

business beyond those discussed above; and (5) PRC government laws and legislative enactments applicable to Rongxin remained the same as in the previous Granting Period.

In prior cases, we have found an absence of *de jure* control absent proof on the record to the contrary. See, e.g., *Notice of Final Determination of Sales at Less Than Fair Value: Furfuryl Alcohol From the People's Republic of China*, 60 FR 22544 (May 8, 1995) ("*Furfuryl Alcohol*"). We have no information in this proceeding that would cause us to reconsider this determination. Thus, we determine that the evidence on the record supports a preliminary finding of absence of *de jure* government control for Rongxin.

Absence of De Facto Control

As stated in previous cases, there is some evidence that certain enactments of the PRC central government have not been implemented uniformly among different sectors and/or jurisdictions in the PRC. See *Silicon Carbide*, 59 FR at 22587. Therefore, the Department has determined that an analysis of *de facto* control is critical in determining whether respondents are, in fact, subject to a degree of government control which would preclude the Department from assigning separate rates.

The Department typically considers the following four factors in evaluating whether a respondent is subject to *de facto* government control of its export functions: (1) Whether the export prices are set by, or subject to the approval of, a government agency; (2) whether the respondent has the 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 the disposition of profits or financing of losses. See *Silicon Carbide*, 59 FR at 22586–87, and *Furfuryl Alcohol*, 60 FR at 22545.

Rongxin has asserted the following: (1) It establishes its own export prices; (2) it negotiates contracts without guidance from any government entities or organizations; (3) it makes its own personnel decisions; and (4) it retains the proceeds of its export sales, uses profits according to its business needs, and has the authority to sell its assets and to obtain loans. Additionally, Rongxin's questionnaire responses indicate that its pricing during the POR was not coordinated with other exporters. As a result, there is a sufficient basis to preliminarily

determine that Rongxin has demonstrated a *de facto* absence of government control of its export functions and it is entitled to a separate rate.

Fair-Value Comparisons

To determine whether Rongxin's sales of subject merchandise were made at less than NV, we compared the NV to individual export price ("EP") transactions in accordance with section 777A(d)(2) of the Act. See "Export Price" and "Normal Value" sections of this notice, below. To determine whether Beijing Dixon's sales were made at less than NV, we compared constructed export price ("CEP") to NV as described in the "Constructed Export Price" section of the notice below.

Export Price

In accordance with section 772(a) of the Act, EP is "the price at which subject merchandise is first sold (or agreed to be sold) before the date of importation by the producer or exporter of the subject merchandise outside of the United States to an unaffiliated purchaser in the United States or to an unaffiliated purchaser for exportation to the United States," as adjusted under section 772(c) of the Act. In accordance with section 772(a) of the Act, we used EPs for sales by Rongxin to the United States because the first sale to an unaffiliated party was made before the date of importation, and CEP methodology was not otherwise indicated. We based EP on the price to unaffiliated purchasers in the United States. In accordance with section 772(c)(2)(A) of the Act, we made deductions for Rongxin's foreign inland freight and foreign brokerage and handling where appropriate.

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 as reported in *Doing Business 2010: India*, published by the World Bank. See Memorandum from David Layton to File, "Factor Valuation for the Preliminary Results Memorandum," dated January 7, 2011 ("Factor Valuation Memorandum").

Constructed Export Price

In accordance with section 772(a) of the Act, CEP is the price at which the subject merchandise is first sold (or agreed to be sold) in the United States before or after the date of importation by or for the account of the producer or exporter of such merchandise or by a seller affiliated with the producer or

² See Rongxin's Separate Rate Certification submission dated February 26, 2010, and Rongxin's Section A submission dated May 6, 2010.

exporter, to a purchaser not affiliated with the producer or exporter, as adjusted under subsections (c) and (d). In its questionnaire responses, Beijing Dixon stated that it made CEP sales through its U.S. affiliate, Dixon Ticonderoga Company. In accordance with section 772(a) of the Act, we used CEP for Beijing Dixon's U.S. sales because all sales to unaffiliated customers were made after the date of importation and by its U.S. affiliate.

The Department calculated CEP based on the packed, delivered prices to unaffiliated purchasers in the United States, net of billing adjustments, rebates and early payment discounts. We adjusted these prices for movement expenses, including foreign inland freight, international freight, marine insurance, foreign and U.S. brokerage and handling (U.S. brokerage and handling was reported as three "other transportation expense" categories), U.S. customs duties, U.S. inland freight from port to warehouse and U.S. inland shipment insurance in accordance with section 772(c)(2)(A) of the Act.

In accordance with section 772(d)(1) of the Act, we deducted from Beijing Dixon's starting price those selling expenses that were incurred in selling the subject merchandise in the United States, including imputed credit expenses, applicable advertising expenses, commissions, royalties and indirect selling expenses. We also made an adjustment for profit in accordance with section 772(d)(3) of the Act. For a detailed description of all adjustments, see Memorandum from Mahnaz Khan to the File, "Analysis for the Preliminary Results of Antidumping Duty Administrative Review of Certain Cased Pencils from the People's Republic of China: Beijing Fila Dixon Stationery Company Ltd.," dated January 7, 2011 ("Beijing Dixon Preliminary Calculation Memo").

For our CEP adjustments for Beijing Dixon, we valued foreign brokerage and handling, and foreign inland truck rates using the same surrogate values described above in the "Export Price" section.

For its calculation of the CEP, the Department changed certain data in Beijing Dixon's U.S. sales database. Beijing Dixon reported no payment date for certain observations in the U.S. sales database. For these observations, the Department, as is its practice, applied as the payment date May 20, 2010, the deadline for submission of factual information in this administrative review as provided in 19 CFR 351.301(b)(2). We have also calculated the credit expense for each of the specific observations with missing

payment dates based on the May 20, 2010 payment date. See Beijing Dixon Preliminary Calculation Memo at 3–4. We have not yet requested clarification from Beijing Dixon regarding the missing payment dates, but intend to do so after these preliminary results.

Normal Value

Section 773(c)(1) of the Act provides that the Department shall determine NV using a FOP methodology if the merchandise is exported from an NME country 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 will base NV on FOPs where the presence of government controls on various aspects of NMEs renders price comparisons and the calculation of production costs invalid under our normal ME methodologies. Therefore, we calculated NV based on FOPs in accordance with sections 773(c)(3) and (4) of the Act and 19 CFR 351.408(c). The FOPs include: (1) Hours of labor required; (2) quantities of raw materials employed; (3) amounts of energy and other utilities consumed; and (4) representative capital costs. We used the FOPs reported by the respondents for materials, energy, labor, and packing.

In accordance with 19 CFR 351.408(c)(1), when a producer sources an input from an ME country and pays for it in ME currency, the Department will normally value the factor using the actual price paid to the ME supplier for the input. See 19 CFR 351.408(c)(1). Where a portion of the input is purchased from an ME supplier and the remainder from an NME supplier, the Department will normally use the price paid for the input sourced from ME suppliers to value all of the input, provided the volume of the ME input as a share of total purchases from all sources is "meaningful." See *Antidumping Duties; Countervailing Duties*, 62 FR 27296, 27366 (May 19, 1997); *Shakeproof Assembly Components, Div. of Ill. Tool Works, Inc. v. United States*, 268 F.3d 1376, 1382 (Fed. Cir. 2001); 19 CFR 351.408(c)(1); see also *Antidumping Methodologies: Market Economy Inputs, Expected Non-Market Economy Wages, Duty Drawback; and Request for Comments*, 71 FR 61716, 61716–61719 (October 19, 2006) (regarding the Department's flexible 33 percent threshold for ME inputs). In this administrative review, Beijing Dixon reports purchasing four ME material inputs in volumes that exceed the threshold percentage that the Department normally considers

"meaningful." See Beijing Dixon Preliminary Calculation Memorandum. At the Department's request, Beijing Dixon provided documentation to support its claim that these four inputs were obtained from ME sources. See Sections C & D First and Second Supplemental Questionnaire Response of Beijing Fila Dixon Stationery Company, Ltd., dated September 10, 2010, at Exhibits Supplemental C–12 and D–5–D–9. Accordingly, we have calculated NV for these preliminary results using the ME prices paid by Beijing Dixon for these four inputs to value the relevant factors.

Factor Valuations

In accordance with section 773(c)(3) of the Act, we calculated NV based on FOPs reported by the respondents for the POR. Except as noted above for Beijing Dixon's ME inputs, we multiplied the reported per-unit factor quantities by publicly available Indian surrogate values. In selecting the surrogate values, we considered the quality, specificity, and contemporaneousness of the data.

In accordance with section 773(c)(1) of the Act, for purposes of calculating NV, we attempted to value the FOPs using surrogate values that were in effect during the POR. If we were unable to obtain surrogate values that were in effect during the POR, we adjusted the values, as appropriate, to account for inflation or deflation between the effective period and the POR. We calculated the inflation or deflation adjustments for all factor values, except labor and utilities, using the India Wholesale Price Index as published in the International Monetary Fund's International Financial Statistics.

When relying on prices of imports into India as surrogate values, we have disregarded prices that we have reason to believe or suspect may be subsidized. See *Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From the People's Republic of China; Final Results of 1999–2000 Administrative Review, Partial Rescission of Review, and Determination Not To Revoke Order in Part*, 66 FR 57420 (November 15, 2001), and accompanying Issues and Decision Memorandum at Comment 1. We have found that Indonesia, South Korea, and Thailand maintain broadly available, non-industry-specific export subsidies. Accordingly, it is reasonable to infer that exports to all markets from those countries may be subsidized. See *Certain Frozen Fish Fillets from the Socialist Republic of Vietnam: Preliminary Results and Preliminary Partial Rescission of Antidumping Duty Administrative Review*, 70 FR 54007,

54011 (September 13, 2005), unchanged in *Certain Frozen Fish Fillets From the Socialist Republic of Vietnam: Final Results of the First Administrative Review*, 71 FR 14170 (March 21, 2006); and *China Nat'l Machinery Import & Export Corp. v. United States*, 293 F. Supp. 2d 1334, 1336 (Ct. Int'l. Trade 2003), *aff'd* 104 Fed. Appx. 183 (Fed. Cir. 2004).

In avoiding the use of prices that may be subsidized, the Department does not conduct a formal investigation to ensure that such prices are not subsidized. See H.R. Rep. 100-576 at 590-91 (1988), *reprinted* in 1988 U.S.C.C.A.N. 1547, 1623. Rather, the Department relies on information that is generally available at the time of its determination. Therefore, we have not used prices from those countries in calculating the Indian import-based surrogate values. See Factor Valuation Memorandum.

As appropriate, we adjusted input prices by including freight costs to make them delivered prices. Specifically, we added to the Indian import surrogate values a surrogate freight cost calculated using the shorter of the reported distance from the domestic supplier to the factory or the distance from the nearest port of export to the factory, where appropriate. This adjustment is in accordance with the decision of the Court of Appeals for the Federal Circuit ("Federal Circuit") in *Sigma Corp. v. United States*, 117 F.3d 1401, 1407-08 (Fed. Cir. 1997). See also Department Policy Bulletin No. 10.2: Inclusion of International Freight Costs When Import Prices Constitute Normal Value, November 1, 2010.

We valued the FOPs as follows:

(1) Except where noted below, we valued all reported material and packing inputs using Indian import data from the Global Trade Atlas for December 2008 through November 2009.

(2) We calculated the slats surrogate value using data from "Paper and Stationery."³ The slats, for which values were reported in "Paper and Stationery," are used for pencil production and are made from Ajanta, valued at Rs. 210 per 1000 cubic feet, and Vatta II, valued at Rs. 200 per 1000 cubic feet. We averaged the values for Ajanta and Vatta II to arrive at a surrogate value of Rs. 205 per 1000 cubic feet. We converted Rupees-per-1000 cubic-feet to Rupees-per-kilogram. We adjusted this value to account for inflation between the effective period and the POR. See

Attachment 4 of the Factor Valuation Memorandum for the calculation of the surrogate values for slats.

(3) We calculated separate surrogate values for black and color cores, and, for valuation purposes, distinguished between regular and thick core dimensions. We obtained surrogate values for black and color cores from "Paper and Stationery."⁴ We adjusted these values to account for inflation between the effective period and the POR. See Attachment 4 of the Factor Valuation Memorandum for the calculation of the surrogate values for black and color cores.

(4) We valued electricity using price data for small, medium, and large industries, as published by the Central Electricity Authority of the Government of India in its publication titled "Electricity Tariff & Duty and Average Rates of Electricity Supply in India," dated March 2008. Those electricity rates represent actual country-wide, publicly-available information on tax-exclusive electricity rates charged to industries in India. See Factor Valuation Memorandum.

(5) For Rongxin, we valued steam coal using data obtained for grade E non-long flame non-coking coal reported on the 2007 Coal India Data website. For Beijing Dixon, we valued steam coal using data obtained for grade C long flame non-coking coal reported on the 2007 Coal India Data Web site. See Factor Valuation Memorandum.

(6) On May 14, 2010, the Federal Circuit in *Dorbest Ltd. v. United States*, 604 F.3d 1363, 1372 (Fed. Cir. 2010), found that the "{regression-based} method for calculating wage rates {as stipulated by 19 CFR 351.408(c)(3)} uses data not permitted by {the statutory requirements laid out in section 773 of the Act (i.e., 19 U.S.C. 1677b(c))}." The Department is continuing to evaluate options for determining labor values in light of the recent Federal Circuit decision. However, for these preliminary results, we have calculated an hourly wage rate to use in valuing the respondents' reported labor input by averaging industry-specific earnings and/or wages in countries that are economically comparable to the PRC and that are significant producers of comparable merchandise. Our methodology is described below.

The Department is valuing labor using a simple average, industry-specific wage rate derived from earnings or wage data reported under Chapter 5B by the International Labor Organization ("ILO"). Specifically, the Department has calculated the wage rate as a simple

average of the data provided to the ILO under Sub-Classification 36 of the ISIC-Revision 3 standard by countries determined to be both economically comparable to the PRC and significant producers of comparable merchandise. The Department finds the two-digit description under ISIC-Revision 3 ("Manufacture of Furniture; Manufacturing n.e.c.") to be the best available information for valuing the respondents' labor input because it is specific and derived from industries that produce merchandise comparable to the subject merchandise.

Consequently, we averaged the ILO industry-specific wage rate data or earnings data available from the following countries found to be economically comparable to the PRC and to be significant producers of comparable merchandise: Ecuador, Egypt, Indonesia, Jordan, Peru, Philippines, and Thailand. On this basis, the Department calculated a simple average, industry-specific wage rate of \$1.23 for these preliminary results. For further information on the calculation of the wage rate, see Factor Valuation Memorandum.

(7) We derived ratios for factory overhead, depreciation, selling, general and administrative expenses, interest expenses, and profit for the finished product using the 2006-2007 financial statement of Triveni Pencils Ltd. ("Triveni"), an Indian producer of pencils, in accordance with the Department's practice with respect to selecting financial statements for use in NME cases. See, e.g., *Notice of Final Determination of Sales at Less Than Fair Value: Chlorinated Isocyanurates From the People's Republic of China*, 70 FR 24502 (May 10, 2005), and accompanying Issues and Decision Memorandum at Comment 2. Reliance upon Triveni's financial statements is consistent with the 2007-2008 administrative review.

(8) We valued inland truck freight expenses using a per-unit average rate calculated from data on the following publicly accessible Web site: <http://www.infobanc.com/logistics/logtruck.htm>. The logistics section of this website contains inland freight truck rates between many large Indian cities. Since the truck rate value is based on an annual per-unit rate and falls within the POR (August 2008 through July 2009), we are treating the derived average rate as contemporaneous with the POR. For rail freight, we used 2006-2007 data from the publicly accessible website <http://www.Indianrailways.gov.in/> to derive, where appropriate, input-specific train rates on a rupees-per-kilogram per-

³ See "Pencil Industry in India—A Robust Future," Divya Jha, in "Paper & Stationery Samachar" (Delhi, November 2008), an Indian trade journal ("Paper and Stationery") at 54, attached as Exhibit 3 to Rongxin's June 25, 2010 Surrogate Value Submission.

⁴ See *id.*

kilometer basis (“Rs/kg/km”). The Department is not inflating the 2006–2007 rail freight data from the <http://www.Indianrailways.gov.in> website since these rates are currently published on their website, and the website does not have any updated rail freights for the POR. Therefore, the Department continues to treat these rail freights on the <http://www.Indianrailways.gov.in> Web site as contemporaneous with the POR in this administrative review.

Currency Conversion

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.

Preliminary Results of Review

We preliminarily determine that the following margins exist for the period December 1, 2008, through November 30, 2009:

Exporter	Margin (percent)
Beijing Dixon Stationery Company Ltd.	0.00
Shandong Rongxin Import and Export Co., Ltd.	0.17

As stated above in the “Separate Rates Determination” section of this notice, Dixon and Rongxin each qualify for a separate rate in this review.

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). 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.

An interested party may request a hearing within 30 days of publication of the preliminary results. See 19 CFR 351.310(c). Interested parties may submit written comments (case briefs) no later than 30 days after publication of these preliminary results of review, and rebuttal comments (rebuttal briefs), which must be limited to issues raised in the case briefs, within five days after the time limit for filing case briefs. See 19 CFR 351.309(c)(1)(ii) and 19 CFR 351.309(d). Parties who submit arguments are requested to submit with the argument: (1) A statement of the issue(s); (2) a brief summary of the argument; and (3) a table of authorities. Further, the Department requests that parties submitting written comments provide the Department with a compact disk containing the public version of those comments. We will issue a memorandum identifying the date and time of a hearing, if one is requested.

The Department will issue the final results of this administrative review, including the results of our analysis of the issues raised by the parties in their comments, within 120 days of publication of the preliminary results, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon completion of this administration review, the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries. The Department intends to issue assessment instructions to CBP 15 days after the date of publication of the final results of review. For assessment purposes, we calculated exporter/importer-specific (or customer-specific) assessment rates for merchandise subject to this review.

Rongxin did not report entered values for its U.S. sales. Therefore, we calculated a per-unit assessment rate for each importer (or customer) by dividing the total dumping margins for reviewed sales to that party by the total sales quantity associated with those transactions. For duty-assessment rates calculated on this basis, we will direct CBP to assess the resulting per-unit rate against the entered quantity of the subject merchandise. 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-specific (or customer-specific) rate is *de minimis* (i.e., less than 0.50 percent), the Department will instruct CBP to liquidate that importer’s (or customer’s) entries of subject merchandise without regard to antidumping duties.

For the companies for which this review is rescinded, antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212.(c)(1)(i). The Department intends to issue appropriate assessment instructions regarding entries of the rescinded companies directly to CBP 15 days after publication of this notice.

Cash Deposit Requirements

The following cash-deposit requirements will apply to all shipments of certain cased pencils from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(1) of the Act: (1) The cash deposit rates for the reviewed companies named above will be the rates for those firms established in the final results of this administrative review; (2) for any previously reviewed or investigated PRC or non-PRC exporter, not covered in this review, with a separate rate, the cash deposit rate will be the company-specific rate established in the most recent segment of this proceeding; (3) for all other PRC exporters, the cash deposit rate will be the PRC-wide rate established in the final results of this review; and (4) the cash-deposit rate for any non-PRC exporter of subject merchandise from the PRC will be the rate applicable to the PRC exporter that supplied that exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Interested Parties

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary’s presumption that reimbursement of antidumping duties

occurred and the subsequent assessment of double antidumping duties.

We are issuing and publishing the preliminary results determination in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: January 7, 2011.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 2011-627 Filed 1-12-11; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-533-820]

Certain Hot-Rolled Carbon Steel Flat Products From India: Notice of Preliminary Results of Antidumping Duty Administrative Review

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

SUMMARY: In response to requests from petitioners,¹ the Department of Commerce (“the Department”) is conducting an administrative review of the antidumping duty order on certain hot-rolled carbon steel flat products from India (“Indian Hot-Rolled”) manufactured by Essar Steel Limited (“Essar”), Ispat Industries Limited (“Ispat”), JSW Steel Limited (“JSW”), and Tata Steel Limited (“Tata”). The period of review (“POR”) covers December 1, 2008, through November 30, 2009. We preliminarily determine that Essar, Ispat, JSW, and Tata had no reviewable entries of subject merchandise during the POR.

Interested parties are invited to comment on these preliminary results. We intend to issue the final results no later than 120 days from the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Tariff Act of 1930, as amended (“the Act”).

DATES: *Effective Date:* January 13, 2011.

FOR FURTHER INFORMATION CONTACT: Christopher Hargett or James Terpstra, AD/CVD Operations Office 3, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482-4161 and (202) 482-3965, respectively.

SUPPLEMENTARY INFORMATION:

¹ The petitioners are the United States Steel Corporation, Nucor Corporation, and ArcelorMittal USA Inc. (collectively “petitioners”).

Background

On December 3, 2001, the Department published in the **Federal Register** the antidumping duty order on Indian Hot-Rolled. See *Notice of Amended Final Antidumping Duty Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Certain Hot-Rolled Carbon Steel Flat Products From India*, 66 FR 60194 (December 3, 2001) (“*Amended Final Determination*”). On December 1, 2009, the Department published in the **Federal Register** a notice titled “Opportunity to Request Administrative Review” of the antidumping duty order on Indian Hot-Rolled. See *Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review*, 74 FR 62743 (December 1, 2009). On December 31, 2009, petitioners requested an administrative review of the antidumping duty order on Indian Hot-Rolled, for subject merchandise produced or exported by Ispat, JSW, Tata, and Essar. On January 29, 2010, the Department published a notice of initiation of antidumping duty administrative review of Indian Hot-Rolled for the period December 1, 2008, through November 30, 2009. See *Initiation of Antidumping and Countervailing Duty Administrative Reviews, Request for Revocation in Part, and Deferal of Initiation of Administrative Review*, 75 FR 4770 (January 29, 2010) (“*Initiation Notice*”). On February 2, 2010, Ispat and Essar, and on February 17, 2010, JSW, each informed the Department that they did not have shipments of subject merchandise to the United States during the POR.

In February 2010, the Department exercised its discretion to toll deadlines for the duration of the closure of the Federal Government from February 5, through February 12, 2010. Thus all deadlines in this segment of the proceeding have been extended for seven days. See Memorandum to the Record from Ronald Lorentzen, DAS for Import Administration, regarding “Tolling of Administrative Deadlines As a Result of the Government Closure During the Recent Snowstorm,” dated February 12, 2010.

On February 16, 2010, the Department issued its antidumping questionnaire to Tata. On February 18, 2010, Tata informed the Department that it had one shipment of subject merchandise that was entered into the United States during the POR, but that shipment was not of normal commercial quantities and was a one-off transaction for testing purposes only. Tata informed the

Department that it would, therefore, not respond to the antidumping questionnaire.

On August 23, 2010, the Department placed on the record and invited interested parties to comment on U.S. Customs and Border Protection (“CBP”) data obtained to corroborate the claims of the respondents. See Memorandum to the File from Christopher Hargett, International Trade Compliance Analyst, through James Terpstra, Program Manager, and Melissa Skinner, Office Director, concerning “Customs and Border Protection (“CBP”) Data for Corroboration of Claims of No Shipments,” dated August 23, 2010 (“August 23 Comment Memorandum”); clarified by Memorandum to the File from Christopher Hargett, International Trade Compliance Analyst, through James Terpstra, Program Manager, and Melissa Skinner, Office Director, concerning “Clarification of Customs and Border Protection (“CBP”) Data for Corroboration of Claims of No Shipments,” dated August 25, 2010 (“August 25 Clarification Memorandum”). On August 31, 2010, we received timely comments from Nucor Corporation.

On September 14, 2010, the Department extended the deadline for the preliminary results to January 7, 2011. See *Certain Hot-Rolled Carbon Steel Flat Products from India: Extension of Time Limit for Preliminary Results of the Antidumping Duty Administrative Review*, 75 FR 55742 (September 14, 2010).

On November 23, 2010, we requested CBP to provide documents associated with certain entries. See Memorandum to Michael Walsh, Director, AD/CVD/Revenue Policy and Programs, Office of International Trade, U.S. Customs and Border Protection, from Melissa Skinner, Office Director, entitled “Request for U.S. Entry Documents—Certain Hot-Rolled Steel Flat Products from India (A-533-820),” dated November 23, 2010 (“November 23 CBP Request Memorandum”). We received such documents on December 23, 2010. See Memorandum from Christopher Hargett, International Trade Compliance Analyst, Office 3, through Melissa Skinner, Office Director, Office 3, AD/CVD Operations, to the File, entitled “Entry Documentation for Corroboration of Claims of No Shipments,” dated January 7, 2011 (“January 7 Entry Documentation Memorandum”).

Period of Review

The POR covered by this review is December 1, 2008, through November 30, 2009.

Scope of the Order

The merchandise subject to this order is certain hot-rolled carbon steel flat products of a rectangular shape, of a width of 0.5 inch or greater, neither clad, plated, nor coated with metal and whether or not painted, varnished, or coated with plastics or other non-metallic substances, in coils (whether or not in successively superimposed layers), regardless of thickness, and in straight lengths, of a thickness of less than 4.75 mm and of a width measuring at least 10 times the thickness.

Universal mill plate (*i.e.*, flat-rolled products rolled on four faces or in a closed box pass, of a width exceeding 150 mm, but not exceeding 1250 mm, and of a thickness of not less than 4 mm, not in coils and without patterns in relief) of a thickness not less than 4.0 mm is not included within the scope of this order.

Specifically included in the scope of this order are vacuum-degassed, fully stabilized (commonly referred to as interstitial-free (“IF”)) steels, high-strength low-alloy (“HSLA”) steels, and the substrate for motor lamination steels. IF steels are recognized as low-carbon steels with micro-alloying levels of elements such as titanium or niobium (also commonly referred to as columbium), or both, added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, vanadium, and molybdenum. The substrate for motor lamination steels contains micro-alloying levels of elements such as silicon and aluminum.

Steel products included in the scope of this order, regardless of definitions in the Harmonized Tariff Schedule of the United States (“HTSUS”), are products in which: (i) Iron predominates, by weight, over each of the other contained elements; (ii) the carbon content is 2 percent or less, by weight; and (iii) none of the elements listed below exceeds the quantity, by weight, respectively indicated:

- 1.80 percent of manganese, or
- 2.25 percent of silicon, or
- 1.00 percent of copper, or
- 0.50 percent of aluminum, or
- 1.25 percent of chromium, or
- 0.30 percent of cobalt, or
- 0.40 percent of lead, or
- 1.25 percent of nickel, or
- 0.30 percent of tungsten, or
- 0.10 percent of molybdenum, or
- 0.10 percent of niobium, or
- 0.15 percent of vanadium, or
- 0.15 percent of zirconium.

All products that meet the physical and chemical description provided

above are within the scope of this order unless otherwise excluded. The following products, by way of example, are outside or specifically excluded from the scope of this order:

- Alloy hot-rolled carbon steel products in which at least one of the chemical elements exceeds those listed above (including, *e.g.*, American Society for Testing and Materials (“ASTM”) specifications A543, A387, A514, A517, A506).

- Society of Automotive Engineers (“SAE”)/American Iron & Steel Institute (“AISI”) grades of series 2300 and higher.

- Ball bearings steels, as defined in the HTSUS.

- Tool steels, as defined in the HTSUS.

- Silico-manganese (as defined in the HTSUS) or silicon electrical steel with a silicon level exceeding 2.25 percent.

- ASTM specifications A710 and A736.

- United States Steel (“USS”) Abrasion-resistant steels (USS AR 400, USS AR 500).

- All products (proprietary or otherwise) based on an alloy ASTM specification (sample specifications: ASTM A506, A507).

- Non-rectangular shapes, not in coils, which are the result of having been processed by cutting or stamping and which have assumed the character of articles or products classified outside chapter 72 of the HTSUS.

The merchandise subject to this order is currently classifiable in the HTSUS at subheadings: 7208.10.15.00, 7208.10.30.00, 7208.10.60.00, 7208.25.30.00, 7208.25.60.00, 7208.26.00.30, 7208.26.00.60, 7208.27.00.30, 7208.27.00.60, 7208.36.00.30, 7208.36.00.60, 7208.37.00.30, 7208.37.00.60, 7208.38.00.15, 7208.38.00.30, 7208.38.00.90, 7208.39.00.15, 7208.39.00.30, 7208.39.00.90, 7208.40.60.30, 7208.40.60.60, 7208.53.00.00, 7208.54.00.00, 7208.90.00.00, 7211.14.00.90, 7211.19.15.00, 7211.19.20.00, 7211.19.30.00, 7211.19.45.00, 7211.19.60.00, 7211.19.75.30, 7211.19.75.60, and 7211.19.75.90.

Certain hot-rolled carbon steel covered by this order, including: vacuum-degassed fully stabilized; high-strength low-alloy; and the substrate for motor lamination steel may also enter under the following tariff numbers:

- 7225.11.00.00, 7225.19.00.00,
- 7225.30.30.50, 7225.30.70.00,
- 7225.40.70.00, 7225.99.00.90,
- 7226.11.10.00, 7226.11.90.30,
- 7226.11.90.60, 7226.19.10.00,
- 7226.19.90.00, 7226.91.50.00,

7226.91.70.00, 7226.91.80.00, and 7226.99.00.00. Subject merchandise may also enter under 7210.70.30.00, 7210.90.90.00, 7211.14.00.30, 7212.40.10.00, 7212.40.50.00, and 7212.50.00.00. Although the HTSUS subheadings are provided for convenience and customs purposes, the Department’s written description of the merchandise subject to this order is dispositive.

Preliminary Results of Review

As noted in the “Background” section above, Essar, Ispat and JSW have each submitted timely-filed certifications indicating that they had no shipments of subject merchandise to the United States during the POR. In addition, Tata informed the Department that it had made one small shipment of subject merchandise that entered the United States during the POR. However, Tata claimed that the shipment was not of normal commercial quantities in the ordinary course of trade. Further, Tata claimed that the shipment to the United States was a one-off transaction for testing purposes only.

In August, 2010, the Department released to interested parties under Administrative Protective Order (“APO”) information it intended to use for corroboration of the respondents’ claims. *See* August 23 Comment Memorandum; clarified by August 25 Clarification Memorandum. In comments submitted on August 31, 2010, Nucor asserted that the data presented failed to confirm the absence of sales, entries, or shipments; alleging instead that the data raise additional questions that the Department should address.

On November 23, 2010, the Department requested from CBP the entry documents associated with certain entries which Nucor alleged raised questions with respect to the assertions of respondent(s). *See* November 23 CBP Request Memorandum.

On December 23, 2010, the Department received the entry documents from CBP. These documents and our analysis are proprietary. *See* January 7 Entry Document Memorandum. Based on the claims of the parties and our analysis of CBP data, we preliminarily determine that the evidence on the record indicates that Essar, Ispat, and JSW did not export subject merchandise to the United States during the POR. Further, the Department preliminarily determines that record evidence indicates that Tata had no reviewable transactions of subject merchandise during the POR. However, based on our review of the recently obtained entry documentation, we

intend to seek clarifying information from Tata after our preliminary results with respect to its exports.

Disclosure

The Department will disclose 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).

Comments

Interested parties are invited to comment on the preliminary results and may submit case briefs and/or written comments within 30 days of the date of publication of this notice. See 19 CFR 351.309(c)(1)(ii). Rebuttal briefs, limited to issues raised in the case briefs, will be due five days later, pursuant to 19 CFR 351.309(d). Parties who submit case or rebuttal briefs in this proceeding are requested to submit with each argument (1) a statement of the issue, and (2) a brief summary of the argument. Parties are requested to provide a summary of the arguments not to exceed five pages and a table of statutes, regulations, and cases cited. See 19 CFR 351.309(c)(2). Additionally, parties are requested to provide their case brief and rebuttal briefs in electronic format (e.g., Microsoft Word, pdf, etc.). Interested parties, who wish to request a hearing or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration 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. See 19 CFR 351.310(c). Issues raised in the hearing will be limited to those raised in case and rebuttal briefs. The Department will issue the final results of this review, including the results of its analysis of issues raised in any such written briefs or at the hearing, if held, not later than 120 days after the date of publication of this notice.

Assessment Rate

The Department intends to issue appropriate assessment instructions directly to CBP 15 days after the publication of the final results of this review.

Since the implementation of the 1997 regulations, our practice concerning no-shipment respondents has been to rescind the administrative review if the respondent certifies that it had no shipments and we have confirmed through our examination of CBP data that there were no shipments of subject merchandise during the POR. See *Antidumping Duties; Countervailing*

Duties, 62 FR 27296, 27393 (May 19, 1997). As a result, in such circumstances, we normally instruct CBP to liquidate any entries from the no-shipment company at the deposit rate in effect on the date of entry.

In our May 6, 2003, "automatic assessment" clarification, we explained that, where respondents in an administrative review demonstrate that they had no knowledge of sales through resellers to the United States, we would instruct CBP to liquidate such entries at the all-others rate applicable to the proceeding. See *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003) (*Assessment Policy Notice*).

Because "as entered" liquidation instructions do not alleviate the concerns which the May 2003 clarification was intended to address, we find it appropriate in this case to instruct CBP to liquidate any existing entries of merchandise produced by Essar, Ispat, JSW, or Tata and exported by other parties at the all-others rate, should we continue to find that Essar, Ispat, and JSW had no shipments of subject merchandise to the United States, and Tata had no reviewable transactions, during the POR, in our final results. See, e.g., *Magnesium Metal From the Russian Federation: Final Results of Antidumping Duty Administrative Review*, 75 FR 56989 (September 17, 2010). In addition, the Department finds that it is more consistent with the May 2003 clarification not to rescind the review in part in these circumstances but, rather, to complete the review with respect to Essar, Ispat, JSW, and Tata and issue appropriate instructions to CBP based on the final results of the review.

Cash Deposit Requirements

The following deposit rates will be effective upon publication of the final results of this administrative review for all shipments of hot-rolled carbon steel flat products from India entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) For Essar, Ispat, JSW, and Tata, and for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent final results in which that manufacturer or exporter participated; (2) if the exporter is not a firm covered in these reviews, a prior review, or the original less-than-fair-value ("LTFV") investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most

recent final results for the manufacturer of the merchandise; and (3) if neither the exporter nor the manufacturer is a firm covered in this or any previous review or the LTFV conducted by the Department, the cash deposit rate will be 23.87 percent, the all-others rate established in the LTFV. See *Amended Final Determination*. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice 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 and countervailing 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 and countervailing duties occurred and the subsequent assessment of double antidumping and countervailing duties.

These preliminary results of review are issued and published in accordance with sections 751(a)(1) and 777(i) of the Act and 19 CFR 351.221(b)(4).

Dated: January 7, 2011.

Ronald K. Lorentzen,
Deputy Assistant Secretary for Import Administration.

[FR Doc. 2011-619 Filed 1-12-11; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

Quarterly Update to Annual Listing of Foreign Government Subsidies on Articles of Cheese Subject to an In-Quota Rate of Duty

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

DATES: *Effective Date:* January 13, 2011.

FOR FURTHER INFORMATION CONTACT: Gayle Longest, AD/CVD Operations, Office 3, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Ave., NW., Washington, DC 20230, *telephone:* (202) 482-3338.

SUPPLEMENTARY INFORMATION: Section 702 of the Trade Agreements Act of 1979 (as amended) ("the Act") requires the Department of Commerce ("the Department") to determine, in consultation with the Secretary of Agriculture, whether any foreign government is providing a subsidy with

respect to any article of cheese subject to an in-quota rate of duty, as defined in section 702(h) of the Act, and to publish an annual list and quarterly updates to the type and amount of those subsidies. We hereby provide the Department's quarterly update of subsidies on articles of cheese that were imported during the period July 1, 2010, through September 30, 2010.

The Department has developed, in consultation with the Secretary of Agriculture, information on subsidies (as defined in section 702(h) of the Act) being provided either directly or indirectly by foreign governments on

articles of cheese subject to an in-quota rate of duty. The appendix to this notice lists the country, the subsidy program or programs, and the gross and net amounts of each subsidy for which information is currently available. The Department will incorporate additional programs which are found to constitute subsidies, and additional information on the subsidy programs listed, as the information is developed.

The Department encourages any person having information on foreign government subsidy programs which benefit articles of cheese subject to an in-quota rate of duty to submit such

information in writing to the Assistant Secretary for Import Administration, U.S. Department of Commerce, 14th Street and Constitution Ave., NW., Washington, DC 20230.

This determination and notice are in accordance with section 702(a) of the Act and 19 CFR 351.601.

Dated: January 7, 2011.

Ronald K. Lorentzen,
Deputy Assistant Secretary for Import Administration.

APPENDIX—SUBSIDY PROGRAMS ON CHEESE SUBJECT TO AN IN-QUOTA RATE OF DUTY

Country	Program(s)	Gross ¹ Subsidy (\$/lb)	Net ² Subsidy (\$/lb)
27 European Union Member States ³	European Union Restitution Payments	\$0.00	\$0.00
Canada	Export Assistance on Certain Types of Cheese	0.34	0.34
Norway	Indirect (Milk) Subsidy Consumer Subsidy	0.00 0.00	0.00 0.00
Switzerland	Total Deficiency Payments	0.00 0.00	0.00 0.00

¹ Defined in 19 U.S.C. 1677(5).

² Defined in 19 U.S.C. 1677(6).

³ The 27 member states of the European Union are: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom.

[FR Doc. 2011-617 Filed 1-12-11; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Availability of Seats for the Stellwagen Bank National Marine Sanctuary Advisory Council

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

ACTION: Notice and request for applications.

SUMMARY: The ONMS is seeking applicants for the following seats on the Stellwagen Bank National Marine Sanctuary Advisory Council: (1) At-Large Alternate seat and (1) Maritime Heritage Member and (1) Maritime Heritage Alternate seat. Applicants are chosen based upon their particular expertise and experience in relation to the seat for which they are applying; community and professional affiliations; philosophy regarding the protection and management of marine resources; and possibly the length of residence in the

area affected by the sanctuary. Applicants who are chosen as members should expect to serve two and three year terms, pursuant to the Council's Charter. The Council consists also of three state and three federal non-voting ex-officio seats.

DATES: Applications are due by 28 February 2011.

ADDRESSES: Application kits may be obtained from *Elizabeth.Stokes@noaa.gov*, Stellwagen Bank National Marine Sanctuary, 175 Edward Foster Road, Scituate, MA 02066. Telephone 781-545-8026, ext. 201. Completed applications should be sent to the same address or email, or faxed to 781-545-8036.

FOR FURTHER INFORMATION CONTACT: Contact *Nathalie.Ward@noaa.gov*, External Affairs Coordinator, telephone: 781-545-8026, ext. 206.

SUPPLEMENTARY INFORMATION: The Council was established in March 2001 to assure continued public participation in the management of the Sanctuary. The Council's 23 members represent a variety of local user groups, as well as the general public, plus seven local, state and federal government agencies. Since its establishment, the Council has played a vital role in advising NOAA on critical issues and is currently focused

on the sanctuary's final five-year Management Plan.

The Stellwagen Bank National Marine Sanctuary encompasses 842 square miles of ocean, stretching between Cape Ann and Cape Cod. Renowned for its scenic beauty and remarkable productivity, the sanctuary supports a rich diversity of marine life including 22 species of marine mammals, more than 30 species of seabirds, over 60 species of fishes, and hundreds of marine invertebrates and plants.

Authority: 16 U.S.C. Sections 1431, *et seq.* (Federal Domestic Assistance Catalog Number 11.429 Marine Sanctuary Program)

Dated: December 28, 2010.

Daniel J. Basta,
Director, Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2011-517 Filed 1-12-11; 8:45 am]

BILLING CODE 3510-NK-M

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration**

RIN 0648-XA140

[File No. 15596]

Endangered Species

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

ACTION: Issuance of permit.

SUMMARY: Notice is hereby given that North Carolina Aquarium at Fort Fisher, North Carolina Department of Environment and Natural Resources, Kure Beach, NC, 28449 [Hap Fatzinger, Responsible Party] has been issued a permit to take shortnose sturgeon (*Acipenser brevirostrum*) for purposes of enhancement.

ADDRESSES: The permit and related documents are available for review upon written request or by appointment in the following offices:

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 713-2289; fax (301) 713-0376 and; Southeast Region, NMFS, 263 13th Ave South, St. Petersburg, FL 33701; phone (727) 824-5312; fax (727) 824-5309.

FOR FURTHER INFORMATION CONTACT: Colette Cairns or Jennifer Skidmore, (301) 713-2289.

SUPPLEMENTARY INFORMATION: On October 5, 2010, notice was published in the **Federal Register** (75 FR 61424) that a request for an enhancement permit to take shortnose sturgeon had been submitted by the North Carolina Aquarium at Fort Fisher. The requested permit has been issued under the authority of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*) and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222-226).

The North Carolina Aquarium at Fort Fisher has been issued a permit to continue enhancement activities previously authorized under Permit No. 1273. Activities include the continued maintenance and educational display of five captive-bred, non-releaseable adult shortnose sturgeon. The permit does not authorize any takes from the wild, nor does it authorize any release of captive sturgeon into the wild. The permit is issued for a duration of 5 years.

Issuance of this permit, as required by the ESA, was based on a finding that

such permit (1) was applied for in good faith, (2) will not operate to the disadvantage of such endangered or threatened species, and (3) is consistent with the purposes and policies set forth in section 2 of the ESA.

Dated: January 7, 2011.

P. Michael Payne,

Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2011-659 Filed 1-12-11; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE**National Technical Information Service****National Technical Information Service Advisory Board**

AGENCY: National Technical Information Service, Commerce.

ACTION: Notice of open meeting.

SUMMARY: This notice announces the next meeting of the National Technical Information Service Advisory Board (the Advisory Board), which advises the Secretary of Commerce and the Director of the National Technical Information Service (NTIS) on policies and operations of the Service.

DATES: The Advisory Board will meet on Tuesday, February 1, 2011 from 9 a.m. to approximately 4:30 p.m.

ADDRESSES: The Advisory Board meeting will be held in Room 115 of the NTIS Facility at 5301 Shawnee Road, Alexandria, Virginia 22312. Please note admittance instructions under the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Mr. Steven D. Needle, (703) 605-6404, sneedle@ntis.gov or Ms. Jill Johnson (703) 605-6401, jjohnson@ntis.gov.

SUPPLEMENTARY INFORMATION: The NTIS Advisory Board is established by Section 3704b(c) of Title 15 of the United States Code. The charter has been filed in accordance with the requirements of the Federal Advisory Committee Act, as amended (5 U.S.C. App.).

The morning session will focus on a review of NTIS' performance in Fiscal Year 2010, its lines of business and its core competencies. The afternoon session is expected to focus on new strategic directions for Fiscal Year 2011, including issues pertaining to the identification of new markets and new ways to enhance NTIS' utility to Federal and non-Federal customers. A final agenda and summary of the proceedings will be posted at the NTIS web site as

soon as they are available (<http://www.ntis.gov/about/advisorybd.asp>).

The NTIS Facility is a secure one. Accordingly, persons wishing to attend should call the contacts identified above to arrange for admission. If there are sufficient expressions of interest up to one-half hour will be reserved for public comments during the afternoon session. Questions from the public will not be considered by the Board but any person who wishes to submit a written statement for the Board's consideration should mail or e-mail it to the contacts named above not later than January 25, 2011.

Dated: January 5, 2011.

Bruce Borzino,

Director.

[FR Doc. 2011-472 Filed 1-12-11; 8:45 am]

BILLING CODE 3510-04-P

DEPARTMENT OF EDUCATION**National Assessment Governing Board: Proposed Information Collection**

AGENCY: National Assessment Governing Board, Education.

ACTION: Agency Information Collection Activities: Submission for OMB Review; Comment Request.

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the National Assessment Governing Board is publishing the following summary of a proposed information collection for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (5) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Type of Information Collection Request: New information collection.

Title of Information Collection: Evaluating Student Need for Developmental or Remedial Courses at Postsecondary Education Institutions

(formerly titled Survey of Placement Tests and Cut-Scores in Higher Education Institutions).

Use: The congressionally authorized National Assessment of Educational Progress (NAEP) reports to the public on the achievement of students at grades 4, 8, and 12 in core subjects. The National Assessment Governing Board oversees and sets policy for NAEP. NAEP and the Governing Board are authorized under the National Assessment of Educational Progress Authorization Act (Pub. L. 107-279).

Among the Board's responsibilities is "to improve the form, content, use, and reporting of [NAEP results]." Toward this end, the Governing Board plans to enable NAEP at the 12th grade to report on the academic preparedness of 12th grade students in reading and mathematics for entry level college credit coursework.

The Governing Board has planned a program of research studies to support the validity of statements about 12th grade student preparedness that would be made in NAEP reports, beginning with the 2009 assessments in 12th grade reading and mathematics. Among the studies planned is a survey of 2-year and 4-year institutions of higher education about the tests and test scores used to place students into entry level college credit coursework leading to a degree and into non-credit remedial or developmental programs in reading and/or mathematics. The data resulting from this survey will be used to help develop valid statements that can be made about the preparedness of 12th grade students in NAEP reports.

Frequency: One operational study; one time only; *Affected Public:* State, Local or Tribal Governments (2-year and 4-year public higher education institutions); Private Sector For-Profit and Not-For-Profit Institutions (2-year and 4-year private higher education institutions);

Number of Respondents: 1,700; *Total Annual Responses:* 1,700; *Total Annual Hours:* 975.

To obtain copies of the proposed survey and/or supporting statement for the proposed paperwork collection referenced above, e-mail your request, including your address and phone number, to Ray.Fields@ed.gov or call 202-357-0395.

To be assured consideration, comments and recommendations for the proposed information collection must be received by the OMB desk officer at the address below, no later than 5 p.m. on February 14, 2011: OMB, Office of Information and Regulatory Affairs, Attention: Education Desk Officer, New Executive Office Building, Room 10235,

Washington, DC 20503, Fax Number: (202) 395-6974.

Dated: January 10, 2011.

Ray Fields,

Authorized Agency Paperwork Contact, National Assessment Governing Board.

[FR Doc. 2011-613 Filed 1-12-11; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

Office of Postsecondary Education; Overview Information; Business and International Education Program

Notice inviting applications for new awards for fiscal year (FY) 2011.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.153A.

DATES:

Applications Available: January 13, 2011.

Deadline for Transmittal of Applications: March 2, 2011.

Deadline for Intergovernmental Review: May 2, 2011.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The Business and International Education (BIE) Program provides grants to enhance international business education programs and to expand the capacity of the business community to engage in international economic activities.

Priorities: Under this competition we are particularly interested in applications that address the following priorities.

Invitational Priority: For FY 2011, these priorities are invitational priorities. Under 34 CFR 75.105(c)(1), we do not give an application that meets these invitational priorities a competitive or absolute preference over other applications.

These priorities are:

Invitational Priority I

Applications from Minority Serving Institutions (MSIs) and community colleges (including those that are eligible to receive assistance under part A or B of Title III or under Title V of the Higher Education Act of 1965, as amended).

Invitational Priority II

Applications that promote sustainable economic growth through export education and support high quality postsecondary programs of study that prepare students for success in the context of a global economy.

Invitational Priority III

Applications that focus on language instruction in any of the following seventy-eight (78) languages selected from the U.S. Department of Education's list of Less Commonly Taught Languages (LCTLs):

Akan (Twi-Fante), Albanian, Amharic, Arabic (all dialects), Armenian, Azeri (Azerbaijani), Balochi, Bamanakan (Bamana, Bambara, Mandikan, Mandingo, Maninka, Dyula), Belarusian, Bengali (Bangla), Berber (all languages), Bosnian, Bulgarian, Burmese, Cebuano (Visayan), Chechen, Chinese (Cantonese), Chinese (Gan), Chinese (Mandarin), Chinese (Min), Chinese (Wu), Croatian, Dari, Dinka, Georgian, Gujarati, Hausa, Hebrew (Modern), Hindi, Igbo, Indonesian, Japanese, Javanese, Kannada, Kashmiri, Kazakh, Khmer (Cambodian), Kirghiz, Korean, Kurdish (Kurmanji), Kurdish (Sorani), Lao, Malay (Bahasa Melayu or Malaysian), Malayalam, Marathi, Mongolian, Nepali, Oromo, Panjabi, Pashto, Persian (Farsi), Polish, Portuguese (all varieties), Quechua, Romanian, Russian, Serbian, Sinhala (Sinhalese), Somali, Swahili, Tagalog, Tajik, Tamil, Telugu, Thai, Tibetan, Tigrigna, Turkish, Turkmen, Ukrainian, Urdu, Uyghur/Uigur, Uzbek, Vietnamese, Wolof, Xhosa, Yoruba, and Zulu.

Program Authority: 20 U.S.C. 1130-1130b.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 84, 85, 86, 97, 98, and 99. (b) The regulations in 34 CFR parts 655 and 661.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

Areas of National Need

In accordance with section 601(c) of the Higher Education Act of 1965, as amended (HEA), 20 U.S.C. 1121(c), the Secretary has consulted with and received recommendations regarding the national need for expertise in foreign languages and world regions from the head officials of a wide range of Federal agencies. These recommendations have been taken into account in developing the request for applications for funding during this grant cycle. A list of foreign languages and world regions identified as areas of national need may be found on the following Web sites: <http://www.ed.gov/about/offices/list/ope/policy.html>, <http://www.ed.gov/programs/iegpsbie/legislation.html>.

Also included on these Web sites are the specific recommendations the Secretary received from Federal agencies.

Program Assurances: Each application must include an assurance that, where applicable, the activities funded by this grant will reflect diverse perspectives and a wide range of views on world regions and international affairs. (20 U.S.C. 1130a(c)).

II. Award Information

Type of Award: Discretionary grants.
Estimated Available Funds: The Administration has requested \$108,360,000 for the Title VI International Education and Foreign Language Studies Programs (also referred to as the International Domestic Programs) for FY 2011, of which we intend to allocate \$2,619,500 for new awards under the Business and International Education Program. The actual level of funding, if any, depends on final Congressional action. However, we are inviting applications to allow enough time to complete the grant process if Congress appropriates funds for this program.

Estimated Range of Awards: \$50,000–\$95,000 per year.

Estimated Average Size of Awards: \$84,000 per year.

Maximum Award: We will reject any application that proposes a budget exceeding \$95,000 for a single budget period of 12 months. The Assistant Secretary for Postsecondary Education may change the maximum amount through a notice published in the **Federal Register**.

Estimated Number of Awards: 31.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 24 months.

III. Eligibility Information

1. *Eligible Applicants:* Institutions of higher education that have entered into agreements with business enterprises, trade organizations, or associations that are engaged in international economic activity—or a combination or consortium of these enterprises, organizations, or associations—for the purposes of pursuing the activities authorized under this program.

2. *Cost Sharing or Matching:* The matching requirement is described in section 613(d) of the HEA (20 U.S.C. 1130a(d)). The HEA provides that the applicant's share of the total cost of carrying out a program supported by a grant under the Business and International Education Program must be no less than 50 percent of the total cost of the project in each fiscal year.

The non-Federal share of the cost may be provided either in-kind or in cash.

IV. Application and Submission Information

1. *Address to Request Application Package:* Susanna Easton, International Education Programs Service, U.S. Department of Education, 1990 K Street, NW., room 6093, Washington, DC 20006–8521. FAX: (202) 502–7860.

If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

Individuals with disabilities can obtain a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or computer diskette) by contacting the program contact person listed in this section.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this program.

Page Limit: The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. You must limit the application narrative [Part III] to no more than 40 pages, using the following standards:

- A “page” is 8.5” x 11”, on one side only, with 1” margins at the top, bottom, and both sides. Page numbers and an identifier may be outside of the 1” margin.

- Double space (no more than three lines per vertical inch) all text in the application narrative, *except* titles, headings, footnotes, quotations, references, captions, and all text in charts, tables, figures, and graphs. These items may be single-spaced. Charts, tables, figures, and graphs in the application narrative count toward the page limit.

- Use a font that is either 12 point or larger, or no smaller than 10 pitch (characters per inch). However, you may use a 10 point font in charts, tables, figures, and graphs.

- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial. An application submitted in any other font (including Times Roman and Arial Narrow) will not be accepted.

The page limit does not apply to Part I, the Application for Federal Assistance face sheet (SF 424); the supplemental information form required by the Department of Education; Part II, the budget information summary form (ED Form 524); and Part IV, the assurances and certifications. The page limit also does not apply to a table of contents.

However, the page limit does apply to all of the application narrative section [Part III]. If you include any attachments or appendices not specifically requested, these items will be counted as part of the application narrative [Part III] for purposes of the page limit requirement. You must include your complete response to the selection criteria in the application narrative.

We will reject your application if you exceed the page limit.

3. *Submission Dates and Times:*

Applications Available: January 13, 2011.

Deadline for Transmittal of Applications: March 2, 2011.

Applications for grants under this program must be submitted electronically using the Grants.gov Apply site (Grants.gov). For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to section IV. 7. *Other Submission Requirements* of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

Deadline for Intergovernmental Review: May 2, 2011.

4. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this program.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, and Central Contractor Registry:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the Central Contractor Registry (CCR), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active CCR registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet. A DUNS number can be created within one business day.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow 2–5 weeks for your TIN to become active.

The CCR registration process may take five or more business days to complete. If you are currently registered with the CCR, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your CCR registration on an annual basis. This may take three or more business days to complete.

In addition, if you are submitting your application via Grants.gov, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with Grants.gov as an AOR. Details on these steps are outlined in the Grants.gov 3-Step Registration Guide (see <http://www.grants.gov/section910/Grants.govRegistrationBrochure.pdf>).

7. Other Submission Requirements: Applications for grants under this program must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. Electronic Submission of Applications.

Applications for grants under the BIE Program, CFDA number 84.153A, must be submitted electronically using the Government-wide Grants.gov Apply site at www.Grants.gov. Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not e-mail an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement and

submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement*.

You may access the electronic grant application for the BIE Program at <http://www.Grants.gov>. You must search for the downloadable application package for this program by the CFDA number. Do not include the CFDA number's alpha suffix in your search (e.g., search for 84.153, not 84.153A).

Please note the following:

- When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.
- Applications received by Grants.gov are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the Grants.gov system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the Grants.gov system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from Grants.gov, we will notify you if we are rejecting your application because it was date and time stamped by the Grants.gov system after 4:30:00 p.m., Washington, DC time, on the application deadline date.

- The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through Grants.gov.

- You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this program to ensure that you submit your application in a timely manner to the Grants.gov system. You can also find the Education Submission Procedures pertaining to Grants.gov under News and Events on the Department's G5 system home page at <http://www.G5.gov>.

- You will not receive additional point value because you submit your

application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.

- You must submit all documents electronically, including all information you typically provide on the following forms: The Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.

- You must attach any narrative sections of your application as files in a .PDF (Portable Document) format only. If you upload a file type other than a .PDF or submit a password-protected file, we will not review that material.

- Your electronic application must comply with any page-limit requirements described in this notice.

- After you electronically submit your application, you will receive from Grants.gov an automatic notification of receipt that contains a Grants.gov tracking number. (This notification indicates receipt by Grants.gov only, not receipt by the Department.) The Department then will retrieve your application from Grants.gov and send a second notification to you by e-mail. This second notification indicates that the Department has received your application and has assigned your application a PR/Award number (an ED-specified identifying number unique to your application).

- We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you are experiencing problems submitting your application through Grants.gov, please contact the Grants.gov Support Desk, toll free, at 1–800–518–4726. You must obtain a Grants.gov Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR**

FURTHER INFORMATION CONTACT in section VII of this notice and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that that problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. The Department will contact you after a determination is made on whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the application deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the Grants.gov system because—

- You do not have access to the Internet; or
- You do not have the capacity to upload large documents to the Grants.gov system; and
- No later than two weeks before the application deadline date (14 calendar days; or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevent you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Susanna Easton, International Education Programs Service, U.S. Department of Education, 1990 K Street, NW., room 6093, Washington, DC 20006–8521. FAX: (202) 502–7860.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. Submission of Paper Applications by Mail. If you qualify for an exception

to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.153A), LBJ Basement Level 1, 400 Maryland Avenue, SW., Washington, DC 20202–4260.

You must show proof of mailing consisting of one of the following:

- (1) A legibly dated U.S. Postal Service postmark.
- (2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.
- (3) A dated shipping label, invoice, or receipt from a commercial carrier.
- (4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

- (1) A private metered postmark.
- (2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. Submission of Paper Applications by Hand Delivery. If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application, by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.153A), 550 12th Street, SW., Room 7041, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

- (1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and
- (2) The Application Control Center will mail to you a notification of receipt of your

grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. Selection Criteria: The selection criteria for this program are in 34 CFR 661.31 and are as follows: (a) Need for the project (25 points); (b) plan of operation (20 points); (c) qualifications of the key personnel (10 points); (d) budget and cost effectiveness (15 points); (e) evaluation plan (25 points); and (f) adequacy of resources (5 points).

2. General: For FY 2011, applications are randomly divided into groupings. International business and outreach experts, organized into panels of three, will review each application. Each panel reviews, scores, and ranks its applications separately from the applications assigned to the other panels. However, ultimately, all applications, without being divided into groups, will be ranked from the highest to the lowest score for funding purposes.

3. Review and Selection Process: We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary also requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

4. Special Conditions: Under 34 CFR 74.14 and 80.12, the Secretary may impose special conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 34 CFR parts 74 or 80, as applicable; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

VI. Award Administration Information

1. Award Notices: If your application is successful, we notify your U.S. Representative and U.S. Senators and

send you a Grant Award Notification (GAN). We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. Administrative and National Policy Requirements: We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. Reporting: (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. Grantees are required to use the electronic data instrument International Resource Information System (IRIS), to complete the final report. Electronically formatted instructional materials such as CDs, DVDs, videos, computer diskettes and books produced by the grantee as part of the grant approved activities are also acceptable as final reports. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to <http://www.ed.gov/fund/grant/apply/appforms/appforms.html>.

4. Performance Measures: The purpose of the BIE Program is to provide funds to institutions of higher education that enter into agreements with trade associations or businesses for one or both of the following purposes: to improve the academic teaching of the business curriculum at institutions of higher education and to conduct outreach activities that expand the capacity of the business community to engage in international economic activities.

The Department will use the following BIE measures to evaluate its success in meeting this objective:

Performance Measure 1: The number of outreach activities that are adopted or disseminated within a year, divided by the total number of BIE outreach activities conducted in the current reporting period.

Performance Measure 2: Percentage of BIE projects judged to be successful by the program officer, based on a review of information provided in annual performance reports.

Efficiency Measure: Cost per high-quality, successfully completed project.

The Department will use information provided by grantees in their performance reports submitted via IRIS as the source of data for these measures. Reporting screens for institutions can be viewed at: <http://www.ieps-iris.org/iris/pdfs/BIE.pdf>.

5. Continuation Awards: In making a continuation award, the Secretary may consider, under 34 CFR 75.253, the extent to which a grantee has made "substantial progress toward meeting the objectives in its approved application." This consideration includes the review of a grantee's progress in meeting the targets and projected outcomes in its approved application, and whether the grantee has expended funds in a manner that is consistent with its approved application and budget. In making a continuation grant, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: Susanna Easton, International Education Programs Service, U.S. Department of Education, 1990 K Street, NW., room 6093, Washington, DC 20006-8521 or by e-mail: susanna.easton@ed.gov.

If you use a TDD, call the FRS, toll free, at 1-800-877-8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (e.g., braille, large print, audiotope, or computer diskette) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice.

Electronic Access to This Document: You can view this document, as well as

all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF), on the Internet at the following site: <http://www.ed.gov/news/fedregister>. To use PDF, you must have Adobe Acrobat Reader, which is available free at this site.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: <http://www.gpoaccess.gov/nara/index.html>.

Dated: January 10, 2011.

Eduardo M. Ochoa,

Assistant Secretary for Postsecondary Education.

[FR Doc. 2011-653 Filed 1-12-11; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

Office of Postsecondary Education; Overview Information; International Research and Studies (IRS) Program; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2011

Catalog of Federal Domestic Assistance (CFDA) Numbers: 84.017A-1 and 84.017A-3.

Dates: Applications Available: January 13, 2011.

Deadline for Transmittal of Applications: March 1, 2011.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The IRS Program provides grants to eligible applicants to conduct research and studies to improve and strengthen instruction in modern foreign languages, area studies, and other international fields.

Priorities: In accordance with 34 CFR 75.105(b)(2)(ii), these priorities are from the regulations for this program (34 CFR 660.10 and 660.34).

Competitive Preference Priorities: For FY 2011, these priorities are competitive preference priorities. Under 34 CFR 75.105(c)(2)(i), we award an additional five points to an application that meets one or more of these priorities.

These priorities are:

Competitive Preference Priority 1—Instructional Materials Applications.

The development of specialized instructional or assessment materials focused on any of the following seventy-eight (78) languages selected from the U.S. Department of Education's list of Less Commonly Taught Languages (LCTLs):

Akan (Twi-Fante), Albanian, Amharic, Arabic (all dialects),

Armenian, Azeri (Azerbaijani), Balochi, Bamanakan (Bamana, Bambara), Mandikan, Mandingo, Maninka, Dyula), Belarusian, Bengali (Bangla), Berber (all languages), Bosnian, Bulgarian, Burmese, Cebuano (Visayan), Chechen, Chinese (Cantonese), Chinese (Gan), Chinese (Mandarin), Chinese (Min), Chinese (Wu), Croatian, Dari, Dinka, Georgian, Gujarati, Hausa, Hebrew (Modern), Hindi, Igbo, Indonesian, Japanese, Javanese, Kannada, Kashmiri, Kazakh, Khmer (Cambodian), Kirghiz, Korean, Kurdish (Kurmanji), Kurdish (Sorani), Lao, Malay (Bahasa Melayu or Malaysian), Malayalam, Marathi, Mongolian, Nepali, Oromo, Panjabi, Pashto, Persian (Farsi), Polish, Portuguese (all varieties), Quechua, Romanian, Russian, Serbian, Sinhala (Sinhalese), Somali, Swahili, Tagalog, Tajik, Tamil, Telugu, Thai, Tibetan, Tigrigna, Turkish, Turkmen, Ukrainian, Urdu, Uyghur/Uigur, Uzbek, Vietnamese, Wolof, Xhosa, Yoruba, and Zulu.

Competitive Preference Priority 2—Research, Surveys, and Studies Applications.

Research and studies that provide information on the effectiveness of Department of Education foreign language and area and international studies programs, such as evaluations of the extent to which programs assisted under Title VI of the HEA address national needs that would not otherwise be addressed and studies assessing the outcomes, including participant outcomes, and effectiveness of programs supported under Title VI of the HEA.

Note: Applicants will receive an additional five points for meeting a competitive preference priority in their applications. Applicants are expected to address only one competitive preference priority in each application, but regardless of how many priorities are addressed, no more than five points in total will be awarded to a single application.

Program Authority: 20 U.S.C. 1125.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 80, 82, 84, 85, 86, 97, 98, and 99. (b) The regulations for this program in 34 CFR parts 655 and 660.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

Areas of National Need: In accordance with section 601(c) of the Higher Education Act of 1965, as amended (HEA), 20 U.S.C. 1121(c), the Secretary has consulted with and received recommendations regarding national need for expertise in foreign

languages and world regions from the head officials of a wide range of Federal agencies. The Secretary has taken these recommendations into account, and a list of foreign languages and world regions identified by the Secretary as areas of national need may be found on links on the following Web sites:

<http://www.ed.gov/about/offices/list/ope/policy.html>

<http://www.ed.gov/programs/iegsirs/legislation.html>

Also included on these Web sites and links are the specific recommendations the Secretary received from Federal agencies.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: The Administration has requested \$108,360,000 for the International Education and Foreign Language Studies programs (also referred to as the International Domestic Programs) for FY 2011, of which we intend to use an estimated \$1,950,000 for awards under these competitions (84.017A–1 and 84.017A–3). The actual level of funding, if any, depends on final congressional action. However, we are inviting applications to allow enough time to complete the grant process if Congress appropriates funds for this program.

Estimated Range of Awards: \$50,000–\$225,000 per year.

Estimated Average Size of Awards: \$170,000.

Maximum Award: We will reject any application that proposes a budget exceeding \$225,000 for a single budget period of 12 months. The Assistant Secretary for Postsecondary Education may change the maximum amount through a notice published in the **Federal Register**.

Estimated Number of Awards: 11.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 36 months.

III. Eligibility Information

1. *Eligible Applicants:* Public and private agencies, organizations, institutions, and individuals.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

IV. Application and Submission Information

1. *Address to Request Application Package:* Carla White, U.S. Department of Education, 1990 K Street, NW., room 6085, Washington, DC 20006–8521. Telephone: (202) 502–7631; or by e-mail: carla.white@ed.gov.

If you use a telecommunications device for the deaf (TDD), call the

Federal Relay Service (FRS), toll free, at 1–800–877–8339.

Individuals with disabilities can obtain a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or computer diskette) by contacting the program contact person listed in this section.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this program. The IRS Program has two application packages. Research, surveys, and studies applicants must use the application package for 84.017A–1. Instructional materials applicants must use the application package for 84.017A–3.

Page Limit: The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. You must limit the application narrative [Part III] to the equivalent of no more than 30 pages, using the following standards:

- A “page” is 8.5” x 11”, on one side only, with 1” margins at the top, bottom, and both sides. Page numbers and an identifier may be outside of the 1” margin.

- Double space (no more than three lines per vertical inch) all text in the application narrative, except titles, headings, footnotes, quotations, references, captions, and all text in charts, tables, figures, and graphs. These items may be single-spaced. Charts, tables, figures, and graphs in the application narrative count toward the page limit.

- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch). However, you may use a 10 point font in charts, tables, figures, and graphs.

- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial. An application submitted in any other font (including Times Roman and Arial Narrow) will not be accepted.

The page limit does not apply to Part I, the Application for Federal Assistance face sheet (SF 424); the supplemental information form required by the Department of Education; Part II, the budget information summary form (ED Form 524); or Part IV, the assurances and certifications. The page limit also does not apply to a table of contents. If you include any additional attachments or appendices not specifically requested in the application package, these items will be counted as part of your application narrative [Part III] for purposes of the page limit requirement. You must include your complete

response to the selection criteria in the application narrative.

We will reject your application if you exceed the page limit.

3. *Submission Dates and Times:*

Applications Available: January 13, 2011.

Deadline for Transmittal of Applications: March 1, 2011.

Applications for grants under this program must be submitted electronically using the Grants.gov Apply site (Grants.gov). For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to section IV. 7. *Other Submission Requirements* of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

4. *Intergovernmental Review:* This program is not subject to Executive Order 12372 and the regulations in 34 CFR part 79.

5. *Funding Restrictions:* See 34 CFR 660.40. We reference regulations outlining additional funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, and Central Contractor Registry:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the Central Contractor Registry (CCR), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active CCR registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet. A DUNS number can be created within one business day.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow 2–5 weeks for your TIN to become active.

The CCR registration process may take five or more business days to complete. If you are currently registered with the CCR, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your CCR registration on an annual basis. This may take three or more business days to complete.

In addition, if you are submitting your application via Grants.gov, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with Grants.gov as an AOR. Details on these steps are outlined in the Grants.gov 3-Step Registration Guide (see <http://www.grants.gov/section910/Grants.govRegistrationBrochure.pdf>).

7. *Other Submission Requirements:*

Applications for grants under this program must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. *Electronic Submission of Applications.*

Applications for grants under the IRS Program, CFDA number 84.017A, must be submitted electronically using the Government-wide Grants.gov Apply site at www.Grants.gov. Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not e-mail an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement and submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement*.

You may access the electronic grant application for the IRS Program at www.Grants.gov. You must search for the downloadable application package

for this program by the CFDA number. Do not include the CFDA number's alpha suffix in your search (e.g., search for 84.326, not 84.326A).

Please note the following:

- When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.

- Applications received by Grants.gov are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the Grants.gov system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the Grants.gov system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from Grants.gov, we will notify you if we are rejecting your application because it was date and time stamped by the Grants.gov system after 4:30:00 p.m., Washington, DC time, on the application deadline date.

- The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through Grants.gov.

- You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this program to ensure that you submit your application in a timely manner to the Grants.gov system. You can also find the Education Submission Procedures pertaining to Grants.gov under News and Events on the Department's G5 system home page at <http://www.G5.gov>.

- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.

- You must submit all documents electronically, including all information you typically provide on the following forms: The Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-

Construction Programs (ED 524), and all necessary assurances and certifications.

- You must attach any narrative sections of your application as files in a .PDF (Portable Document) format only. If you upload a file type other than a .PDF or submit a password-protected file, we will not review that material.

- Your electronic application must comply with any page-limit requirements described in this notice.

- After you electronically submit your application, you will receive from Grants.gov an automatic notification of receipt that contains a Grants.gov tracking number. (This notification indicates receipt by Grants.gov only, not receipt by the Department.) The Department then will retrieve your application from Grants.gov and send a second notification to you by e-mail. This second notification indicates that the Department has received your application and has assigned your application a PR/Award number (an ED-specified identifying number unique to your application).

- We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you are experiencing problems submitting your application through Grants.gov, please contact the Grants.gov Support Desk, toll free, at 1-800-518-4726. You must obtain a Grants.gov Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that that problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. The

Department will contact you after a determination is made on whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the application deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the Grants.gov system because—

- You do not have access to the Internet; or
- You do not have the capacity to upload large documents to the Grants.gov system; and

- No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevent you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Carla White, U.S. Department of Education, 1990 K Street, NW., room 6085, Washington, DC 20006-8521. FAX: (202) 502-7860.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. Submission of Paper Applications by Mail.

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.017A) LBJ Basement Level 1, 400 Maryland Avenue, SW., Washington, DC 20202-4260.

You must show proof of mailing consisting of one of the following:

- (1) A legibly dated U.S. Postal Service postmark.

- (2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

- (3) A dated shipping label, invoice, or receipt from a commercial carrier.

- (4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

- (1) A private metered postmark.

- (2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. Submission of Paper Applications by Hand Delivery.

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.017A) 550 12th Street, SW., Room 7041, Potomac Center Plaza, Washington, DC 20202-4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

- (1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

- (2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245-6288.

V. Application Review Information

1. *General:* Applications are divided into two groups, instructional materials (CFDA 84.017A-3) and research, surveys, and studies (CFDA 84.017A-1).

Review panels will be assigned to read either instructional materials applications or research, surveys, and studies applications. The number of panels for each category will depend on the number of applications received. Each panel reviews, scores, and ranks its applications separately from the applications assigned to other panels. All instructional materials applications will be ranked together from the highest to the lowest score for funding purposes; and, all research, surveys, and studies applications will be ranked together from the highest to the lowest score for funding purposes.

2. *Selection Criteria:* The selection criteria for this program are from 34 CFR 655.31, 660.31, 660.32, and 660.33 and are as follows:

For applications proposing to develop specialized instructional materials—

Need for the project (10 points); Potential for the use of materials in other programs (5 points); Account of related materials (10 points); Likelihood of achieving results (10 points); Expected contribution to other programs (5 points); Plan of operation (10 points); Quality of key personnel (5 points); Budget and cost effectiveness (5 points); Evaluation plan (15 points); Adequacy of resources (5 points); Description of final form of materials (5 points); and Provisions for pretesting and revision (15 points).

For applications proposing research, surveys and studies—

Need for the project (10 points); Usefulness of expected results (10 points); Development of new knowledge (10 points); Formulation of problems and knowledge of related research (10 points); Specificity of statement of procedures (5 points); Adequacy of methodology and scope of project (10 points); Plan of operation (10 points); Quality of key personnel (10 points); Budget and cost effectiveness (5 points); Evaluation plan (15 points); and Adequacy of resources (5 points).

Further information about these selection criteria is in the application package for this competition.

3. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary also requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

4. *Special Conditions:* Under 34 CFR 74.14 and 80.12, the Secretary may impose special conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 34 CFR parts 74 or 80, as applicable; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN). We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. Grantees are required to use the electronic data instrument International Resource Information System (IRIS), to complete the final report. Electronically formatted instructional materials such as CDs,

DVDs, videos, computer diskettes and books produced by the grantee as part of the grant approved activities are also acceptable as final reports. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to <http://www.ed.gov/fund/grant/apply/appforms/appforms.html>.

4. *Performance Measures:* The objective for the IRS Program is to support surveys, studies, and the development of instructional materials to improve and strengthen instruction in modern foreign languages, area studies, and other international fields. The Department will use the following measures to evaluate the success of the IRS Program:

Performance Measure 1: Percentage of IRS Program projects judged to be successful by the program officer, based on a review of information provided in annual performance reports.

Performance Measure 2: Number of outreach activities that are adopted or disseminated within a year, divided by the total number of IRS Program outreach activities conducted in the current reporting period.

Efficiency Measure: Cost per high-quality, successfully completed IRS Program project.

The information provided by grantees in their performance reports submitted via IRIS will be the source of data for these measures. Reporting screens can be viewed at: <http://iris.ed.gov/iris/pdfs/IRS.pdf>.

5. *Continuation Awards:* In making a continuation award, the Secretary may consider, under 34 CFR 75.253, the extent to which a grantee has made "substantial progress toward meeting the objectives in its approved application." This consideration includes the review of a grantee's progress in meeting the targets and projected outcomes in its approved application, and whether the grantee has expended funds in a manner that is consistent with its approved application and budget. In making a continuation grant, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Agency Contact

For Further Information Contact: Beth MacRae, International and Foreign Language Education, U.S. Department of Education, 1990 K Street, NW., room

6088, Washington, DC 20006–8521. Telephone: (202) 502–7596; or by e-mail: beth.macrae@ed.gov.

If you use a TDD, call the FRS, toll free, at 1–800–877–8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or computer diskette) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice.

Electronic Access to This Document: You can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: <http://www.ed.gov/news/fedregister>. To use PDF you must have Adobe Acrobat Reader, which is available free at this site.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: <http://www.gpoaccess.gov/nara/index.html>.

Dated: January 10, 2011.

Eduardo M. Ochoa,

Assistant Secretary for Postsecondary Education.

[FR Doc. 2011–681 Filed 1–12–11; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP11–53–000]

Texas Eastern Transmission Company and Dominion Transmission, Inc.; Notice of Application To Amend Certificate of Public Convenience and Necessity

January 5, 2011.

Take notice that on December 14, 2010, Texas Eastern Transmission, LP (Texas Eastern”), 5400 Westheimer Court, Houston, Texas 77056–5310, and Dominion Transmission, Inc. (DTI), 701 East Cary Street, Richmond, Virginia 23219, filed in the above referenced docket an Abbreviated Application to Amend Certificate of Public Convenience and Necessity (Application) pursuant to Section 7 of the Natural Gas Act, as amended, and

the regulations of the Federal Energy Regulatory Commission (FERC or Commission) thereunder. By the Application, Texas Eastern and DTI request authorization to amend the certificate to reflect backhaul entitlements on their jointly owned facilities. Texas Eastern and DTI request that the Commission issue a final amended certificate of public convenience and necessity granting the authorizations requested herein as soon as possible and, to the extent feasible, on or before March 14, 2011. The filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission’s Web site at <http://www/ferc.gov> using the “eLibrary” link. Enter the docket number excluding the last three digits in the docket number filed to access the document. For assistance, contact FERC at FERCOnlineSupport@ferc.gov or call toll-free, (866) 208–3676, or TTY, (202) 502–8659.

Any questions concerning this application may be directed to Berk Donaldson, Director, Rates and Certificates, Texas Eastern Transmission, LP, P.O. Box 1642, Houston, TX 77251–1642, by telephone at (713) 627–4488, by facsimile at (713) 627–5947 or Matthew R. Bley, Manager, Gas Transmission Certificates, Dominion Transmission, Inc., 701 East Cary Street, Richmond, VA 23219, by telephone at (804) 819–2877 or by facsimile at (804) 819–2064.

There are two ways to become involved in the Commission’s review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission’s Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 7 copies of filings made in the proceeding with the Commission and must mail a copy to the applicant and to every other party. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments

considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission’s rules require that persons filing comments in opposition to the project provide copies of their protest only to the party or parties directly involved in the protest.

For your convenience, there are three methods which you can use to submit your comments to the Commission. In all instances please reference the docket number with your submission. The Commission encourages electronic filing of comments and has expert eFiling staff available to assist you at (202) 502–8258 or efiling@ferc.gov.

(1) You may file your comments electronically by using the *eComment* feature, which is located on the Commission’s Web site at <http://www.ferc.gov> under the link to *Documents and Filings*. An eComment is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You may file your comments electronically by using the *eFiling* feature, which is located on the Commission’s Web site at <http://www.ferc.gov> under the link to *Documents and Filings*. With eFiling you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on “*eRegister*.” You will be asked to select the type of filing you are making. A comment on a particular project is considered a “Comment on a Filing”; or

(3) You may file a paper copy of your comments at the following address:

Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Room 1A, Washington, DC 20426.

Comment Date: 5 p.m. Eastern Time on January 25, 2011.

Kimberly D. Bose,
Secretary.

[FR Doc. 2011–533 Filed 1–12–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Project No. 13637-001]

Great River Hydropower, LLC; Notice of Application Accepted for Filing and Soliciting Motions To Intervene and Protests

January 5, 2011.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Original Major License.

b. *Project No.:* P-13637-001.

c. *Date filed:* July 12, 2010.

d. *Applicant:* Great River Hydropower, LLC.

e. *Name of Project:* Upper Mississippi River Lock & Dam No. 21 Hydroelectric Project.

f. *Location:* The proposed project would be located on the Mississippi River in Marion County, Missouri. The proposed project would occupy 5 acres of federal lands.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791 (a)-825(r)

h. *Applicant Contact:* Mr. Arie DeWaal, Mead & Hunt Inc., 6501 Watts Road, Madison, WI 53719; Telephone (608) 273-6380.

i. *FERC Contact:* Janet Hutzell, Telephone (202) 502-8675, or by e-mail at janet.hutzell@ferc.gov.

j. *Deadline for filing motions to intervene and protests:* February 7, 2011.

All documents may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov or toll free at 1-866-208-3676, or for TTY, (202) 502-8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an

original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The Commission's Rules of Practice and Procedures require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted for filing, but is not ready for environmental analysis at this time.

l. The proposed project would utilize the existing U.S. Army Corps of Engineers' Lock and Dam No. 21, and would consist of the following facilities: (1) A new 796-foot-long by 46-foot-wide by 25-foot-high concrete hydropower structure consisting of 30 turbine bays, located about 100 feet downstream of the existing dam; (2) 30 turbine-generator units having a total installed capacity of 15 megawatts; (3) two new 48-foot-long by 15-foot-wide by 45-foot-high concrete towers; (4) a new 40-foot-long by 30-foot-wide by 20-foot-high control building; (5) a new 120-foot-long by 120-foot-wide substation; (6) a new 1.5-mile-long access road; (7) a new 1.6-mile-long, 69-kilovolt transmission line; and (8) appurtenant facilities.

m. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's 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. A copy is also available for inspection and reproduction at the address in item h above.

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.

n. Any qualified applicant desiring to file a competing application must submit to the Commission, on or before the specified intervention deadline date, a competing development application,

or a notice of intent to file such an application. Submission of a timely notice of intent allows an interested person to file the competing development application no later than 120 days after the specified intervention deadline date. Applications for preliminary permits will not be accepted in response to this notice.

A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit a development application. A notice of intent must be served on the applicant(s) named in this public notice.

Anyone may submit a protest or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, and 385.214. In determining the appropriate action to take, the Commission will consider all protests filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any protests or motions to intervene must be received on or before the specified deadline date for the particular application.

When the application is ready for environmental analysis, the Commission will issue a public notice requesting comments, recommendations, terms and conditions, or prescriptions.

All filings must (1) bear in all capital letters the title "PROTEST" or "MOTION TO INTERVENE," "NOTICE OF INTENT TO FILE COMPETING APPLICATION," or "COMPETING APPLICATION;" (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application.

Kimberly D. Bose,
Secretary.

[FR Doc. 2011-544 Filed 1-12-11; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12715-001]

Fairlawn Hydroelectric Company, LLC; Notice of Application Tendered for Filing With the Commission and Establishing Procedural Schedule for Licensing and Deadline for Submission of Final Amendments

January 6, 2011.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Original Major License.

b. *Project No.:* 12715-001.

c. *Date Filed:* December 23, 2010.

d. *Applicant:* Fairlawn Hydroelectric Company, LLC.

e. *Name of Project:* Jennings Randolph Hydroelectric Project.

f. *Location:* The proposed project would be at the U.S. Army Corps of Engineers' Jennings Randolph dam located on the North Branch Potomac River in Garrett County, Maryland and Mineral County, West Virginia. The project would occupy 5.0 acres of federal land managed by the U.S. Army Corps of Engineers.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. §§ 791(a)-825(r).

h. *Applicant Contact:* Clifford Phillips, Fairlawn Hydroelectric Company LLC, 150 North Miller Road, Suite 450 C, Fairlawn, OH 44333; Telephone (330) 869-8451.

i. *FERC Contact:* Michael Spencer, (202) 502-6093 or michael.spencer@ferc.gov.

j. This application is not ready for environmental analysis at this time.

k. *The Project Description:* The proposed Jennings Randolph Project would use the existing Corps of Engineers' Jennings Randolph dam and reservoir and consist of the following proposed features: (1) A 10-foot-diameter, 530-foot-long underwater multi-level intake structure with 24 intake ports to be built on the upstream face of the dam; (2) a 10-foot-diameter, 1,400-foot-long lined tunnel through the dam; (3) a 10-foot-diameter, 1,100-foot-long penstock; (4) the penstock would bifurcate into 96-inch-diameter and 66-inch-diameter penstocks at the entrance to the powerhouse; (5) a powerhouse approximately 54 feet long, 54 feet wide, and 40 feet high that would contain two generating units with a total capacity of 14.0 megawatts; (6) a 40-foot-long tailrace; (7) a 0.7-mile-long, 25-kilovolt partially buried transmission line; (8) a substation; and (9) new compacted gravel access roads to be constructed to the powerhouse and along the transmission line to the

project's substation. The proposed project would have an estimated average annual generation of 56,000 megawatt-hours and would bypass 150 feet of the North Branch Potomac River.

l. *Locations of the Application:* A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at <http://www.ferc.gov> using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at FERCOnlineSupport@ferc.gov or toll-free at 1-866-208-3676, or for TTY, (202) 502-8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. 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.

n. *Procedural Schedule:*

The application will be processed according to the following preliminary Hydro Licensing Schedule. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Notice of Acceptance/Notice of Ready for Environmental Analysis (when FERC approved studies are complete)	February 21, 2011.
Filing of recommendations, preliminary terms and conditions, and fishway prescriptions	April 22, 2011.
Commission issues Non-Draft EA	August 20, 2011.
Comments on EA	October 4, 2011.
Modified terms and conditions	December 5, 2011.

o. Final amendments to the application must be filed with the Commission no later than 30 days from

the issuance date of the notice of ready for environmental analysis.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011-543 Filed 1-12-11; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application

January 5, 2011.

Texas Eastern Transmission, LP	Docket Nos. CP11-56-000
Algonquin Gas Transmission, LLC	PF10-17-000

Take notice that on December 20, 2010, Texas Eastern Transmission, LP, (Texas Eastern) 5400 Westheimer Court, Houston, Texas 77056 and Algonquin Gas Transmission, LLC, (Algonquin) 5400 Westheimer Court, Houston, Texas 77056 (collectively, the Applicants), jointly filed in the above referenced docket an application pursuant to sections 7(b) and 7(c) of the Natural Gas

Act (NGA) for the proposed New Jersey-New York Expansion Project (NJ-NY Project). Specifically, the Applicants request: (i) Authorization for Texas Eastern to construct, install, own, operate, and maintain 4.84 miles of 42-inch pipeline, 15.5 miles of 30-inch pipelines, four new meter and regulating stations, and appurtenances; (ii) authorization for Texas Eastern to

lease from Algonquin 730,000 dekatherms per day (Dth/d) of firm capacity rights, plus applicable shrinkage requirements on Texas Eastern's system, on Algonquin's mainline; (iii) authorization for Algonquin to construct, install, own, operate, and maintain certain proposed facilities and to lease capacity to Texas Eastern; (iv) authorization for Texas

Eastern to abandon in place eight miles of 20- and 24-inch pipeline; (v) authority to charge an incremental initial recourse rate, incremental access charges and incremental fuel, as applicable for the NJ-NY Project; and (vi) any waivers, authority, and further relief as may be necessary to implement the proposed facilities. The Applicants state that the proposed project will provide a total of 800,000 Dth/d of firm transportation service. The Applicants estimate the total cost of the NJ-NY Project to be approximately \$857 million, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site Web at <http://www.ferc.gov> using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at FERCOnlineSupport@ferc.gov or call toll-free, (886) 208-3676 or TTY, (202) 502-8659.

Any questions concerning this application may be directed to Berk Donaldson, Director, Rates and Certificates, Texas Eastern Transmission, LP, PO Box 1642, Houston, Texas 77251-1642, by telephone at (713) 627-4488 or by facsimile at (713) 627-5947.

On April 23, 2010, the Commission staff granted the Applicants' request to utilize the Pre-Filing Process and assigned Docket No. PF10-17-000 to staff activities involved in the NJ-NY Project. Now as of the filing the December 20, 2010 application, the Pre-Filing Process for this project has ended. From this time forward, this proceeding will be conducted in Docket No. CP11-56-000, as noted in the caption of this Notice.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit

7 copies of filings made in the proceeding with the Commission and must mail a copy to the applicant and to every other party. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, 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: January 26, 2011.

Kimberly D. Bose,
Secretary.

[FR Doc. 2011-537 Filed 1-12-11; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PR11-77-000]

Atmos Energy—Kentucky/Mid-States Division; Notice of Baseline Filing

January 5, 2011.

Take notice that on December 30, 2010, Atmos Energy—Kentucky/Mid-States Division submitted a revised baseline filing of their Statement of Operating Conditions for services provided under Section 311 of the Natural Gas Policy Act of 1978 ("NGPA").

Any person desiring to participate in this rate proceeding must file a motion 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 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 pm Eastern Time on Friday, January 14, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011-546 Filed 1-12-11; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

December 13, 2010.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG11-33-000.

Applicants: Windstar Energy, LLC.

Description: Self-Certification of EG of Windstar Energy, LLC.

Filed Date: 12/10/2010.

Accession Number: 20101210-5214

Comment Date: 5 p.m. Eastern Time on Monday, January 3, 2011.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10-2295-000.

Applicants: WSPP Inc.

Description: Response to October 26, 2010, Request for Additional Information.

Filed Date: 12/10/2010.

Accession Number: 20101210-5225.

Comment Date: 5 p.m. Eastern Time on Monday, January 3, 2011.

Docket Numbers: ER10-2626-001.

Applicants: TEC Trading, Inc.

Description: TEC Trading, Inc.

submits tariff filing per 35: Tec Trading, Inc. Compliance Filing to be effective 9/14/2010.

Filed Date: 12/10/2010.

Accession Number: 20101210-5136.

Comment Date: 5 p.m. Eastern Time on Monday, January 3, 2011.

Docket Numbers: ER10-2786-004.

Applicants: Washington Gas Energy Services, Inc.

Description: Washington Gas Energy Services, Inc. submits tariff filing per 35: Washington Gas Energy Services Tariff to be effective 12/12/2010.

Filed Date: 12/13/2010.

Accession Number: 20101213-5001.

Comment Date: 5 p.m. Eastern Time on Monday, January 3, 2011.

Docket Numbers: ER10-3092-001;

ER10-2989-001; ER10-2991-001;

ER10-2993-001.

Applicants: Solios Power LLC, Solios Power Mid-Atlantic Trading LLC, Solios Power Midwest Trading LLC, Solios Power Trading LLC.

Description: Solios Entities submits Notice of Change in Status.

Filed Date: 12/13/2010.

Accession Number: 20101213-5063.

Comment Date: 5 p.m. Eastern Time on Monday, January 3, 2011.

Docket Numbers: ER11-21-001.

Applicants: Consolidated Edison Company of New York.

Description: Consolidated Edison Company of New York, Inc. submits tariff filing per 35: Correction of Compliance Filing to be effective 12/2/2010.

Filed Date: 12/02/2010.

Accession Number: 20101202-5119.

Comment Date: 5 p.m. Eastern Time on Thursday, December 23, 2010.

Docket Numbers: ER11-1870-001.

Applicants: Consolidated Edison Company of New York, Inc.

Description: Consolidated Edison Company of New York, Inc. submits tariff filing per 35.17(b): Amendment and deferral of DR filing to be effective 12/31/9998.

Filed Date: 12/10/2010.

Accession Number: 20101210-5233.

Comment Date: 5 p.m. Eastern Time on Monday, January 3, 2011.

Docket Numbers: ER11-2334-003.

Applicants: Midwest Independent Transmission System Operator, Inc.

Description: Midwest Independent Transmission System Operator, Inc. submits tariff filing per 35.17(b): (4) ATC Notice of Succession to be effective 2/9/2011.

Filed Date: 12/10/2010.

Accession Number: 20101210-5179.

Comment Date: 5 p.m. Eastern Time on Monday, January 3, 2011.

Docket Numbers: ER11-2334-004.

Applicants: Midwest Independent Transmission System Operator, Inc.

Description: Midwest Independent Transmission System Operator, Inc. submits tariff filing per 35.17(b): (5) ATC Notice of Succession to be effective 2/9/2011.

Filed Date: 12/10/2010.

Accession Number: 20101210-5198.

Comment Date: 5 p.m. Eastern Time on Monday, January 3, 2011.

Docket Numbers: ER11-2334-005.

Applicants: Midwest Independent Transmission System Operator, Inc.

Description: Midwest Independent Transmission System Operator, Inc. submits tariff filing per 35.17(b): (6) ATC Notice of Succession to be effective 2/9/2011.

Filed Date: 12/10/2010.

Accession Number: 20101210-5222.

Comment Date: 5 p.m. Eastern Time on Monday, January 3, 2011.

Docket Numbers: ER11-2338-000.

Applicants: Cianbro Energy, LLC.

Description: Cianbro Energy, LLC submits tariff filing per 35.1: FERC Electric Tariff to be effective 12/10/2010.

Filed Date: 12/10/2010.

Accession Number: 20101210-5216.

Comment Date: 5 p.m. Eastern Time on Monday, January 3, 2011.

Docket Numbers: ER11-2339-000.

Applicants: Corinth Energy, LLC.

Description: Corinth Energy, LLC submits tariff filing per 35.1: FERC Electric Tariff to be effective 12/10/2010.

Filed Date: 12/10/2010.

Accession Number: 20101210-5217.

Comment Date: 5 p.m. Eastern Time on Monday, January 3, 2011.

Docket Numbers: ER11-2340-000.

Applicants: Dennis Energy Company

Description: Dennis Energy Company submits tariff filing per 35.1: FERC Electric Tariff to be effective 12/10/2010.

Filed Date: 12/10/2010.

Accession Number: 20101210-5218.

Comment Date: 5 p.m. Eastern Time on Monday, January 3, 2011.

Docket Numbers: ER11-2341-000.

Applicants: East Avenue Energy, LLC.

Description: East Avenue Energy, LLC submits tariff filing per 35.1: FERC Electric Tariff to be effective 12/10/2010.

Filed Date: 12/10/2010.

Accession Number: 20101210-5219.

Comment Date: 5 p.m. Eastern Time on Monday, January 3, 2011.

Docket Numbers: ER11-2343-000.

Applicants: Mid-Continent Area Power Pool.

Description: Request of Mid-Continent Area Power Pool for waiver of requirements to revise tariff to implement MOD Reliability Standards.

Filed Date: 12/10/2010.

Accession Number: 20101210-5209.

Comment Date: 5 p.m. Eastern Time on Monday, January 3, 2011.

Docket Numbers: ER11-2344-000.

Applicants: Florida Power Corporation.

Description: Florida Power Corporation submits tariff filing per 35.13(a)(2)(iii): Rate Schedule No. 193 of Florida Power Corporation to be effective 1/1/2011.

Filed Date: 12/13/2010.

Accession Number: 20101213-5033.

Comment Date: 5 p.m. Eastern Time on Monday, January 3, 2011.

Docket Numbers: ER11–2345–000.
Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc. submits tariff filing per 35.13(a)(2)(iii): Formula Update—KCPL, KCPL–GMO to be effective 7/26/2010.

Filed Date: 12/13/2010.

Accession Number: 20101213–5080.

Comment Date: 5 p.m. Eastern Time on Monday, January 3, 2011.

Docket Numbers: ER11–2346–000.

Applicants: Florida Power Corporation.

Description: Florida Power Corporation submits tariff filing per 35.13(a)(2)(iii): Rate Schedule No. 106 of Florida Power Corporation to be effective 12/31/2010.

Filed Date: 12/13/2010.

Accession Number: 20101213–5081.

Comment Date: 5 p.m. Eastern Time on Monday, January 3, 2011.

Docket Numbers: ER11–2347–000.

Applicants: CornerStone Power Develo p.m.ent, LLC.

Description: Notice of Cancellation of Market-Based Rate Tariff in ER10–854, Motion for Expedited Action, and Request for Shortened Comment Period of CornerStone Power Develo p.m.ent, LLC.

Filed Date: 12/13/2010.

Accession Number: 20101213–5145.

Comment Date: 5 p.m. Eastern Time on Monday, December 27, 2010.

Docket Numbers: ER11–2348–000.

Applicants: ISO New England Inc.

Description: Resource Termination Filing CL&P.

Filed Date: 12/13/2010.

Accession Number: 20101213–5146.

Comment Date: 5 p.m. Eastern Time on Monday, January 3, 2011.

Docket Numbers: ER11–2349–000.

Applicants: ISO New England Inc.

Description: Resource Termination Filing EnerNOC.

Filed Date: 12/13/2010.

Accession Number: 20101213–5147.

Comment Date: 5 p.m. Eastern Time on Monday, January 3, 2011.

Docket Numbers: ER11–2350–000.

Applicants: Midwest Independent Transmission System Operator, Inc.

Description: Midwest Independent Transmission System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii): 12–13–10 Schedule 1 Revisions to be effective 1/1/2011.

Filed Date: 12/13/2010.

Accession Number: 20101213–5155.

Comment Date: 5 p.m. Eastern Time on Monday, January 3, 2011.

Docket Numbers: ER11–2351–000.

Applicants: WSPP Inc.

Description: WSPP Inc. submits tariff filing per 35.13(a)(2)(iii): Incorporation

of Rate Schedules into WSPP Agreement to be effective 10/1/2010.

Filed Date: 12/13/2010.

Accession Number: 20101213–5167.

Comment Date: 5 p.m. Eastern Time on Monday, January 3, 2011.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

As it relates to any qualifying facility filings, the notices of self-certification [or self-recertification] listed above, do not institute a proceeding regarding qualifying facility status. A notice of self-certification [or self-recertification] simply provides notification that the entity making the filing has determined the facility named in the notice meets the applicable criteria to be a qualifying facility. Intervention and/or protest do not lie in dockets that are qualifying facility self-certifications or self-recertifications. Any person seeking to challenge such qualifying facility status may do so by filing a motion pursuant to 18 CFR 292.207(d)(iii). Intervention and protests may be filed in response to notices of qualifying facility dockets other than self-certifications and self-recertifications.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email FERCOnlineSupport@ferc.gov or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–527 Filed 1–12–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

December 14, 2010.

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC11–30–000.

Applicants: COLMAC Energy Inc.

Description: Application of COLMAC Energy, Inc. under FPA Section 203.

Filed Date: 12/13/2010.

Accession Number: 20101213–5250.

Comment Date: 5 p.m. Eastern Time on Monday, December 27, 2010.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER03–40–000.

Applicants: Accent Energy Midwest LLC.

Description: Accent Energy Midwest LLC submits a Notice of Cancellation of its Original Sheet No 1–2, First Revised FERC Electric Rate Tariff, Original Volume No 1.

Filed Date: 12/13/2010.

Accession Number: 20101214–0201.

Comment Date: 5 p.m. Eastern Time on Monday, January 3, 2011.

Docket Numbers: ER10–2490–001; ER10–2491–001.

Applicants: The Dayton Power and Light Company; The DPL Energy, LLC.

Description: Submission of 2010 Market Power Analysis of The Dayton Power and Light Company and DPL Energy, LLC.

Filed Date: 12/14/2010.

Accession Number: 20101214–5043.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 4, 2011.

Docket Numbers: ER10–2786–004.

Applicants: Washington Gas Energy Services, Inc.

Description: Washington Gas Energy Services, Inc. submits tariff filing per 35: Washington Gas Energy Services Tariff to be effective 12/12/2010.

Filed Date: 12/13/2010.

Accession Number: 20101213-5001.

Comment Date: 5 p.m. Eastern Time on Monday, January 3, 2011.

Docket Numbers: ER10-2994-001.

Applicants: Iberdrola Renewables, Inc.

Description: Iberdrola Renewables, Inc. submits tariff filing per 35: Compliance Filing to Baseline MBR Tariff to be effective 9/27/2010.

Filed Date: 12/14/2010.

Accession Number: 20101214-5103.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 4, 2011.

Docket Numbers: ER10-2995-001.

Applicants: Juniper Canyon Wind Power LLC.

Description: Juniper Canyon Wind Power LLC submits tariff filing per 35: Compliance Filing to Baseline MBR Tariff to be effective 9/27/2010.

Filed Date: 12/14/2010.

Accession Number: 20101214-5104.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 4, 2011.

Docket Numbers: ER10-3001-001.

Applicants: Lempster Wind, LLC.

Description: Lempster Wind, LLC submits tariff filing per 35: Compliance Filing to Baseline MBR to be effective 9/27/2010.

Filed Date: 12/14/2010.

Accession Number: 20101214-5105.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 4, 2011.

Docket Numbers: ER10-3004-001.

Applicants: Locust Ridge Wind Farm II, LLC.

Description: Locust Ridge Wind Farm II, LLC submits tariff filing per 35: Compliance Filing to Baseline MBR to be effective 9/27/2010.

Filed Date: 12/14/2010.

Accession Number: 20101214-5106.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 4, 2011.

Docket Numbers: ER10-3005-001.

Applicants: MinnDakota Wind LLC.

Description: MinnDakota Wind LLC submits tariff filing per 35: Compliance Filing to MBR Tariff to be effective 9/27/2010.

Filed Date: 12/14/2010.

Accession Number: 20101214-5118.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 4, 2011.

Docket Numbers: ER10-3007-001.

Applicants: Moraine Wind II LLC.

Description: Moraine Wind II LLC submits tariff filing per 35: Compliance

Filing to Baseline MBR Tariff to be effective 9/27/2010.

Filed Date: 12/14/2010.

Accession Number: 20101214-5119.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 4, 2011.

Docket Numbers: ER10-3008-001.

Applicants: Northern Iowa Windpower II LLC.

Description: Northern Iowa Windpower II LLC submits tariff filing per 35: Compliance Filing to Baseline MBR Tariff to be effective 9/27/2010.

Filed Date: 12/14/2010.

Accession Number: 20101214-5138.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 4, 2011.

Docket Numbers: ER10-3009-001.

Applicants: Pebble Springs Wind LLC.

Description: Pebble Springs Wind LLC submits tariff filing per 35: Compliance Filing to Baseline MBR Tariff to be effective 9/27/2010.

Filed Date: 12/14/2010.

Accession Number: 20101214-5139.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 4, 2011.

Docket Numbers: ER10-3011-001.

Applicants: Rugby Wind LLC.

Description: Rugby Wind LLC submits tariff filing per 35: Compliance Filing to Baseline MBR Tariff to be effective 9/27/2010.

Filed Date: 12/14/2010.

Accession Number: 20101214-5150.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 4, 2011.

Docket Numbers: ER11-2358-000.

Applicants: Westar Energy, Inc.

Description: Westar Energy, Inc. submits tariff filing per 35.13(a)(2)(iii): Mid-Kansas Electric Company, LLC to be effective 8/31/2010.

Filed Date: 12/14/2010.

Accession Number: 20101214-5009.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 4, 2011.

Docket Numbers: ER11-2359-000.

Applicants: Midwest Independent

Description: Midwest Independent Transmission System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii): CapX-Bemidji-Otter Tail to be effective 12/15/2010.

Filed Date: 12/14/2010.

Accession Number: 20101214-5044.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 4, 2011.

Docket Numbers: ER11-2360-000.

Applicants: Midwest Independent

Description: Midwest Independent Transmission System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii): CapX-Bemidji Minnkota Power to be effective 12/15/2010.

Filed Date: 12/14/2010.

Accession Number: 20101214-5045.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 4, 2011.

Docket Numbers: ER11-2361-000.

Applicants: Midwest Independent Transmission System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii): CapX-Bemidji-MN Power to be effective 12/15/2010.

Filed Date: 12/14/2010.

Accession Number: 20101214-5046.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 4, 2011.

Docket Numbers: ER11-2362-000.

Applicants: PJM Interconnection, L.L.C.

Description: PJM Interconnection, L.L.C. submits tariff filing per 35.13(a)(2)(iii): WMPA No. 2705, Queue W1-121, EffiSolar Energy Corp. and PSE&G to be effective 11/15/2010.

Filed Date: 12/14/2010.

Accession Number: 20101214-5047.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 4, 2011.

Docket Numbers: ER11-2363-000.

Applicants: Chestnut Flats Wind, LLC.

Description: Chestnut Flats Wind, LLC submits tariff filing per 35.13(a)(2)(iii): Market-Based Rate Tariff to be effective 12/14/2010.

Filed Date: 12/14/2010.

Accession Number: 20101214-5078.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 4, 2011.

Docket Numbers: ER11-2364-000.

Applicants: Sandy Ridge Wind, LLC.

Description: Sandy Ridge Wind, LLC submits tariff filing per 35.13(a)(2)(iii): Market-Based Rate Tariff to be effective 12/15/2010.

Filed Date: 12/14/2010.

Accession Number: 20101214-5093.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 4, 2011.

Docket Numbers: ER11-2365-000.

Applicants: Paradise Solar Urban

Description: Paradise Solar Urban Renewal, L.L.C. submits tariff filing per 35.12: Paradise Solar Urban Renewal, L.L.C. to be effective 12/15/2010.

Filed Date: 12/14/2010.

Accession Number: 20101214-5101.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 4, 2011.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES11-8-000.

Applicants: PJM Interconnection, L.L.C., PJM Settlement, Inc.

Description: Response to December 8, 2010 Request for Additional Information.

Filed Date: 12/13/2010.

Accession Number: 20101213-5234.

Comment Date: 5 p.m. Eastern Time on Friday, December 17, 2010.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email FERCOnlineSupport@ferc.gov or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Kimberly D. Bose,
Secretary.

[FR Doc. 2011-528 Filed 1-12-11; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Effectiveness of Exempt Wholesale Generator Status

January 6, 2011.

	Docket No.
Ashtabula Wind III, LLC	EG11-1-000
Iberdrola Renewables, Inc.	EG11-2-000
Flat Water Wind Farm, LLC ...	EG11-3-000
Wildorado Wind Two, LLC	EG11-4-000
Sandy Ridge Wind, LLC	EG11-5-000
AES ES Deepwater, LLC	EG11-6-000
Elk City II Wind, LLC	EG11-7-000

Take notice that during the month of December 2010, the status of the above-captioned entities as Exempt Wholesale Generators became effective by operation of the Commission's regulations. 18 CFR 366.7(a).

Kimberly D. Bose,
Secretary.

[FR Doc. 2011-540 Filed 1-12-11; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13-023]

Green Island Power Authority; Notice of Availability of Final Environmental Assessment

January 5, 2011.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's regulations, 18 CFR part 380 (Order No. 486, 52 FR 47897), the Office of Energy Projects has reviewed the application for a new license for the 6.0-megawatt Green Island Hydroelectric Project, located on the Hudson River, in Albany County, New York, and has prepared a Final Environmental Assessment (FEA). In the FEA, Commission staff analyzes the potential environmental effects of relicensing the project and conclude that issuing a new 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 FEA is on file with the Commission and is available for public inspection. The FEA 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 documents. For assistance, contact FERC Online Support at FERCOnlineSupport@ferc.gov or toll-free at 1-866-208-3676, or for TTY, (202) 502-8659. For further information, contact Tom Dean at (202) 502-6041.

Kimberly D. Bose,
Secretary.

[FR Doc. 2011-542 Filed 1-12-11; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP11-39-000]

Dominion Transmission, Inc.; Notice of Intent To Prepare an Environmental Assessment for the Northeast Expansion Project and Request for Comments on Environmental Issues

January 5, 2011.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the Northeast Expansion Project (Project) proposed by Dominion Transmission, Inc. (DTI). The Project consists of a total of 32,440 horsepower (hp) of compression to be installed at three existing compressor stations, a new meter station, and an upgrade at an existing regulator station, all located at existing DTI facilities in Pennsylvania. This EA will be used by the Commission in its decision-making process to determine whether the Project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies on the Project. Your input will help the Commission staff determine what issues need to be evaluated in the EA. Please note that the scoping period will close on February 4, 2011.

This notice is being sent to the Commission's current environmental mailing list for this Project. State and local government representatives are asked to notify their constituents of this planned Project and encourage them to comment on their areas of concern.

Summary of the Proposed Project

DTI is seeking authorization to construct, own, and operate the proposed Project, which would involve expansion at several of DTI's existing aboveground facilities in Western

Pennsylvania. DTI is proposing to install additional compression units at its existing Punxsutawney, Ardell, and Finnefrock Compressor Station in Jefferson/Indiana, Elk, and Clinton Counties, Pennsylvania. All construction would take place within the stations fence lines and in adjacent stations areas within DTI's property boundaries. DTI states that the Project would provide 200,000 dekatherms per day of firm transportation services in Pennsylvania, creating increased access for production in this region to major natural gas markets of the Northeast and Mid-Atlantic regions of the United States.

The proposed Project consists of the following:

- *Punxsutawney Compressor Station*—install one gas turbine/compressor package that would consist of a Solar C404 compressor driven by a Solar Centaur gas turbine rated at 6,130 hp. The turbine would be fueled by natural gas and would be placed in a new compressor building.
- *Ardell Compressor Station*—install one gas turbine/compressor package that would consist of a Solar C45 compressor driven by a Solar Taurus 70 gas turbine rated at 10,310 hp. The turbine would be fueled by natural gas and would be placed in a new compressor building.
- *Finnefrock Compressor Station*—install one gas turbine/compressor package that would consist of a Solar C453 centrifugal compressor driven by a Solar Mars 100 gas turbine, rated at 16,000 hp.
- *Leidy Compressor Station*—upgrade an existing Measurement and Regulation (M&R) facility within the fence line of the Leidy Compressor Station.
- *Punxsutawney Compressor Station*—install one new crossover line with M&R which links the existing suction piping to LN-280.

The general location of the Project facilities is shown in appendix 1.¹

Land Requirement for Construction

Construction of the Project would involve temporary disturbance of a total of 41.5 acres of land with DTI's property boundaries which would include an 18.2 acres within existing compressor station fence lines and 23.2 acres within DTI's property. For construction

activities within DTI's property, 14.6 acres would be required for the Punxsutawney Station, 1.4 acres for the Ardell Station, and 6.2 acres for the Finnefrock Station. DTI would utilize the construction work areas for equipment and materials laydown, and parking. Following construction, these construction work areas would be restored, stabilized, and seeded. Operation of the Project would involve 1.9 acres of lands.

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us² to discover and address concerns the public may have about proposals. This process is referred to as "scoping". The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in the EA. All comments received will be considered during the preparation of the EA.

In the EA we will discuss impacts that could occur as a result of the construction and operation of the proposed Project under these general headings:

- Geology and soils;
- Land use;
- Water resources, fisheries, and wetlands;
- Cultural resources;
- Vegetation and wildlife, including migratory birds;
- Air quality and noise;
- Endangered and threatened species; and
- Public safety.

We will also evaluate reasonable alternatives to the proposed Project or portions of the Project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

Our independent analysis of the issues will be presented in the EA. The EA will be placed in the public record and, depending on the comments received during the scoping process, may be published and distributed to the public. A comment period will be allotted if the EA is published for review. We will consider all comments on the EA before we make our recommendations to the Commission. To ensure your comments are

considered, please carefully follow the instructions in the Public Participation section below.

With this notice, we are asking agencies with jurisdiction and/or special expertise with respect to environmental issues to formally cooperate with us in the preparation of the EA. These agencies may choose to participate once they have evaluated the proposal relative to their responsibilities. Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice.

Public Participation

You can make a difference by providing us with your specific comments or concerns about the Project. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that your comments are timely and properly recorded, please send your comments so that they will be received in Washington, DC on or before February 4, 2011.

For your convenience, there are three methods which you can use to submit your comments to the Commission. In all instances please reference the Project docket number (CP11-39-000) with your submission. The Commission encourages electronic filing of comments and has expert eFiling staff available to assist you at (202) 502-8258 or efiling@ferc.gov.

(1) You may file your comments electronically by using the eComment feature, which is located on the Commission's Web site at <http://www.ferc.gov> under the link to *Documents and Filings*. An eComment is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You may file your comments electronically by using the eFiling feature, which is located on the Commission's Web site at <http://www.ferc.gov> under the link to *Documents and Filings*. With eFiling you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on "eRegister." You will be asked to select the type of filing you are making. A comment on a particular project is considered a "Comment on a Filing"; or

(3) You may file a paper copy of your comments at the following address:

¹ The appendices referenced in this notice are not being printed in the **Federal Register**. Copies of appendices were sent to all those receiving this notice in the mail and are available at <http://www.ferc.gov> using the link called "eLibrary" or from the Commission's Public Reference Room, 888 First Street, NE., Washington, DC 20426, or call (202) 502-8371. For instructions on connecting to eLibrary, refer to the last page of this notice.

² "We", "us", and "our" refer to the environmental staff of the Commission's Office of Energy Projects.

Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Room 1A, Washington, DC 20426.

Environmental Mailing List

The environmental mailing list includes Federal, State, and local government representatives and agencies; elected officials; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the Project. We will update the environmental mailing list as the analysis proceeds to ensure that we send the information related to this environmental review to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed Project.

If the EA is published for distribution, copies will be sent to the environmental mailing list for public review and comment.

Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an "intervenor" which is an official party to the Commission's proceeding. Intervenor play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene. Instructions for becoming an intervenor are included in the User's Guide under the "e-filing" link on the Commission's Web site.

Additional Information

Additional information about the Project is available from the Commission's Office of External Affairs, at (866) 208-FERC, or on the FERC Web site at <http://www.ferc.gov> using the "eLibrary" link. Click on the eLibrary link, click on "General Search" and enter the docket number, excluding the last three digits in the Docket Number field (i.e., CP11-39). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at FercOnlineSupport@ferc.gov or toll free at (866) 208-3676, or for TTY, contact (202) 502-8659. The eLibrary link also provides access to the texts of formal documents issued by the

Commission, such as orders, notices, and rulemakings.

In addition, the Commission now offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to <http://www.ferc.gov/esubscribenow.htm>.

Finally, public meetings or site visits will be posted on the Commission's calendar located at <http://www.ferc.gov/EventCalendar/EventsList.aspx> along with other related information.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011-535 Filed 1-12-11; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP10-486-000]

Colorado Interstate Gas Company; Notice of Availability of the Environmental Assessment for the Proposed Spruce Hill Air Blending Project

January 5, 2011.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared an environmental assessment (EA) for the Spruce Hill Air Blending Project proposed by Colorado Interstate Gas Company (CIG) in the above-referenced docket. CIG requests authorization to construct, operate, and maintain a new air blending compressor station in Douglas County, Colorado. This facility would allow CIG to meet the gas quality specifications for its existing Line No. 9A system.

The EA assesses the potential environmental effects of the construction and operation of the Spruce Hill Air Blending Project in accordance with the requirements of the National Environmental Policy Act of 1969. The FERC staff concludes that approval of the proposed project, with appropriate mitigating measures, would not constitute a major Federal action significantly affecting the quality of the human environment.

The proposed Spruce Hill Air Blending Project includes the following facilities:

- An air blending station comprised of three air compressors ranging from 215 to 500 horsepower;
- A back-pressure regulator;
- Air blending controls and instrumentation;
- A gas heater;
- Auxiliary facilities and piping;
- Modifications to the existing Spruce Hill Meter Station; and
- A FERC non-jurisdictional electric utility connection.

The EA has been placed in the public files of the FERC and is available for public viewing on the FERC's Web site at <http://www.ferc.gov> using the eLibrary link. A limited number of copies of the EA are available for distribution and public inspection at: Federal Energy Regulatory Commission, Public Reference Room, 888 First Street, NE., Room 2A, Washington, DC 20426. (202) 502-8371.

Copies of the EA have been mailed to Federal, State, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; potentially affected landowners and other interested individuals and groups; newspapers and libraries in the project area; and parties to this proceeding.

Any person wishing to comment on the EA may do so. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that your comments are properly recorded and considered prior to a Commission decision on the proposal, it is important that the FERC receives your comments in Washington, DC on or before February 4, 2011.

For your convenience, there are three methods you can use to submit your comments to the Commission. In all instances, please reference the project docket number (CP10-486-000) with your submission. The Commission encourages electronic filing of comments and has dedicated eFiling expert staff available to assist you at (202) 502-8258 or efiling@ferc.gov.

(1) You may file your comments electronically by using the *eComment* feature, which is located on the Commission's Web site at <http://www.ferc.gov> under the link to *Documents and Filings*. An eComment is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You may file your comments electronically by using the *eFiling* feature, which is located on the Commission's Web site at <http://www.ferc.gov>

www.ferc.gov under the link to *Documents and Filings*. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on “eRegister.” You will be asked to select the type of filing you are making. A comment on a particular project is considered a “Comment on a Filing”; or

(3) You may file a paper copy of your comments at the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Room 1A, Washington, DC 20426.

Although your comments will be considered by the Commission, simply filing comments will not serve to make the commenter a party to the proceeding. Any person seeking to become a party to the proceeding must file a motion to intervene pursuant to Rule 214 of the Commission’s Rules of Practice and Procedures (18 CFR 385.214).¹ Only intervenors have the right to seek rehearing of the Commission’s decision.

Affected landowners and parties with environmental concerns may be granted intervenor status upon showing good cause by stating that they have a clear and direct interest in this proceeding which would not be adequately represented by any other parties. You do not need intervenor status to have your comments considered.

Additional information about the project is available from the Commission’s Office of External Affairs, at (866) 208–FERC or on the FERC Web site (<http://www.ferc.gov>) using the eLibrary link. Click on the eLibrary link, click on “General Search” and enter the docket number excluding the last three digits in the Docket Number field (*i.e.*, CP10–486). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at FercOnlineSupport@ferc.gov or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document

summaries, and direct links to the documents. Go to <http://www.ferc.gov/esubscribenow.htm>.

Kimberly D. Bose,
Secretary.

[FR Doc. 2011–534 Filed 1–12–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PR11–78–000]

Washington 10 Storage Corporation; Notice of Filing

January 5, 2011.

Take notice that on January 4, 2011, Washington 10 Storage Corporation filed a Statement of Operating Conditions to revise certain provisions of its Firm and Interruptible Parking and Loaning Services in addition to other revisions as more fully described in the filing.

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 Friday, January 14, 2011.

Kimberly D. Bose,
Secretary.

[FR Doc. 2011–539 Filed 1–12–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER11–2331–000]

Balance Power Systems, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

December 13, 2010.

This is a supplemental notice in the above-referenced proceeding of Balance Power Systems, 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 January 3, 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

¹ Interventions may also be filed electronically via the Internet in lieu of paper. See the previous discussion on filing comments electronically.

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 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.

Kimberly D. Bose,
Secretary.

[FR Doc. 2011-526 Filed 1-12-11; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD11-6-000]

Priorities for Addressing Risks to the Reliability of the Bulk-Power System; Notice of Technical Conference

December 16, 2010.

Take notice that the Federal Energy Regulatory Commission will hold a Technical Conference on Tuesday, February 8, 2011 from 10 a.m. to 5 p.m. This Commissioner-led conference will be held in the Commission Meeting Room at the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. The conference will be open for the public to attend and advance registration is not required. The purpose of the conference is to discuss policy issues related to reliability of the Bulk-Power System, including priorities for addressing risks to reliability.

The agenda for this conference will be issued at a later date. Information on this event will be posted on the Calendar of Events on the Commission's Web site, <http://www.ferc.gov>, prior to the event. The conference will be Webcast. Anyone with Internet access who desires to listen to this event can do so by navigating to <http://www.ferc.gov>'s Calendar of Events and locating this event in the Calendar. The event will contain a link to the webcast. The Capitol Connection provides technical support for webcasts and offers the option of listening to the meeting via phone-bridge for a fee. If you have any questions, visit <http://www.CapitolConnection.org> or call 703-993-3100.

www.CapitolConnection.org or call 703-993-3100.

Commission conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations, please send an e-mail to accessibility@ferc.gov or call toll free 1-866-208-3372 (voice) or 202-208-1659 (TTY), or send a FAX to 202-208-2106 with the required accommodations.

For more information about this conference, please contact: Sarah McKinley, Office of External Affairs, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502-8368, sarah.mckinley@ferc.gov.

Kimberly D. Bose,
Secretary.

[FR Doc. 2011-572 Filed 1-12-11; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Staff Attendance at Southwest Power Pool Markets and Operation Policy Committee and Strategic Planning Committee Meetings

January 5, 2011.

The Federal Energy Regulatory Commission hereby gives notice that members of its staff may attend the meetings of the Southwest Power Pool, Inc. (SPP) Markets and Operations Policy Committee (MOPC) and the Strategic Planning Committee (SPC), as noted below. Their attendance is part of the Commission's ongoing outreach efforts.

SPP MOPC

January 11, 2011 (1 p.m.-5 p.m.),
January 12, 2011 (8 a.m.-3 p.m.),
Doubletree Hotel, 300 Canal Street,
New Orleans, LA 70130. 504-581-1300.

SPP SPC

January 13, 2011 (8 a.m.-3 p.m.),
Doubletree Hotel, 300 Canal Street,
New Orleans, LA 70130. 504-581-1300.

The discussions may address matters at issue in the following proceedings:
Docket No. ER06-451, *Southwest Power Pool, Inc.*
Docket No. ER08-1419, *Southwest Power Pool, Inc.*
Docket No. ER09-35, *Tallgrass Transmission LLC.*
Docket No. ER09-36, *Prairie Wind Transmission LLC.*

Docket No. ER09-659, *Southwest Power Pool, Inc.*
Docket No. ER09-1050, *Southwest Power Pool, Inc.*
Docket No. OA08-61, *Southwest Power Pool, Inc.*
Docket No. OA08-104, *Southwest Power Pool, Inc.*
Docket No. ER10-659, *Southwest Power Pool, Inc.*
Docket No. ER10-696, *Southwest Power Pool, Inc.*
Docket No. ER10-941, *Southwest Power Pool, Inc.*
Docket No. ER10-1069, *Southwest Power Pool, Inc.*
Docket No. ER10-1254, *Southwest Power Pool, Inc.*
Docket No. ER10-1269, *Southwest Power Pool, Inc.*
Docket No. ER10-1697, *Southwest Power Pool, Inc.*
Docket No. ER10-1960, *Southwest Power Pool, Inc.*
Docket No. ER10-2244, *Southwest Power Pool, Inc.*
Docket No. ER11-13, *Southwest Power Pool, Inc.*
Docket No. ER11-2071, *Southwest Power Pool, Inc.*
Docket No. ER11-2101, *Southwest Power Pool, Inc.*
Docket No. ER11-2103, *Southwest Power Pool, Inc.*
Docket No. ER11-2188, *Southwest Power Pool, Inc.*
Docket No. ER11-2190, *Southwest Power Pool, Inc.*
Docket No. ER11-2194, *Southwest Power Pool, Inc.*
Docket No. ER11-2198, *Southwest Power Pool, Inc.*
Docket No. ER11-2103, *Southwest Power Pool, Inc.*
Docket No. ER11-2188, *Southwest Power Pool, Inc.*
Docket No. ER11-2190, *Southwest Power Pool, Inc.*
Docket No. ER11-2194, *Southwest Power Pool, Inc.*
Docket No. ER11-2198, *Southwest Power Pool, Inc.*
Docket No. ER11-2205, *Southwest Power Pool, Inc.*
Docket No. ER11-2220, *Southwest Power Pool, Inc.*
Docket No. ER11-2291, *Southwest Power Pool, Inc.*
Docket No. ER11-2303, *Southwest Power Pool, Inc.*
Docket No. ER11-2308, *Southwest Power Pool, Inc.*
Docket No. ER11-2309, *Southwest Power Pool, Inc.*
Docket No. ER11-2315, *Southwest Power Pool, Inc.*
Docket No. ER11-2317, *Southwest Power Pool, Inc.*
Docket No. ER11-2345, *Southwest Power Pool, Inc.*

Docket No. ER11-2385, *Southwest Power Pool, Inc.*

Docket No. ER11-2401, *Southwest Power Pool, Inc.*

Docket No. ER11-2415, *Southwest Power Pool, Inc.*

Docket No. ER11-2425, *Southwest Power Pool, Inc.*

Docket No. ER11-2428, *Southwest Power Pool, Inc.*

Docket No. ER11-2525, *Southwest Power Pool, Inc.*

Docket No. ER11-2528, *Southwest Power Pool, Inc.*

Docket No. ER11-2619, *Southwest Power Pool, Inc.*

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.

Kimberly D. Bose,
Secretary.

[FR Doc. 2011-541 Filed 1-12-11; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13863-000]

Mount Storm Hydro, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

January 6, 2011.

On October 14, 2010, Mount Storm Hydro, LLC filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Mount Storm Pumped Storage Project to be located near Maysville, in Grant County, West Virginia. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The project would consist of two artificial, lined reservoirs created by the construction of embankments. Two options for the upper reservoir site are proposed. The Option A upper reservoir would be joined with the lower reservoir by approximately 7,600 feet of conduit. Maximum hydraulic head would be 1,590 feet. Equipment would

consist of one 200-megawatt (MW), one 100-MW, and one 50-MW reversible pump-turbines, totaling 350 MW of generating capacity, with up to 100 MW of additional pumping capacity, for a total of 450 MW pumping capacity. Annual energy production is projected to be approximately 1,073,100 megawatt-hours (MWh).

The Option B upper reservoir would be joined with the lower reservoir by approximately 13,870 feet of conduit. Maximum hydraulic head would be 1,470 feet. Equipment would consist of one 150-MW, one 100-MW, and one 50-MW reversible pump-turbines, totaling 300 MW of generating capacity, with up to 100 MW of additional pumping capacity, for a total of 400 MW pumping capacity. Annual energy production is projected to be approximately 919,800 MWh.

For either option, the project would interconnect with either of three possible 500-kilovolt (kV) lines on the Allegheny Power system via a new, single-circuit 230-kV line about 4 miles in length. These 500-kV lines include the Greenland Gap-Meadow Brook line, the Mt. Storm-Doubs line, and the planned Trans-Allegheny Interstate line.

Applicant Contact: Matthew Shapiro, CEO, Gridflex Energy, LLC, 1210 W. Franklin St., Ste. 2, Boise, ID 83702; phone: (904) 216-0254, e-mail: mshapiro@gridflexenergy.com.

FERC Contact: John Mudre (202) 502-8902 or john.mudre@ferc.gov.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

More information about this project, including a copy of the application, can be viewed or printed on the "eLibrary" link of the Commission's Web site at <http://www.ferc.gov/docs-filing/elibrary.asp>. Enter the docket number (P-13863-000) in the docket number field to access the document. For assistance, contact FERC Online Support at FERCOnlineSupport@ferc.gov; call toll-free at (866) 208-3676; or, for TTY, contact (202) 502-8659.

Kimberly D. Bose,
Secretary.

[FR Doc. 2011-545 Filed 1-12-11; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP11-55-000]

Gulf South Pipeline Company, LP; Notice of Request Under Blanket Authorization

January 5, 2011.

Take notice that on December 20, 2010, Gulf South Pipeline Company, LP (Gulf South), 9 Greenway Plaza, Suite 2800, Houston, Texas 77046, filed in Docket No. CP11-55-000, a prior notice request pursuant to sections 157.205 and 157.2216 of the Federal Energy Regulatory Commission's regulations under the Natural Gas Act (NGA) and Gulf South's blanket certificate for authorization to construct, operate, and maintain one new 8,180 horsepower (hp) compressor unit at the existing Hall Summit Compressor Station located in Bienville Parish, Louisiana. Specifically, Gulf South seeks to enhance service provided to customers from its Bistineau Storage Field (Bistineau) by increasing pressure of the gas flowing on its line Index 266-17 from Bistineau to allow it to enter Gulf South's high pressure 42-inch pipeline. Gulf South avers that the new unit will operate only as a pressure management unit and no new capacity will be created, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing may also be viewed on the Web at <http://www.ferc.gov> using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at FERCOnlineSupport@ferc.gov or call toll-free, (866) 208-3676 or TTY, (202) 502-8659.

Any questions regarding this Application should be directed to Michael E. McMahon, Senior Vice President and General Counsel, Boardwalk Pipeline Partners, LP, 9 Greenway Plaza, Suite 2800, Houston, Texas 77046, or call (713) 479-8252, or fax (713) 479-1745, or by e-mail mike.mcmahon@bwpmlp.com.

Any person may, within 60 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention. Any person filing to intervene or the Commission's staff may, pursuant to section 157.205 of the Commission's Regulations under the NGA (18 CFR 157.205) file a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commentary, will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests, and interventions via the internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (<http://www.ferc.gov>) under the "e-Filing" link.

Kimberly D. Bose,
Secretary.

[FR Doc. 2011-536 Filed 1-12-11; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP11-57-000]

Columbia Gas Transmission, LLC; Notice of Request Under Blanket Authorization

January 5, 2011.

Take notice that on December 22, 2010, Columbia Gas Transmission, LLC (Columbia) 5151 San Felipe, Suite 2500, Houston, Texas 77056, filed in Docket No. CP11-57-000, an application pursuant to sections 157.205 and 157.216(b) of the Commission's Regulations under the Natural Gas Act (NGA) as amended, to convert and abandon certain natural gas storage facilities in its Ripley storage field in Jackson County, West Virginia, under Columbia's blanket certificate issued in Docket No. CP83-76-000,¹ all as more fully set forth in the application which is on file with the Commission and open to the public for inspection.

Columbia proposes to convert Storage Wells 7300 and 7320 from active injection/withdrawal status to observation well status and abandon storage well pipelines Lines X-59W-7300, X-59W-7320, and X-59-F-2 along with their respective appurtenances. Columbia also proposes to abandon natural gas service to one landowner who would be directly affected by abandonment of the facilities herein. Columbia states that it would compensate the landowner's transition to an alternative source of energy.

Any questions concerning this application may be directed to Fredric J. George, Senior Counsel, Columbia Gas Transmission, LLC, P.O. Box 1273, Charleston, West Virginia 25325-1273 or via telephone at (304) 357-2359 or by facsimile (304) 357-3206.

This filing is available for review at the Commission or may be viewed on the Commission's Web site at <http://www.ferc.gov>, using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number filed to access the document. For assistance, please contact FERC Online Support at FERC OnlineSupport@ferc.gov or call toll-free at (866) 206-3676, or, for TTY, contact (202) 502-8659. Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link. The

Commission strongly encourages intervenors to file electronically.

Any person or the Commission's staff may, within 60 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the regulations under the NGA (18 CFR 157.205), a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the allowed time for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

Kimberly D. Bose,
Secretary.

[FR Doc. 2011-538 Filed 1-12-11; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-9252-6]

Notice of a Regional Project Waiver of Section 1605 (Buy American) of the American Recovery and Reinvestment Act of 2009 (ARRA) to the Hyannis Water System in Hyannis, MA

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The EPA is hereby granting a waiver of the Buy American requirements of ARRA Section 1605 under the authority of Section 1605(b)(2) [manufactured goods are not produced in the United States in sufficient and reasonably available quantities and of a satisfactory quality] to the Hyannis Water System in Hyannis, Massachusetts ("System") for the purchase of fourteen security cameras as part of a Security and Fire Alarm System Project. This is a project specific waiver and only applies to the use of the specified product for the ARRA project being proposed. Any other ARRA recipient that wishes to use the same product must apply for a separate waiver based on project specific circumstances. Based upon information submitted by the System and its consulting engineer, it has been determined that there are currently no domestically manufactured security cameras available to meet its proposed project specifications. The Regional

¹ 22 FERC ¶ 62,029 (1983).

Administrator is making this determination based on the review and recommendations of the Municipal Assistance Unit. The Assistant Administrator of the Office of Administration and Resources Management has concurred on this decision to make an exception to Section 1605 of ARRA. This action permits the purchase of fourteen security cameras by the System, as specified in its October 19, 2010 request.

DATES: *Effective Date:* January 5, 2011.

FOR FURTHER INFORMATION CONTACT: Katie Connors, Environmental Engineer, (617) 918-1658, or David Chin, Environmental Engineer, (617) 918-1764, Municipal Assistance Unit (CMU), Office of Ecosystem Protection (OEP), U.S. EPA, 5 Post Office Square, Suite 100, Boston, MA 02109-3912.

SUPPLEMENTARY INFORMATION: In accordance with ARRA Section 1605(c), the EPA hereby provides notice that it is granting a project waiver of the requirements of Section 1605(b)(2) of Public Law 111-5, Buy American requirements, to the System for the purchase of non-domestically manufactured security cameras to meet the System's specifications as part of their Security and Fire Alarm System Project.

Section 1605 of the ARRA requires that none of the appropriated funds may be used for the construction, alteration, maintenance, or repair of a public building or a public works project unless all of the iron, steel, and manufactured goods used in the project is produced in the United States, or unless a waiver is provided to the recipient by the head of the appropriate agency, here the EPA. A waiver may be provided if EPA determines that (1) applying these requirements would be inconsistent with the public interest; (2) iron, steel, and the relevant manufactured goods are not produced in the United States in sufficient and reasonably available quantities and of a satisfactory quality; or (3) inclusion of iron, steel, and the relevant manufactured goods produced in the United States will increase the cost of the overall project by more than 25 percent.

EPA has also evaluated the System's request to determine if its submission is considered late or if it could be considered timely, as per the OMB Guidance at 2 CFR 176.120. EPA will generally regard waiver requests with respect to components that were specified in the bid solicitation or in a general/primary construction contract as "late" if submitted after the contract

date. However, EPA could also determine that a request be evaluated as timely, though made after the date that the contract was signed, if the need for a waiver was not reasonably foreseeable. If the need for a waiver is reasonably foreseeable, then EPA could still apply discretion in these late cases as per the OMB Guidance, which says "the award official may deny the request." For those waiver requests that do not have a reasonably unforeseeable basis for lateness, but for which the waiver basis is valid and there is no apparent gain by the ARRA recipient or loss on behalf of the government, then EPA will still consider granting a waiver.

In this case, there are no U.S. manufacturers that meet the System's project specifications for these security cameras. The waiver request was submitted after the contract date during the shop drawing phase. An extensive search was conducted by the recipient for a domestic security camera which would meet the project specifications but none were available at the time of the request. Although it was known that the security cameras would be needed for this project, it was the last contract for the project and was not looked at until much later in the construction timeline. There is no indication that the System failed to request a waiver in order to avoid the requirements of the ARRA, particularly since there are no domestically manufactured products available that meet the project specifications. EPA will consider the System's waiver request a foreseeable late request, as though it had been timely made since there is no gain by the System and no loss by the government due to the late request.

The System is requesting a waiver from the Buy American provision of ARRA for fourteen Panasonic Super Dynamic III PTZ color CCD security cameras manufactured by the Panasonic Corporation. The security cameras are scheduled for installation by early December 2010. The technical specifications indicate that the security cameras should be IP cameras with a 1/4-inch progressive scan charge-coupled device (CCD) imager with 380,000 (768 × 494) pixels resolution. Additionally, the specifications include that the cameras should have digital signal processing, 0.7 lux sensitivity in color mode, both standard and fast shutter speeds, image processing of both long and short charges, image hold capability, auto back light compensation, automatic tracing white balance adjustment for day and night, built-in digital motion-detector, performance in extreme low-light conditions, scene-change detection with

an alarm, shutter adjustable from 1/60 to 1/10,000 second, eight privacy zones, focal length of 3.79 to 83.4 mm, continuous zoom of 10X for a total magnification of 220X, and aperture of f/1.6 at wide angle and f/3.0 at telephoto. The detailed technical specifications were written as such in order to ensure that the security cameras installed as part of the project would be able to utilize advanced programming technology. The security cameras are required not only to be configured with the alarm system, but to transfer images through the facility's current computer system.

The System has researched 36 foreign and domestic manufacturers of security cameras and has determined that domestic manufacturers are not able to manufacture a camera that would meet the technical specifications. The System has proposed the Panasonic Super Dynamic III PTZ color CCD security camera because it meets all the technical specifications.

An evaluation of all of the submitted documentation by EPA's technical review team supports and confirms the System's claim that there are currently no domestic manufacturers that can provide a security camera that meets all the project specifications. An independent review of the submitted documentation by EPA's national contractor found four possible domestic manufacturers. However, none of the manufacturers contacted currently provides a product that would meet all the project specifications. The domestic products in general give less resolution, have fewer functions, and are not as instantly Internet-accessible. In addition, the evaluation of the supporting documentation demonstrated that foreign manufactured security cameras are available and will be able to meet the proposed specifications.

The April 28, 2009 EPA HQ Memorandum, "Implementation of Buy American provisions of Public Law 111-5, the 'American Recovery and Reinvestment Act of 2009'" ("Memorandum"), defines *reasonably available quantity* as "the quantity of iron, steel, or relevant manufactured good is available or will be available at the time needed and place needed, and in the proper form or specification as specified in the project plans and design." The same Memorandum defines "satisfactory quality" as "the quality of steel, iron or manufactured good specified in the project plans and designs."

The purpose of the ARRA is to stimulate economic recovery by funding current infrastructure construction, not

to delay or require the substantial redesign of projects that are “shovel ready”, such as this project at the Hyannis Water System. The implementation of the ARRA Buy American requirements in this case could result in additional cost for this project and unreasonable delay in its completion. Such delay would also directly conflict with a fundamental economic purpose of ARRA, which is to create or retain jobs.

The Municipal Assistance Unit (CMU) has reviewed this waiver request and has determined that the supporting documentation provided by the System establishes both a proper basis to specify a particular manufactured good, and that the domestically manufactured good that is currently available does not meet the specifications for the proposed project. The information provided is sufficient to meet the following criteria listed under Section 1605(b) of the ARRA and in the April 28, 2009 Memorandum: Iron, steel, and the manufactured goods are not produced in the United States in sufficient and reasonably available quantities and of a satisfactory quality.

The March 31, 2009 Delegation of Authority Memorandum provided Regional Administrators with the temporary authority to issue exceptions to Section 1605 of the ARRA within the geographic boundaries of their respective regions and with respect to requests by individual grant recipients.

Having established both a proper basis to specify the particular good required for this project and that this manufactured good was not available from a producer in the United States, the Hyannis Water System is hereby granted a waiver from the Buy American requirements of Section 1605(a) of Public Law 111–5. This waiver permits use of ARRA funds for the purchase of fourteen security cameras documented in System’s waiver request submittal dated October 19, 2010. This supplementary information constitutes the detailed written justification required by Section 1605(c) for waivers based on a finding under subsection (b).

Authority: Pub. L. 111–5, section 1605.

Dated: January 5, 2011.

Ira W. Leighton,

Acting Regional Administrator, EPA Region 1—New England.

[FR Doc. 2011–636 Filed 1–12–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9252–2]

Science Advisory Board Staff Office; Request for Nominations of Experts to Augment the SAB Scientific and Technological Achievement Awards Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The EPA Science Advisory Board (SAB) Staff Office is requesting public nominations for scientists and engineers to augment the SAB Scientific and Technological Achievement Awards (STAA) Committee.

DATES: Nominations should be submitted by February 3, 2011 per instructions below.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing further information regarding this Notice and Request for Nominations may contact Mr. Edward Hanlon, Designated Federal Officer (DFO), SAB Staff Office, by telephone/voice mail at (202) 564–2134; by fax at (202) 565–2098 or via email at hanlon.edward@epa.gov. General information concerning the EPA Science Advisory Board can be found at the EPA SAB Web site at <http://www.epa.gov/sab>.

SUPPLEMENTARY INFORMATION:

Background: The SAB (42 U.S.C. 4365) is a chartered Federal Advisory Committee that provides independent scientific and technical peer review, advice, consultation, and recommendations to the EPA Administrator on the technical basis for EPA actions. As a Federal Advisory Committee, the SAB conducts business in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2) and related regulations. The SAB will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

EPA’s STAA Program was established in 1980 to recognize Agency scientists and engineers who published their work in the peer-reviewed literature. The STAA Program is an annual Agency-wide competition to promote and recognize scientific and technological achievements by EPA employees. The STAA program is administered and managed by EPA’s Office of Research and Development (ORD). ORD requested SAB to review scientific publications nominated by EPA managers and make recommendations to the Administrator for STAA awards.

A STAA Committee was formed in June 2009 to provide recommendations to the Administrator regarding the nominated 2009, 2010 and 2011 STAA awards. The STAA Committee was augmented with additional experts to make recommendations for the 2010 STAA awards (**Federal Register** Notice Volume 75, Number 44, Pages 10481–10482, published on March 8, 2010). There is a need to supplement the STAA Committee with additional expertise to review the 2011 STAA nominations.

Request for Nominations: The SAB Staff Office is seeking nominations of nationally and internationally recognized scientists and engineers having experience and expertise in environmental and human health sciences, ecology, risk assessment, environmental engineering, environmental lifecycle or systems analysis, and in environmental sustainability fields such as in green chemistry, green technologies, and green building design.

Process and Deadline for Submitting Nominations: Any interested person or organization may nominate qualified individuals in the areas of expertise described above for possible service on this expert *ad hoc* Panel. Nominations should be submitted in electronic format (which is preferred over hard copy) following the instructions for “Nominating Experts to Advisory Panels and Ad Hoc Committees Being Formed” provided on the SAB Web site. The instructions can be accessed through the “Nomination of Experts” link on the blue navigational bar on the SAB Web site at <http://www.epa.gov/sab>. To receive full consideration, nominations should include all of the information requested.

EPA’s SAB Staff Office requests: contact information about the person making the nomination; contact information about the nominee; the disciplinary and specific areas of expertise of the nominee; the nominee’s curriculum vita; sources of recent grant and/or contract support; and a biographical sketch of the nominee indicating current position, educational background, research activities, and recent service on other national advisory committees or national professional organizations.

Persons having questions about the nomination procedures, or who are unable to submit nominations through the SAB Web site, should contact Mr. Edward Hanlon, DFO, as indicated above in this notice. Nominations should be submitted in time to arrive no later than February 3, 2011. EPA values and welcomes diversity. In an effort to

obtain nominations of diverse candidates, EPA encourages nominations of women and men of all racial and ethnic groups.

The EPA SAB Staff Office will acknowledge receipt of nominations. The names and biosketches of qualified nominees identified by respondents to this **Federal Register** notice, and additional experts identified by the SAB Staff, will be posted in a List of Candidates on the SAB Web site at <http://www.epa.gov/sab>. Public comments on this List of Candidates will be accepted for 21 days. The public will be requested to provide relevant information or other documentation on nominees that the SAB Staff Office should consider in evaluating candidates.

For the EPA SAB Staff Office, a balanced subcommittee or review panel includes candidates who possess the necessary domains of knowledge, the relevant scientific perspectives (which, among other factors, can be influenced by work history and affiliation), and the collective breadth of experience to adequately address the charge. In augmenting the SAB STAA Committee, the SAB Staff Office will consider public comments on the List of candidates, information provided by the candidates themselves, and background information independently gathered by the SAB Staff Office. Selection criteria to be used for Panel membership include: (a) Scientific and/or technical expertise, knowledge, and experience (primary factors); (b) availability and willingness to serve; (c) absence of financial conflicts of interest; (d) absence of an appearance of a lack of impartiality; and (e) skills working in committees, subcommittees and advisory panels; and, for the Panel as a whole, (f) diversity of expertise and viewpoints.

The SAB Staff Office's evaluation of an absence of financial conflicts of interest will include a review of the "Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at the U.S. Environmental Protection Agency" (EPA Form 3110-48). This confidential form allows Government officials to determine whether there is a statutory conflict between that person's public responsibilities (which includes membership on an EPA Federal advisory committee) and private interests and activities, or the appearance of a lack of impartiality, as defined by Federal regulation. The form may be viewed and downloaded from the following URL address at <http://>

www.epa.gov/sab/pdf/epaform3110-48.pdf.

The approved policy under which the EPA SAB Office selects subcommittees and review panels is described in the following document: *Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board* (EPA-SAB-EC-02-010), which is posted on the SAB Web site at <http://www.epa.gov/sab/pdf/ec02010.pdf>.

Dated: January 6, 2011.

Vanessa T. Vu,

Director, EPA Science Advisory Board Staff Office.

[FR Doc. 2011-641 Filed 1-12-11; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-9252-5]

Tentative Approval and Solicitation of Request for a Public Hearing for Public Water System Supervision Program Revision for New Jersey

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Notice is hereby given that the State of New Jersey is revising its approved Public Water System Supervision Program to adopt EPA's National Primary Drinking Water Regulations for four major rules and six technical corrections. The EPA has determined that these revisions are no less stringent than the corresponding Federal regulations. Therefore, the EPA intends to approve these program revisions. All interested parties may request a public hearing.

DATES: This determination to approve New Jersey's primacy program revision application is made pursuant to 40 CFR 142.12(d)(3). It shall become final and effective unless (1) a timely and appropriate request for a public hearing is received or (2) the Regional Administrator elects to hold a public hearing on his own motion. Any interested person, other than Federal Agencies, may request a public hearing. A request for a public hearing must be submitted to the Regional Administrator at the address shown below February 14, 2011. If a substantial request for a public hearing is made within the requested thirty day time frame, a public hearing will be held and a notice will be given in the **Federal Register** and a newspaper of general circulation. Frivolous or insubstantial requests for a hearing may be denied by the Regional

Administrator. If no timely and appropriate request for a hearing is received and the Regional Administrator does not elect to hold a hearing on his own motion, this determination shall become final and effective February 14, 2011.

ADDRESSES: Any request for a public hearing shall include the following information: (1) Name, address and telephone number of the individual, organization or other entity requesting a hearing; (2) a brief statement of the requesting person's interest in the Regional Administrator's determination and a brief statement on information that the requesting person intends to submit at such hearing; (3) the signature of the individual making the requests or, if the request is made on behalf of an organization or other entity, the signature of a responsible official of the organization or other entity. Requests for Public Hearing shall be addressed to: Regional Administrator, U.S.

Environmental Protection Agency—Region 2, 290 Broadway, New York, New York 10007-1866.

All documents relating to this determination are available for inspection between the hours of 9 a.m. and 4:30 p.m., Monday through Friday, at the following offices:

New Jersey Department of Environmental Protection, P.O. Box CN-426, 401 East State Street, Floor 3, Trenton, New Jersey 08625-0426; U.S. Environmental Protection Agency—Region 2, 24th Floor Drinking Water Ground Water Protection Section, 290 Broadway, New York, New York 10007-1866.

FOR FURTHER INFORMATION CONTACT: Michael J. Lowy, Drinking Water Ground Water Protection Section, U.S. Environmental Protection Agency—Region 2, (212) 637-3830.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the United States Environmental Protection Agency (EPA) has determined to approve an application by the State of New Jersey Department of Environmental Protection to revise its Public Water Supply Supervision Primacy Program to incorporate regulations no less stringent than the EPA's National Primary Drinking Water Regulations (NPDWR) for National Primary Drinking Water Regulations: Stage 2 Disinfectants and Disinfection Byproducts Rule; Final Rule, promulgated by EPA January 4, 2006 (71 FR 388), with the following Technical Corrections promulgated by EPA January 27, 2006 (71 FR 4644), June 29, 2006 (71 FR 37168), and June 29, 2009 (74 FR 30953), National Primary

Drinking Water Regulations: Long Term 2 Enhanced Surface Water Treatment Rule; Final Rule, promulgated by EPA January 5, 2006 (71 FR 654), with the following Technical Corrections promulgated by EPA January 30, 2006 (71 FR 4968) and February 6, 2006 (71 FR 6136), National Primary Drinking Water Regulations: Ground Water Rule, Final Rule, promulgated by EPA November 8, 2006 (71 FR 67427), and the following Technical Correction promulgated by EPA November 21, 2006 (71 FR 67427), and National Primary Drinking Water Regulations for Lead and Copper: Short-Term Revisions and Clarifications; Final Rule, promulgated by EPA October 10, 2007 (72 FR 5782).

The application demonstrates that New Jersey has adopted drinking water regulations which satisfy the NPDWRs for the above. The USEPA has determined that New Jersey's regulations are no less stringent than the corresponding Federal Regulations and that New Jersey continues to meet all requirements for primary enforcement responsibility as specified in 40 CFR 142.10.

Authority: (Section 1413 of the Safe Drinking Water Act, as amended, 40 U.S.C. 300g-2, and 40 CFR 142.10, 142.12(d) and 142.13)

Dated: December 14, 2010.

Judith A. Enck,

Regional Administrator, Region 2.

[FR Doc. 2011-640 Filed 1-12-11; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

December 27, 2010.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, 44 U.S.C. 3501-3520. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to

minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and (e) ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before March 14, 2011. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to the Federal Communications Commission. To submit your PRA comments by e-mail send them to: PRA@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information, contact Judith B. Herman at 202-418-0214 or via the Internet at Judith-B.Herman@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060-0767.

Title: Sections 1.2110, 1.2111, and 1.2112, Auction Forms and License Transfer Disclosure Requirements.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit, not-for-profit institutions, and state, local or tribal government.

Number of Respondents: 22,000 respondents; 22,000 responses.

Estimated Time per Response: 17.6 hours (average).

Frequency of Response: On occasion reporting requirement, recordkeeping requirement and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. sections 154(i) and 309(j).

Total Annual Burden: 390,750 hours.

Total Annual Cost: \$23,966,750.

Privacy Act Impact Assessment: Yes.

Nature and Extent of Confidentiality:

In general, there is no need for confidentiality. Applicants may seek confidential treatment of their information or material under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: The Commission will submit this expiring information collection to the Office of Management and Budget (OMB) after this 60 day comment period in order to obtain the full three year clearance from them. The Commission is requesting OMB approval for an extension (no change in the reporting, recordkeeping and/or third party disclosure requirements). There is no change in the Commission's burden estimates.

Disclosures regarding ownership and gross revenues information and calculations are designed to ensure that applicants are qualified to participate in Commission auctions and to ensure that license winners are entitled to receive small business preferences. Disclosures regarding joint bidding agreements and the associated certification are designed to prevent collusion. Disclosure of information regarding license transfers and partitioning is designed to deter unjust enrichment. Finally, records retention and maintenance by small business licensees is designed to prevent unjust enrichment and facilitate enforcement efforts, if necessary.

OMB Control Number: 3060-0262.

Title: Section 90.179, Shared Use of Radio Stations.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit, not-for-profit institutions, and State, local or tribal government.

Number of Respondents: 42,000 respondents; 42,000 responses.

Estimated Time per Response: 15 minutes for records maintenance; and 45 minutes for preparation of sharing agreements; 1 hour total.

Frequency of Response: On occasion reporting requirement, recordkeeping requirement and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. sections 154(i), 161, 303(g), 303(r), and 332(c)(7).

Total Annual Burden: 42,000 hours.

Total Annual Cost: N/A.

Privacy Act Impact Assessment: N/A.

Nature and Extent of Confidentiality: There is no need for confidentiality.

Needs and Uses: The Commission will submit this expiring information collection to the Office of Management and Budget (OMB) after this 60 day comment period in order to obtain the full three year clearance from them. The Commission is requesting OMB approval for an extension (no change in the reporting, recordkeeping and/or third party disclosure requirements).

There is no change in the Commission's burden estimates.

The Commission was directed by the United States Congress, in the Balanced Budget act of 1997, to dedicate 2.4 MHz of electromagnetic spectrum in the 746–806 MHz band for public safety services. Section 90.179 requires that Part 90 licensees that share use of their private land mobile radio facility on a non-profit, cost-sharing basis keep a written agreement as part of the station records. Regardless of the method of sharing, an up-to-date list of persons who are sharing the station and the basis of their eligibility under Part 90 must be maintained. The requirement is necessary to identify users of the system should interference problems develop. This information is used by the Commission to investigate interference complaints and resolve interference and operational complaints that may arise among the users.

OMB Control Number: 3060–0774.

Title: Parts 36, and 54, Universal Service Reporting, Disclosure and Records Retention Requirements.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit, not-for-profit institutions, and state, local or tribal government.

Number of Respondents: 7,060,500 respondents; 7,631,034 responses.

Estimated Time per Response: .084 hours to 125 hours.

Frequency of Response: On occasion, annual, quarterly and five year reporting requirements, recordkeeping requirements and third party disclosure requirements.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. sections 151–154, 201–205, 214, 218–220, 254, 303(r), 403, and 410.

Total Annual Burden: 1,279,455 hours.

Total Annual Cost: N/A.

Privacy Act Impact Assessment: N/A.

Nature and Extent of Confidentiality: The Commission is not requesting that respondents submit confidential information to the Commission. If the Commission requests applicants to submit information that the respondents believe is confidential, respondents may request confidential treatment of such information under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: The Commission will submit this expiring information collection to the Office of Management and Budget (OMB) after this 60 day comment period in order to obtain the

three year clearance from them. The Commission is requesting OMB approval for an extension (no change in the reporting, recordkeeping and/or third party disclosure requirements). There is no change in the Commission's previous burden estimates.

The Telecommunications Act of 1996 (1996 Act) directed the Commission to initiate a rulemaking to reform the system of universal service so that universal service is preserved and advanced as markets move toward competition. To fulfill that mandate, on March 9, 1996, the Commission adopted a *Notice of Proposed Rulemaking (NPRM)* in CC Docket No. 96–45 to implement the congressional directives set out in section 254 of the Communications Act of 1934, as amended by the 1996 Act. Pursuant to section 254(a)(1), the *NPRM* also referred numerous issues related to universal service to a Federal-State Joint Board for a recommended decision.

On November 8, 1996, the Joint Board released a Recommended Decision in which it made recommendations to assist and counsel the Commission in the creation of an effective universal service support mechanism that would ensure that the goals of affordable, quality service and access to advanced services are met by means that enhance competition.

On November 18, 1996, the Commission's Common Carrier Bureau (now the Wireline Competition Bureau) released a Public Notice (DA 96–1891) seeking public comment on the issues addressed and recommendations made by the Joint Board in the Recommended Decision. In a *Report and Order* issued in CC Docket No. 96–45, released on May 8, 1997, and other proceedings, the Commission adopted rules that were designed to implement the universal service provisions of section 254.

On August 29, 2007, the Commission released the *Report and Order*, 2007 Comprehensive Review of the Universal Service Fund Management, Administration and Oversight, WC Docket Nos. 05–192, 02–60, 03–109, and CC Docket Nos. 96–45, 02–6, 97–21, FCC 07–150. In this *Order*, the Commission took several further steps to safeguard the universal service fund from waste, fraud and abuse, including imposing document retention rules on all universal service programs and program contributors.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2011–554 Filed 1–12–11; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

December 29, 2010.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, 44 U.S.C. 3501–3520. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and (e) ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before March 14, 2011. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to the Federal Communications Commission. To submit your PRA comments by e-mail send them to: PRA@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information, contact Judith B. Herman at 202–418–0214 or via the Internet at Judith-B.Herman@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0850.
Title: Quick Form Application for Authorization in the Ship, Aircraft, Amateur, Restricted and Commercial

Operator, and General Mobile Radio Services.

Form No.: FCC Form 605.

Type of Review: Revision of a currently approved collection.

Respondents: Individuals or households, business or other for-profit, not-for-profit institutions, and state, local or tribal government.

Number of Respondents: 130,000 respondents; 130,000 responses.

Estimated Time per Response: .264 minutes (.44 hours).

Frequency of Response: On occasion and five and ten-year reporting requirements, recordkeeping requirement and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. There is no statutory authority for this information collection.

Total Annual Burden: 57,200 hours.

Total Annual Cost: \$2,676,700.

Privacy Act Impact Assessment: Yes. Records may include information about individuals or households, e.g., personally identifiable information or PII, and the use(s) and disclosure of this information is governed by the requirements of a system of records notice (SORN), FCC/WTB-1, "Wireless Services Licensing Records." There are no additional impacts under the Privacy Act.

Nature and Extent of Confidentiality: To protect the privacy of its applicants, the FCC will redact the telephone number(s) of the applicants and the birth date of the Commercial Radio Operator applicants.

Needs and Uses: The Commission will submit this expiring information collection to the Office of Management and Budget (OMB) after this 60 day comment period in order to obtain the full three year clearance from them. The Commission is requesting OMB approval for revision of this information collection. The Commission is revising FCC 605 Schedule D to rearrange the layout of Question 2 for Vanity Call Sign Change; to further clarify the filing instructions; and to define the term "in-law". The Commission is requesting an adjustment reduction in the number of respondents from 175,000 to 130,000. There is an increase in annual cost to the respondents due to an increase in the average filing fee required to accompany applications. The cost increased by \$138,000.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2011-562 Filed 1-12-11; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Submitted for Review and Approval to the Office of Management and Budget (OMB), Comments Requested

December 23, 2010.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, 44 U.S.C. 3501-3520. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and (e) ways to further reduce the information collection burden for small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid OMB control number.

DATES: Submit written Paperwork Reduction Act (PRA) comments on or before February 14, 2011. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Submit all PRA comments to Nicholas A. Fraser, Office of Management and Budget, via fax at 202-395-5167 or the Internet at Nicholas.A.Fraser@omb.eop.gov; and to Judith-B.Herman@fcc.gov, Federal Communications Commission. Send your PRA comments by e-mail to PRA@fcc.gov. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page <http://reginfo.gov/public/do/PRAMain>, (2) look for the section of the

Web page called "Currently Under Review", (3) click on the downward-pointing arrow in the "Select Agency" box below the "Currently Under Review" heading, (4) select "Federal Communications Commission" from the list of agencies presented in the "Select Agency" box, (5) click the "Submit" button to the right of the "Select Agency" box, and (6) when the list of FCC ICRs currently under review appears, look for the title of this ICR (or its OMB Control Number, if there is one) and then click on the ICR Reference Number to view detailed information about this ICR.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Judith B. Herman at 202-418-0214 or via the Internet at Judith-B.Herman@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060-0800.

Title: FCC Application for Assignment of Authorization or Transfer of Control: Wireless Telecommunications Bureau and Public Safety and Homeland Security Bureau.

Form No.: FCC Form 603.

Type of Review: Revision of a currently approved collection.

Respondents: Individuals or households, business or other for-profit, not-for-profit institutions and state, local or tribal government.

Number of Respondents: 2,447 respondents; 2,447 responses.

Estimated Time per Response: .5 hours-1.75 hours.

Frequency of Response: On occasion reporting requirement and recordkeeping requirement.

Obligation to Respond: Mandatory. Statutory authority for this information collection is contained in 47 U.S.C. sections 4(i), 154(i), 303(r) and 309(j).

Total Annual Burden: 36,846 hours.

Total Annual Cost: \$335,497.

Privacy Act Impact Assessment: Yes. Records may include information about individuals or households, e.g., personally identifiable information or PII, and the use(s) and disclosure of this information are governed by the requirements of a system of records notice or "SORN", FCC/WTB-1, "Wireless Services Licensing Records." There are no additional impacts under the Privacy Act.

Nature and Extent of Confidentiality: Respondents may request materials or information submitted to the Commission be withheld from public inspection under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: The Commission will submit this expiring information collection (IC) to the OMB as a revision

during this comment period to obtain the full three-year clearance from them. The Commission is reporting a 34,092 total annual hour decrease and a \$2,775,798 annual cost decrease. This adjustment is due to a 30,304 fewer responses since this was last submitted to OMB in 2008. The revision for which the Commission is seeking OMB approval is due to minor changes to the wording of FCC Form 603 data elements, adding a question inquiring if filing is the lead application on the Main Form, and changing the wording in the instructions. The FCC uses the information in FCC Form 603 to determine whether the applicant is legally, technically, and financially qualified to obtain a license. Without such information, the Commission cannot determine whether to issue the licenses to the applicants that provide telecommunications services to the public, and therefore, to fulfill its statutory responsibilities in accordance with the Communications Act of 1934, as amended. Information provided on this form will also be used to update the database and to provide for proper use of the frequency spectrum.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2011-557 Filed 1-12-11; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Submitted for Review and Approval to the Office of Management and Budget (OMB), Comments Requested

December 21, 2010.

SUMMARY: As part of its continuing effort to reduce paperwork burden and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3520), the Federal Communications Commission invites the general public and other Federal agencies to comment on the following information collection. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated

collection techniques or other forms of information technology; and (e) ways to further reduce the information collection burden for small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before February 14, 2011. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget, via fax at 202-395-5167 or the Internet at *Nicholas.A.Fraser@omb.eop.gov*; and to the Federal Communications Commission's PRA mailbox (*e-mail address: PRA@fcc.gov*). Include in the e-mail the OMB control number of the collection as shown in the "Supplementary Information" section below, or if there is no OMB control number, include the Title as shown in the "Supplementary Information" section. If you are unable to submit your comments by e-mail, contact the person listed below to make alternate arrangements.

FOR FURTHER INFORMATION CONTACT: For additional information, contact Judith B. Herman at 202-418-0214 or via the Internet at *Judith-b.herman@fcc.gov*.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060-0698.

Title: Sections 25.203(i) and 73.1030(a)(2), Radio Astronomy Coordination Zone in Puerto Rico.

Form No.: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit, not-for-profit institutions, and State, local or tribal government.

Number of Respondents: 200 respondents; 1,000 responses.

Estimated Time per Response: 5-40 minutes (.0833 hours to .667 hours).

Frequency of Response: On occasion reporting requirement and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. sections 154(i), 303(f), 303(r), and 309(j)(13).

Total Annual Burden: 142 hours.

Total Annual Cost: N/A.

Privacy Act Impact Assessment: N/A.

Nature and Extent of Confidentiality:

There is no need for confidentiality.

Needs and Uses: The Commission will submit this expiring information collection (IC) to the OMB during this comment period. The Commission is seeking OMB approval for a revision. The Commission is reporting a 114 hour program change decrease to the total burden hour estimate. The revision is because 47 CFR section 23.20 has been removed from this information collection since the last time OMB approved this information collection.

The Commission adopted and released a *Report and Order*, IB Docket No. 05-216, FCC 10-7, which eliminated Part 23 rules because there were no International Fixed Public Radiocommunications Services (IFPRS) licenses in operation.

The information collected is used to facilitate coordination between the Observatory and Commission-licensed services in the Commonwealth of Puerto Rico. Applicants for new or modified radio communication facilities within the Coordination Zone are required to submit technical information concerning the applicant's proposed services to enable the Observatory to determine the potential for interference with its operations. The Observatory will perform interference evaluations at no cost to the applicants. If potential interference problems are identified, applicants are required to make reasonable attempts to resolve or mitigate such problems in order to protect the Observatory.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2011-558 Filed 1-12-11; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Submitted for Review and Approval to the Office of Management and Budget (OMB), Comments Requested

January 6, 2011.

SUMMARY: As part of its continuing effort to reduce paperwork burden and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3520), the Federal Communications Commission invites the general public and other Federal agencies to comment on the following information collection. Comments are requested concerning:

(a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and (e) ways to further reduce the information collection burden for small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before February 14, 2011. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget, via fax at 202-395-5167 or the Internet at Nicholas_A_Fraser@omb.eop.gov; and to the Federal Communications Commission's PRA mailbox (e-mail address: PRA@fcc.gov). Include in the e-mail the OMB control number of the collection as shown in the

SUPPLEMENTARY INFORMATION section below, or if there is no OMB control number, include the Title as shown in the **SUPPLEMENTARY INFORMATION** section. If you are unable to submit your comments by e-mail, contact the person listed below to make alternate arrangements.

FOR FURTHER INFORMATION CONTACT: For additional information, contact Judith B. Herman at 202-418-0214 or via the Internet at Judith-b.herman@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060-1094.
Title: Sections 27.14 and 27.1221, Licensing, Operation and Transition of the 2500-2690 MHz Band.

Form No.: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit, not-for-profit institutions, and state, local or tribal government.

Number of Respondents: 2,500 respondents; 5,140 responses.

Estimated Time per Response: .50 hours-2.25 hours.

Frequency of Response: On occasion and one time reporting requirements, third party disclosure requirement and recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. sections 151, 154(i), 301, 303(f), 303(g), 303(r), 307, 308 and 316.

Total Annual Burden: 3,510 hours.

Total Annual Cost: \$302,667.

Privacy Act Impact Assessment: N/A.

Nature and Extent of Confidentiality: There is no need for confidentiality. Respondents or applicants may request materials or information submitted to the Commission be withheld from public inspection under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: The Commission will submit this information collection (IC) to the OMB during this comment period as a revision. The Commission is seeking OMB approval because the FCC adopted and released a *Fourth Memorandum Opinion and Order*, (2008 Order), FCC 08-83, which adopted section 27.14(o) of the Commission's rules. That rule requires all Broadband Radio Service (BRS) and Educational Broadband Service (EBS) licensees to make a showing of "substantial service" no later than May 1, 2011 on a license-by-license basis. This requirement was modified by the *Third Report and Order* (2010 Order), FCC 10-107, to require that licensees issued a new BRS license on or After November 6, 2009, would have four years from the date of initial license grant to provide substantial service. A licensee must demonstrate that it provided service which is sound, favorable, and substantially above a level of mediocre service which might minimally warrant renewal.

The Commission has changed its burden estimates for this information collection. The Commission has recalculated (adjusted) the burden hours because the number of respondents/responses has been reduced by 4,947 hours. This is due to fewer respondents since this was last submitted to OMB. The transition to the new band plan is largely complete and most of the transition-related requirements contained in this collection are no longer necessary. The program change increase in annual costs is due to approximately two-third of respondents will contract out to an outside source to prepare the "substantial showing" requirement.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2011-566 Filed 1-12-11; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission for Extension Under Delegated Authority, Comments Requested

January 3, 2011

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3501-3520.

Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and (e) ways to further reduce the information collection burden for small business concerns with fewer than 25 employees

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid OMB control number.

DATES: Persons wishing to comment on this information collection should submit their PRA comments March 14, 2011. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Submit all PRA comments to Nicholas A. Fraser, Office of Management and Budget (OMB), via fax at 202-395-5167, or via the Internet at Nicholas_A_Fraser@omb.eop.gov and to Judith-B.Herman@fcc.gov, Federal

Communications Commission (FCC). To submit your PRA comments by e-mail send them to: PRA@fcc.gov.

To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page <http://www.reginfo.gov/public/do/PRAMain>, (2) look for the section of the web page called "Currently Under Review", (3) click the downward-pointing arrow in the "Select Agency" box below the "Currently Under Review" heading, (4) select "Federal Communications Commission" from the list of agencies presented in the "Select Agency" box, (5) click the "Submit" button to the right of the "Select Agency" box and (6) when the list of FCC ICRs currently under review appears, look for the title of this ICR (or its OMB Control Number, if there is one) and then click on the ICR Reference Number to view detailed information about this ICR.

FOR FURTHER INFORMATION CONTACT: For additional information, send an e-mail to Judith-B.Herman@fcc.gov or contact her at 202-418-0214.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060-0391.

Title: Program to Monitor the Impacts of the Universal Service Support Mechanism, CC Docket Nos. 98-202 and 96-45.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents: 288 respondents; 1,152 responses.

Estimated Time per Response: 40 minutes.

Frequency of Response: Quarterly and annual reporting requirements and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. sections 151, 152, 154, 201-205, 215, 218, 220, 229, 254, and 410.

Total Annual Burden: 770 hours.

Total Annual Cost: N/A.

Privacy Act Impact Assessment: N/A.

Nature and Extent of Confidentiality: The respondents may request confidentiality protection for the special access performance information. The respondents are not required to file their customers' monthly usage information with the Federal Communications Commission (FCC).

Needs and Uses: The Commission will submit this expiring information collection to the Office of Management and Budget (OMB) after this 60 day comment period in order to obtain the full three year clearance from them. The

Commission is requesting an extension (no change in the reporting requirements and/or third party disclosure requirements) of this information collection. The Commission is reporting a 243 hour increase in the total annual burden. The increase is due to a re-calculation of the estimated number of respondents/responses.

The monitoring program is necessary for the Commission, the Joint Board, Congress and the general public to assess the impact of the universal service support mechanisms. The program requires periodic reporting by telephone companies and the universal service administrator. Failure to implement the program would make it impossible to determine the impact of these mechanisms and to assure that the implementation of section 254 fulfills the intent of Congress and furthers the public interest. This information collection should be continued because the Commission had adopted new mechanisms to implement section 254 of the Act and because the network usage and growth data have proven to be a valuable source of information about the advancement of universal service.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2011-561 Filed 1-12-11; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

December 22, 2010.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, 44 U.S.C. 3501-3520. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated

collection techniques or other forms of information technology; and (e) ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before March 14, 2011. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to the Federal Communications Commission. To submit your PRA comments by e-mail send them to: PRA@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information, contact Judith B. Herman at 202-418-0214 or via the Internet at Judith-B.Herman@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060-0004.

Title: Sections 1.1307 and 1.1311, Guidelines for Evaluating the Environmental Effects of Radiofrequency, Second Memorandum Opinion and Order, ET Docket No. 93-62.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Individuals or households, business or other for-profit, not-for-profit institutions, and state, local or tribal government.

Number of Respondents: 190,905 respondents; 190,905 responses.

Estimated Time per Response: .36 hours (average).

Frequency of Response: On occasion reporting requirement and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. sections 154, 302, 303 and 307.

Total Annual Burden: 69,463 hours.

Total Annual Cost: \$10,355,260.

Privacy Act Impact Assessment: N/A.

Nature and Extent of Confidentiality: There is a minimal exemption from the Freedom of Information Act (FOIA), 5 U.S.C. 552(b)(4), and 47 CFR 0.459 of the Commission's rules, that is granted

for trade secrets, which may be submitted to the Commission as part of the documentation of test results. No other assurances of confidentiality are provided to respondents.

Needs and Uses: The Commission will submit this expiring information collection to the Office of Management and Budget (OMB) after this 60-day comment period in order to obtain the full three-year clearance from them. The Commission is requesting OMB approval for an extension (no change in the reporting and/or third party disclosure requirements). The Commission is reporting a 94,469 total annual burden reduction and an \$18,336,443 annual cost reduction. This is due to fewer responses than the last time this collection was submitted to OMB for review and approval.

This information collection is a result of responsibility placed on the FCC by the National Environmental Policy Act (NEPA) of 1969. NEPA requires that each federal agency evaluate the impact of "major actions significantly affecting the quality of the human environment." It is the FCC's opinion that this is the most efficient and reasonable method of complying with NEPA with regard to the environmental issue of radiofrequency radiation from FCC-regulated transmitters.

The Commission requires applicants to submit limited information during the licensing and authorization process. In many services, the Commission simply requires licensees to provide reliable service to specific geographic areas, but does not require licensees to file site-specific information. It does not appear that the FCC's present licensing methods can provide public notification of site-specific information without imposing new and significant additional burden to the Commission's applicants. However, we note that applicants with the greatest potential to exceed the Commission's exposure limits are required to perform an environmental evaluation as part of the licensing and authorization process.

The Commission advises concerned members of the public, seeking site-specific information, to contact the FCC for the name and telephone number of the service providers in the concerned party's area. The Commission encourages all service providers to provide site-specific, technical information and environmental evaluation documentation upon public request. In addition, we note alternative sources of information may be state and local governments, which may collect some site-specific information as part of the zoning process.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2011-559 Filed 1-12-11; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

January 4, 2011.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, 44 U.S.C. 3501-3520. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and (e) ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before March 14, 2011. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to PRA@fcc.gov and Cathy.Williams@fcc.gov. Include in the e-mail the OMB control number of the collection. If you are unable to submit your comments by e-mail contact the

person listed below to make alternate arrangements.

FOR FURTHER INFORMATION CONTACT: For additional information, contact Cathy Williams on (202) 418-2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060-1111.

Title: Sections 225 and 255, Interconnected Voice over Internet Protocol Services (VoIP).

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 2,301 respondents and 30,841 responses.

Estimated Time per Response: .25-25 hours.

Frequency of Response: Annual, on occasion, and one-time reporting requirements; Recordkeeping requirement; Third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for the information collection requirements is contained in Section 225 of the Communications Act of 1934, as amended (Act) [47 U.S.C. 225], Telecommunications Services for Hearing-Impaired and Speech-Impaired Individuals; the Americans with Disabilities Act of 1990, Public Law 101-336, 104 Stat. 327, 336-69, enacted on July 26, 1990; Section 255 [47 U.S.C. 255] Access By Persons with Disabilities, Public Law 104-104, 110 Stat. 56, added to the Act by the Telecommunications Act of 1996; and section 4(i) of the Act, 47 U.S.C. 154(i).

Total Annual Burden: 33,200 hours.

Total Annual Cost: \$3,171,000.

Nature and Extent of Confidentiality: Confidentiality is an issue to the extent that individuals and households provide personally identifiable information, which is covered under the FCC's system of records notice (SORN), FCC/CGB-1, "Informal Complaints and Inquiries." As required by the Privacy Act, 5 U.S.C. 552a, the Commission published revisions to the SORN in the **Federal Register** on December 15, 2009 (74 FR 66356), and they became effective on January 25, 2010.

Privacy Impact Assessment: Yes. The Privacy Impact Assessment (PIA) was completed on June 28, 2007. It may be reviewed at: <http://www.fcc.gov/omd/privacyact/>

Privacy Impact Assessment.html. The Commission is in the process of updating the PIA to incorporate various revisions made to the SORN.

Needs and Uses: On June 15, 2007, the Commission released a Report and

Order, *IP-Enabled Services; Implementation of Sections 255 and 251(a)(2) of the Communications Act of 1934, as Enacted by the Telecommunications Act of 1996: Access to Telecommunications Service, Telecommunications Equipment and Customer Premises Equipment by Persons with Disabilities; Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities; and the Use of N11 Codes and Other Abbreviated Dialing Arrangements*, FCC 07-110, published at 72 FR 43546, August 6, 2007. FCC 07-110 extended the disability access requirements that apply to telecommunications service providers and equipment manufacturers under section 255 of the Act, to providers of "interconnected voice over Internet Protocol (VoIP) services," as defined by the Commission, and to manufacturers of specially designed equipment used to provide those services. In addition, the Commission extended the Telecommunications Relay Services requirements contained in its regulations, pursuant to section 225 of the Act, to interconnected VoIP providers. As applied to interconnected VoIP providers and to manufacturers of specialized VoIP equipment, several requirements adopted in FCC 07-110 contain information collection requirements. In particular, the following rules, as applied to interconnected VoIP providers and to manufacturers of specialized VoIP equipment and customer premises equipment, contain information collection requirements: 47 CFR 6.11(a), 6.11(b), 6.18(b), 6.19, 64.604(a)(5), 64.604(c)(1)(i), 64.604(c)(1)(ii), 64.604(c)(2), 64.604(c)(3), 64.604(c)(5)(iii)(C), 64.604(c)(5)(iii)(E), 64.604(c)(5)(iii)(G), 64.604(c)(6)(v)(A)(3), 64.604(c)(6)(v)(G), 64.604(c)(7), and 64.607(b).

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2011-564 Filed 1-12-11; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

Radio Broadcasting Services; AM or FM Proposals To Change the Community of License

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: The following applicants filed AM or FM proposals to change the community of license: Educational Radio for the Public of the New Millennium, Station WRJI, Facility ID 93884, BPED-20101126AAP, From East Greenwich, RI, to Providence, RI; Franciscan University of Steubenville, Station NEW, Facility ID 171722, BMPED-20101129APH, From Hopedale, OH, To Wintersville, OH; Grace Broadcasting Services, Inc., Station WFGZ, Facility ID 50126, BPH-20101122AKC, From Lobelville, TN, to Burns, TN; Millennium Broadcasting Corp, Station KYZQ, Facility ID 121233, BMPED-20101116BHB, From Mount Pleasant, TX, To Mount Vernon, TX; Moberly/Macon License Co, LLC, Station NEW, Facility ID 183331, BNPH-20091019ABJ, From Moberly, MO, To Cairo, MO; Sanpete County Broadcasting Co., Station KLGL, Facility ID 41895, BPH-20101206AAK, From richfield, UT, to Mount Pleasant, UT; Sierra Radio, Inc., Station KTOR, Facility ID 82891, BPH-20101123ASC, From Westwood, CA, To Gerber, CA; Western New Life, Inc., Station WQML, Facility ID 183333, BMPH-20101202ABW, From Charlotte Amalie, VI, To Culebra, PR.

DATES: Comments may be filed through March 14, 2011.

ADDRESSES: Federal Communications Commission, 445 Twelfth Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Tung Bui, 202-418-2700.

SUPPLEMENTARY INFORMATION: The full text of these applications is available for inspection and copying during normal business hours in the Commission's Reference Center, 445 12th Street, SW., Washington, DC 20554 or electronically via the Media Bureau's Consolidated Data Base System, http://svartifoss2.fcc.gov/prod/cdbs/pubacc/prod/cdbs_pa.htm. A copy of this application may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY-B402, Washington, DC, 20554, telephone 1-800-378-3160 or <http://www.BCPIWEB.com>.

Federal Communications Commission.

James D. Bradshaw,

Deputy Chief, Audio Division, Media Bureau.

[FR Doc. 2011-563 Filed 1-12-11; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission an application for a license as a Non-Vessel-Operating Common Carrier (NVO) and/or Ocean Freight Forwarder (OFF)—Ocean Transportation Intermediary (OTI) pursuant to section 19 of the Shipping Act of 1984 as amended (46 U.S.C. Chapter 409 and 46 CFR 515). Notice is also hereby given of the filing of applications to amend an existing OTI license or the Qualifying Individual (QI) for a license.

Interested persons may contact the Office of Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573, by telephone at (202) 523-5843 or by e-mail at OTI@fmc.gov.

A.W.L.I Group of Florida, Inc. (OFF), 1358 NW 78th Avenue, Miami, FL 33126. *Officers:* David Rosendorf, Director/President, (Qualifying Individual), Keith Milliner.

Application Type: Name Change. Crescent Line Inc. dba Globe Express Services (NVO & OFF), 535 Regal Row, Dallas, TX 75247. *Officers:* Gilbert Khoury, President/Secretary/Director, (Qualifying Individual), George Romanos, Vice President/Director. *Application Type:* Trade Name Change.

Globe Shipping Inc. (NVO), 820 S. Garfield Avenue, #202, Alhambra, CA 91801. *Officers:* Eric G. Qian, CEO, (Qualifying Individual), Jian Q. Sun, Secretary. *Application Type:* New NVO License.

Hydra Logistics, Inc. dba Globe Express Services (NVO & OFF), 14205 Westfair West Drive, Houston, TX 77041. *Officers:* Gilbert Khoury, President/Director, (Qualifying Individual), Jim Swann, VP/Secretary/Director. *Application Type:* Trade Name Change.

JSJ Express, Inc. (NVO), 140-15 Holly Avenue, Suite 201, Flushing, NY 11355. *Officer:* Yaokun Chen, President/VP/Secretary/Treasurer, (Qualifying Individual). *Application Type:* New NVO License.

Salinas International Freight Co. (OFF), 535 Regal Row, Dallas, TX 75247. *Officer:* Gilbert R. Khoury, President, (Qualifying Individual). *Application Type:* Trade Name Change.

Sealaska Global Logistics LLC (NVO & OFF), 1691 Phoenix Blvd., Suite 170, Atlanta, GA 30349. *Officers:* Angela Higgs, Vice President Ocean Freight, (Qualifying Individual), Wade

Zammit, President/CEO. *Application*
Type: QI Change.

Dated: January 7, 2011.

Karen V. Gregory,
Secretary.

[FR Doc. 2011-574 Filed 1-12-11; 8:45 am]

BILLING CODE 6730-01-P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Reissuance

Notice is hereby given that the following Ocean Transportation Intermediary licenses have been

reissued by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. Chapter 409) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR part 515.

License No.	Name/address	Date reissued
004027F	U.S. Airfreight, Inc., 2624 N.W. 112th Avenue, Miami, FL 33172	October 28, 2010.
017330N	Geomarine Shipping Inc., 27 Cambridge Road, East Rockaway, NY 11518	November 10, 2010.
018429F	AB Shipping, Inc., 5428 El Monte Avenue, Temple City, CA 91780	November 15, 2010.
018525N	Valu Freight Consolidators, Inc., 1325 NW 21th Street, Miami, FL 33142	November 19, 2010.
020258NF	Sistemas Aereos LLC, 11027 NW 122nd Street, Medley, FL 33178	November 19, 2010.
020264N	Empire Shipping Co. Inc., 100 East Peddie Street, Newark, NJ 07114	November 6, 2010.
021534N	Martinez Cargo Express, Corp., 8026 Sunport Drive, Units 301-302, Orlando, FL 32809.	November 19, 2010.
021694N	Wheelsky Logistics, Inc., 14515 East Don Julian Road, City of Industry, CA 91746 ..	November 19, 2010.
022244N	Golden Freight, Inc., dba Saigon Express, 510 Parrott Street, Suite 2, San Jose, CA 95112.	November 15, 2010.

Sandra L. Kusumoto,

Director, Bureau of Certification and Licensing.

[FR Doc. 2011-576 Filed 1-12-11; 8:45 am]

BILLING CODE 6730-01-P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License; Rescission of Order of Revocation

Notice is hereby given that the Order revoking the following license is being rescinded by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. Chapter 409) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR Part 515.

License Number: 020667N.

Name: Atlas Logistics (U.S.A.), Inc.

Address: 2401 E. Atlantic Blvd., Suite 310, Pompano Beach, FL 33062.

Order Published: FR: 12/22/10 (Volume 75, No. 245, Pg. 80501).

Sandra L. Kusumoto,

Director, Bureau of Certification and Licensing.

[FR Doc. 2011-575 Filed 1-12-11; 8:45 am]

BILLING CODE 6730-01-P

or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than January 28, 2011.

A. Federal Reserve Bank of Atlanta (Clifford Stanford, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30309:

1. *SG-BBC, LLC, and The Stephens Group, LLC*, both of Little Rock, Arkansas; to acquire voting shares of Brand Group Holdings, Inc., and thereby indirectly acquire voting shares of The Brand Banking Company, both of Lawrenceville, Georgia.

Board of Governors of the Federal Reserve System, January 10, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011-599 Filed 1-12-11; 8:45 am]

BILLING CODE 6210-01-P

STATUS: Parts will be open to the public and parts closed to the public.

MATTERS TO BE CONSIDERED:

Parts Open to the Public

1. Approval of the minutes of the December 13, 2010 Board member meeting
2. Thrift Savings Plan activity report by the Executive Director
 - a. Monthly Participant Activity Report
 - b. Quarterly Investment Policy Review
 - c. Legislative Report
3. Vendor Financials Report
4. Annual Expense Ratio Review
5. Erroneous Required Minimum Distribution Payment Report
6. TSP Investment Funds DVD Demonstration

Parts Closed to the Public

7. Confidential Financial Information
8. Personnel

CONTACT PERSON FOR MORE INFORMATION:

Thomas J. Trabucco, Director, Office of External Affairs, (202) 942-1640.

Dated: January 10, 2011.

Thomas K. Emswiler,

Secretary, Federal Retirement Thrift Investment Board.

[FR Doc. 2011-719 Filed 1-11-11; 4:15 pm]

BILLING CODE 6760-01-P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Sunshine Act; Notice of Meeting

TIME AND DATE: 9 a.m. (Eastern Time), January 25, 2011.

PLACE: 4th Floor Conference Room, 1250 H Street, NW., Washington, DC 20005.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Proposed HHS Recommendation for Fluoride Concentration in Drinking Water for Prevention of Dental Caries

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) seeks public comment on proposed new guidance which will update and replace the 1962 U.S. Public Health Service Drinking Water Standards related to recommendations for fluoride concentrations in drinking water. The U.S. Public Health Service recommendations for optimal fluoride concentrations were based on ambient air temperature of geographic areas and ranged from 0.7–1.2 mg/L.

HHS proposes that community water systems adjust the amount of fluoride to 0.7 mg/L to achieve an optimal fluoride level. For the purpose of this guidance, the optimal concentration of fluoride in drinking water is that concentration that provides the best balance of protection from dental caries while limiting the risk of dental fluorosis. Community water fluoridation is the adjusting and monitoring of fluoride in drinking water to reach the optimal concentration (Truman BI, *et al*, 2002).

This updated guidance is intended to apply to community water systems that are currently fluoridating or will initiate fluoridation.¹ This guidance is based on several considerations that include:

- Scientific evidence related to effectiveness of water fluoridation on caries prevention and control across all age groups.
- Fluoride in drinking water as one of several available fluoride sources.
- Trends in the prevalence and severity of dental fluorosis.
- Current evidence on fluid intake in children across various ambient air temperatures.

DATES: To receive consideration, comments on the proposed recommendations for fluoride concentration in drinking water for the prevention of dental caries should be received no later than February 14, 2011.

ADDRESSES: Comments are preferred electronically and may be addressed to CWFcomments@cdc.gov. Written responses should be addressed to the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, CWF Comments, Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), 4770 Buford Highway, NE, MS F-10, Atlanta, GA 30341-3717.

¹ Community water fluoridation of public drinking water systems has been demonstrated to be effective in reducing caries and producing cost-savings from a societal perspective. (Truman B *et al*, 2002). If local goals and resources permit, the use of this intervention should be continued, initiated, or increased (CDC 2001a).

FOR FURTHER INFORMATION CONTACT: Barbara F. Gooch, Associate Director for Science (Acting), 770-488-6054, CWFcomments@cdc.gov, Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention, 4770 Buford Highway, NE., MS F-10, Atlanta, GA 30341-3717.

SUPPLEMENTARY INFORMATION: The U.S. Public Health Service has provided recommendations regarding optimal fluoride concentrations in drinking water from community water systems (CWS)² for the prevention of dental caries (US DHEW, 1962). HHS proposes to update and replace these recommendations because of new data that address changes in the prevalence of dental fluorosis, fluid intake among children, and the contribution of fluoride in drinking water to total fluoride exposure in the United States. As of December 31, 2008, the Centers for Disease Control and Prevention (CDC) estimated that 16,977 community water systems provided fluoridated water to 196 million people. 95% of the population receiving fluoridated water was served by community water systems that added fluoride to water, or purchased water with added fluoride from other systems. The remaining 5% were served by systems with naturally occurring fluoride at or above the recommended level. More statistics about water fluoridation in the United States are available at <http://www.cdc.gov/fluoridation/statistics/2008stats.htm>. Guidance for systems with naturally occurring fluoride levels above the recommended level are beyond the scope of this document. Systems that have fluoride levels greater than the national primary (4.0 mg/L) or secondary (2.0 mg/L) drinking water standards established by EPA can find more information at the following EPA Web site: <http://water.epa.gov/drink/contaminants/basicinformation/fluoride.cfm>. CDC's Recommendations for Fluoride Use (CDC, 2001b), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5014a1.htm>, provides guidance on community water

² For purposes of this guidance, a water system is considered a community water system if so designated by the State drinking water administrator in accordance with the regulatory requirements of the U.S. Environmental Protection Agency. In general, public water systems provide water for human consumption through pipes or other constructed conveyances to at least 15 service connections or serves an average of at least 25 people for at least 60 days a year. A community water system is a public water system that supplies water to the same population year-round, <http://water.epa.gov/infrastructure/drinkingwater/pws/factoids.cfm>.

fluoridation and use of other fluoride-containing products.

Recommendation

HHS proposes that community water systems adjust their fluoride content to 0.7 mg/L [parts per million (ppm)].

Rationale

Importance of community water fluoridation:

Community water fluoridation is a major factor responsible for the decline of the prevalence and severity of dental caries (tooth decay) during the second half of the 20th century. From the early 1970's to the present, the prevalence of dental caries in at least one permanent tooth (excluding third molars) among adolescents, aged 12–17 years,³ has decreased from 90% to 60% and the average number of teeth affected by dental caries (*i.e.*, decayed, missing and filled) from 6.2 to 2.6 (Kelly JE, 1975, Dye B, *et al*, 2007). Adults have also benefited from community water fluoridation. Among adults, aged 35–44 years,⁴ the average number of affected teeth decreased from 18 in the early 1960's to 10 among adults, aged 35–49 years, in 1999–2004 (Kelly JE, *et al*, 1967; Dye B, *et al*, 2007). Although there have been notable declines in tooth decay, it remains one of the most common chronic diseases of childhood (USDHHS, 2000; Newacheck PW *et al*, 2000). Effective population-based interventions to prevent and control dental caries, such as community water fluoridation, are still needed (CDC, 2001a).

Systematic reviews of the scientific evidence related to fluoride have concluded that community water fluoridation is effective in decreasing dental caries prevalence and severity (McDonagh MS, *et al*, 2000a, McDonagh MS, *et al*, 2000b, Truman BI, *et al*, 2002, Griffin SO, *et al*, 2007). Effects included significant increases in the proportion of children who were caries-free and significant reductions in the number of teeth or tooth surfaces with caries in both children and adults (McDonagh MS, *et al*, 2000b, Griffin SO, *et al*, 2007). When analyses were limited to studies

³ There were slight differences in the age groups used in both surveys. The 1971–1974 survey reported on adolescents aged 12–17 years (Kelly JE, 1975) while the 1999–2004 survey reported on adolescents and youths aged 12–19 years (Dye B, *et al*, 2007). Because the prevalence of dental caries increases with age, the estimates for 12–17 year olds in the most recent survey (1999–2004) should be slightly lower than those published for 12–19 year olds (Dye B, *et al*, 2007).

⁴ There were slight differences in the age groups used in both surveys. The 1962 survey reported on adults aged 35–44 years (Kelly JE *et al* 1967) while the 1999–2004 survey reported on adults aged 35–49 years (Dye B, *et al*, 2007).

conducted after the introduction of other sources of fluoride, especially fluoride toothpaste, beneficial effects across the lifespan from community water fluoridation were still apparent (McDonagh MS, *et al*, 2000b; Griffin SO, *et al*, 2007).

Fluoride works primarily to prevent dental caries through topical remineralization of tooth surfaces when small amounts of fluoride, specifically in saliva and accumulated plaque, are present frequently in the mouth (Featherstone JDB, 1999). Consuming fluoridated water and beverages and foods prepared or processed with fluoridated water routinely introduces a low concentration of fluoride into the mouth. Although other fluoride-containing products are available and contribute to the prevention and control of dental caries, community water fluoridation has been identified as the most cost-effective method of delivering fluoride to all members of the community regardless of age, educational attainment, or income level (CDC, 1999, Burt BA, 1989). Studies continue to find that community water fluoridation is cost-saving (Truman B, *et al*, 2002).

Trends in Availability of Fluoride Sources

Community water fluoridation and fluoride toothpaste are the most common sources of non-dietary fluoride in the United States (CDC, 2001b). Community water fluoridation began in 1945, reaching almost 50% of the U.S. population by 1975 and 64% by 2008, <http://www.cdc.gov/fluoridation/statistics/2008stats.htm>; <http://www.cdc.gov/fluoridation/pdf/statistics/1975.pdf>. Toothpaste containing fluoride was first marketed in the United States in 1955 (USDHEW, 1980) and by the 1990's accounted for more than 90 percent of the toothpaste market (Burt BA and Eklund SA, 2005). Other products that provide fluoride now include mouthrinses, fluoride supplements, and professionally applied fluoride compounds. More detailed explanations of these products are published elsewhere (CDC, 2001b) (ADA, 2006) (USDHHS, 2010). More information on all sources of fluoride and their relative contribution to total fluoride exposure in the United States is presented in a report by EPA (US EPA 2010a).

Dental Fluorosis

Fluoride ingestion while teeth are developing can result in a range of visually detectable changes in the tooth enamel (Aoba T and Fejerskov O, 2002). Changes range from barely visible lacy

white markings in milder cases to pitting of the teeth in the rare, severe form. The period of possible risk for fluorosis in the permanent teeth, excluding the third molars,⁵ extends from about birth through 8 years of age when the preruleptive maturation of tooth enamel is complete (CDC, 2001b; Massler M and Schour I, 1958). When communities first began adding fluoride to their public water systems in 1945, drinking water and foods and beverages prepared with fluoridated water were the primary sources of fluoride for most children (McClure FJ, 1943). Since the 1940's, other sources of ingested fluoride, such as fluoride toothpaste (if swallowed) and fluoride supplements, have become available. Fluoride intake from these products, in addition to water and other beverages and infant formula prepared with fluoridated water, have been associated with increased risk of dental fluorosis (Levy SL, *et al*, 2010, Wong MCM, *et al*, 2010, Osuji OO *et al*, 1988, Pendrys DG *et al*, 1994, Pendrys DG and Katz RV 1989, Pendrys DG, 1995). Both the 1962 USPHS recommendations and the current proposal for fluoride concentrations in community drinking water were set to achieve a reduction in dental caries while minimizing the risk of dental fluorosis.

Results of two national surveys indicate that the prevalence of dental fluorosis has increased since the 1980's, but mostly in the very mild or mild forms. The most recent data on prevalence of dental fluorosis come from the National Health and Nutrition Examination Survey (NHANES), 1999–2004. NHANES assessed the prevalence and severity of dental fluorosis among persons, aged 6 to 49 years. Twenty-three percent had dental fluorosis of which the vast majority was very mild or mild. Approximately 2% of persons had moderate dental fluorosis, and less than 1% had severe. Prevalence was higher among younger persons and ranged from 41% among adolescents aged 12–15 years to 9% among adults, aged 40–49 years. The higher prevalence of dental fluorosis in the younger persons probably reflects the increase in fluoride exposures across the U.S. population through community water

⁵ Risk for the third molars (*i.e.*, wisdom teeth) extends to age 14 years (Massler M, 1958). Third molars are much less likely than other teeth to erupt fully into a functional position due to space constraints in the dental arch and may be impacted, partially erupted, or extracted. For these reasons third molars are not assessed for dental caries or dental fluorosis in national surveys in the U.S. In addition, based on their placement, these teeth are unlikely to be of aesthetic concern.

fluoridation and increased use of fluoride toothpaste.

The prevalence and severity of dental fluorosis among 12–15 year olds in 1999–2004 were compared to estimates from the Oral Health of United States Children Survey, 1986–87, which was the first national survey to include measures of dental fluorosis. Although these two national surveys differed in sampling and representation (schoolchildren versus household), findings support the hypothesis that there has been an increase in dental fluorosis that was very mild or greater between the two surveys. In 1986–87 and 1999–2004 the prevalence of dental fluorosis was 23% and 41%, respectively, among adolescents aged 12 to 15. (Beltrán-Aguilar ED, *et al*, 2010a). Similarly, the prevalence of very mild fluorosis (17.2% and 28.5%), mild fluorosis (4.1% and 8.6%) and moderate and severe fluorosis combined (1.3% and 3.6%) have increased. The estimates for severe fluorosis for adolescents in both surveys were statistically unreliable because of too few cases in the samples.

More information on fluoride concentrations in drinking water and the impact of severe dental fluorosis in children is presented in a report by EPA (US EPA 2010 b).

Relationship between dental caries and fluorosis at varying water fluoridation concentrations:

The 1986–87 Oral Health of United States Children Survey is the only national survey that measured the child's water fluoride exposure and can link that exposure to measures of caries and fluorosis (U.S. DHHS, 1989). An additional analysis of data from this survey examined the relationship between dental caries and fluorosis at varying water fluoride concentrations for children aged 6 to 17 years (Heller KE, *et al*, 1997). Findings indicate that there was a gradual decline in dental caries as fluoride content in water increased from negligible to 0.7 mg/L. Reductions plateaued at concentrations from 0.7 to 1.2 mg/L. In contrast, the percentage of children with at least very mild dental fluorosis increased with increasing fluoride concentrations in water. The published report did not report standard errors.

In Hong Kong a small change of about 0.2 mg/L⁶ in the mean fluoride concentration in drinking water in 1978 was associated with a detectable reduction in fluorosis prevalence by the

⁶ Fluoride concentrations in drinking water before and after the 1978 reduction were 0.82 and 0.64 mg F/L, respectively.

mid 1980's⁷ (Evans R.W, Stamm JW., 1991). Across all age groups more than 90% of fluorosis cases were very mild or mild. (Evans R.W, Stamm JW., 1991). The study did not include measures of fluoride intake. Concurrently, dental caries prevalence did not increase. (Lo ECM *et al*, 1990). Although not fully generalizable to the current U.S. context, these findings, along with those from the 1986–87 survey of U.S. schoolchildren, suggest that risk of fluorosis can be reduced and caries prevention maintained toward the lower end (*i.e.*, 0.7 mg/L) of the 1962 USPHS recommendations for fluoride concentrations for community water systems.

Relationship of fluid intake and ambient temperature among children and adolescents in the United States:

The 1962 USPHS recommendations stated that community drinking water should contain 0.7–1.2 mg/L [ppm] fluoride, depending on the ambient air temperature of the area. These temperature-related guidelines were based on studies conducted in two communities in California in the early 1950's. Findings indicated that a lower fluoride concentration was appropriate for communities in warmer climates because children drank more tap water on warm days (Galagan DJ, 1953; Galagan DJ and Vermillion JR, 1957; Galagan DJ *et al*, 1957). Social and environmental changes, including increased use of air conditioning and more sedentary lifestyles, have occurred since the 1950's, and thus, the assumption that children living in warmer regions drink more tap water than children in cooler regions may no longer be valid.

Studies conducted since 2001 suggest that fluid intake in children does not increase with increases in ambient air temperature (Sohn W, *et al*, 2001; Beltrán-Aguilar ED, *et al*, 2010b). One study conducted among children using nationally representative data from 1988 to 1994 did not find an association between fluid intake and ambient air temperature (Sohn W, *et al*, 2001). A similar study using nationally representative data from 1999 to 2004 also found no association between fluid intake and ambient temperature among children or adolescents (Beltrán-Aguilar ED, *et al*, 2010b). These recent findings demonstrating a lack of an association between fluid intake among children and adolescents and ambient temperature support use of a single target concentration for community

water fluoridation in all temperature zones of the United States.

Conclusions

HHS recommends an optimal fluoride concentration of 0.7 mg/L for community water systems based on the following information:

- Community water fluoridation is the most cost-effective method of delivering fluoride for the prevention of tooth decay;
- In addition to drinking water, other sources of fluoride exposure have contributed to the prevention of dental caries and an increase in dental fluorosis prevalence;
- Significant caries preventive benefits can be achieved and risk of fluorosis reduced at 0.7 mg/L, the lowest concentration in the range of the USPHS recommendation.
- Recent data do not show a convincing relationship between fluid intake and ambient air temperature. Thus, there is no need for different recommendations for water fluoride concentrations in different temperature zones.

Surveillance Activities

CDC and the National Institute of Dental and Craniofacial Research (NIDCR), in coordination with other Federal agencies, will enhance surveillance of dental caries, dental fluorosis, and fluoride intake with a focus on younger populations at higher risk of fluorosis to obtain the best available and most current information to support effective efforts to improve oral health.

Process

The U.S. Department of Health and Human Services (HHS) convened a Federal inter-departmental, inter-agency panel of scientists (Appendix A) to review scientific evidence related to the 1962 USPHS Drinking Water Standards related to recommendations for fluoride concentrations in drinking water in the United States and to update these proposed recommendations. Panelists included representatives from the Centers for Disease Control and Prevention, the National Institutes of Health, the Food and Drug Administration, the Agency for Healthcare Research and Quality, the Office of the Assistant Secretary for Health, the U.S. Environmental Protection Agency, and the U.S. Department of Agriculture. The panelists evaluated existing recommendations for fluoride in drinking water, systematic reviews of the risks and benefits from fluoride in drinking water, the epidemiology of

dental caries and fluorosis in the U.S., and current data on fluid intake in children, aged 0 to 10 years, across temperature gradients in the U.S. Conclusions were reached and are summarized along with their rationale in this proposed guidance document. This guidance will be advisory, not regulatory, in nature. Guidance will be submitted to the **Federal Register** and will undergo public and stakeholder comment for 30 days, after which HHS will review comments and consider changes.

Dated: January 7, 2011.

Kathleen Sebelius,
Secretary.

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⁷ Fluorosis prevalence ranged from 64% (SE = 4.1) to 47% (SE = 4.5) based on the upper right central incisor only.

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Appendix A—HHS Federal Panel on Community Water Fluoridation

Peter Briss, MD, MPH—Panel Chair, Medical Director, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

Laurie K. Barker, MSPH, Statistician, Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

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Mary Beth Bigley, DrPH, MSN, ANP, Acting Director, Office of Science and Communications, Office of the Surgeon General, U.S. Department of Health and Human Services.

Linda Birnbaum, PhD, DABT, ATS, Director, National Institute of Environmental Health Sciences and National Toxicology Program, National Institutes of Health, U.S. Department of Health and Human Services.

John Bucher, PhD, Associate Director, National Toxicology Program, National Institute of Environmental Health Sciences, National Institutes of Health, U.S. Department of Health and Human Services.

Amit Chattopadhyay, PhD, Office of Science and Policy Analysis, National Institute of Dental and Craniofacial Research, National Institutes of Health, U.S. Department of Health and Human Services.

Joyce Donohue, PhD, Health Scientist, Health and Ecological Criteria Division, Office of Science and Technology, Office of Water, U.S. Environmental Protection Agency.

Elizabeth Doyle, PhD, Chief, Human Health Risk Assessment Branch, Health and Ecological Criteria Division, Office of Science and Technology, Office of Water, U.S. Environmental Protection Agency.

Isabel Garcia, DDS, MPH, Acting Director, National Institute of Dental and Craniofacial Research, National Institutes of Health, U.S. Department of Health and Human Services.

Barbara Gooch, DMD, MPH, Acting Associate Director for Science, Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

Jesse Goodman, MD, MPH, Chief Scientist and Deputy Commissioner for Science and Public Health, Food and Drug Administration, U.S. Department of Health and Human Services.

J. Nadine Gracia, MD, MSCE, Chief Medical Officer, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services.

Susan O. Griffin, PhD, Health Economist, Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

Laurence Grummer-Strawn, PhD, Chief, Maternal and Child Nutrition Branch, Division of Nutrition, Physical Activity, and Obesity, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

Jay Hirschman, MPH, CNS, Director, Special Nutrition Staff, Office of Research and Analysis, Food and Nutrition Service, U.S. Department of Agriculture.

Frederick Hyman, DDS, MPH, Division of Dermatology and Dental Products, Center for Drug Evaluation and Research, Food and Drug Administration, U.S. Department of Health and Human Services.

Timothy Iafolla, DMD, MPH, Office of Science and Policy Analysis, National Institute of Dental and Craniofacial Research, National Institutes of Health, U.S. Department of Health and Human Services.

William Kohn, DDS, Director, Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

Richard Manski, DDS, MBA, PhD, Senior Scholar, Center for Financing, Access and Cost Trends, Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services.

Benson Silverman, MD, Staff Director, Infant Formula and Medical Foods, Center for Food Safety and Applied Nutrition, Food and Drug Administration, U.S. Department of Health and Human Services.

Thomas Sinks, PhD, Deputy Director, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

[FR Doc. 2011-637 Filed 1-12-11; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Biodefense Science Board

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services is hereby giving notice that the National Biodefense Science Board (NBSB) will be holding a public meeting. The meeting is open to the public.

DATES: The NBSB will hold a public meeting on January 25, 2011 from 1:15 p.m. to 3 p.m. ET. The agenda is subject to change as priorities dictate.

ADDRESSES: Department of Health and Human Services; Hubert H. Humphrey Building, Room 800; 200 Independence Avenue, SW., Washington, DC 20201. To attend by teleconference, call 1-866-395-4129, pass-code "ASPR." Please call 15 minutes prior to the beginning of the conference call to facilitate attendance. Pre-registration is required for public attendance. Individuals who wish to attend the meeting in person should send an email to NBSB@HHS.GOV with "NBSB Registration" in the subject line.

FOR FURTHER INFORMATION CONTACT: E-mail: NBSB@HHS.GOV.

SUPPLEMENTARY INFORMATION: Pursuant to section 319M of the Public Health Service Act (42 U.S.C. 247d-7f) and section 222 of the Public Health Service Act (42 U.S.C. 217a), the Department of Health and Human Services established the National Biodefense Science Board. The Board shall provide expert advice and guidance to the Secretary on scientific, technical, and other matters of special interest to the Department of Health and Human Services regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate. The Board may also provide advice and guidance to the Secretary and/or the Assistant Secretary for Preparedness and Response on other matters related to public health emergency preparedness and response.

Background: A portion of this public meeting will be dedicated to swearing in the six new voting members who will replace the members whose 3-year terms expired on December 31, 2010. The Board will be asked to consider the various components of a science response to disasters. Subsequent agenda topics will be added as priorities dictate.

Availability of Materials: The meeting agenda and materials will be posted on the NBSB Web site at <http://www.phe.gov/Preparedness/legal/boards/nbsb/Pages/default.aspx> prior to the meeting.

Procedures for Providing Public Input: Any member of the public providing oral comments at the meeting must sign in at the registration desk and provide his/her name, address, and affiliation. All written comments must be received prior to January 18, 2011 and should be sent by e-mail to NBSB@HHS.GOV with "NBSB Public Comment" as the subject line. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should e-mail NBSB@HHS.GOV.

Dated: January 7, 2011.

Nicole Lurie,

Assistant Secretary for Preparedness and Response.

[FR Doc. 2011-684 Filed 1-12-11; 8:45 am]

BILLING CODE 4150-37-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Federal Agency Responses to Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Recommendations on Two Nonradioactive Versions of the Murine Local Lymph Node Assay (LLNA) for Assessing Allergic Contact Dermatitis (ACD) Hazard Potential of Chemicals and Products, and Expanded Uses of the LLNA for Pesticide Formulations and Other Products; Notice of Availability

AGENCY: National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), HHS.

ACTION: Notice of Availability.

SUMMARY: U.S. Federal agency responses to ICCVAM test method recommendations on two nonradioactive versions of the LLNA for assessing the ACD hazard potential of chemicals and products and for expanded uses of the LLNA for pesticide formulations and other products are now available on the NICEATM-ICCVAM Web site at <http://iccvam.niehs.nih.gov/methods/immunotox/llna.htm>. ICCVAM recommended the nonradioactive LLNA: 5-bromo-2-deoxyuridine-enzyme-linked immunosorbent assay

(BrdU-ELISA) and LLNA: Daicel Adenosine Triphosphate (DA), and expanded uses for the LLNA. In accordance with the ICCVAM Authorization Act (42 U.S.C. 2851–3(e)(4)), ICCVAM forwarded recommendations to Federal agencies and made these recommendations available to the public (75 FR 37443). Agencies have now notified ICCVAM in writing of their findings and ICCVAM is making these responses available to the public.

FOR FURTHER INFORMATION CONTACT: Dr. William S. Stokes, Director, NICEATM, NIEHS, P.O. Box 12233, Mail Stop: K2–16, Research Triangle Park, NC 27709, (telephone) 919–541–2384, (fax) 919–541–0947, (e-mail) niceatm@niehs.nih.gov. Courier address: NICEATM, NIEHS, Room 2034, 530 Davis Drive, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Background

In 1999, ICCVAM recommended the LLNA as a valid safety test for assessing the ACD hazard potential of many chemicals and products (NIH Publication No. 99–4494; available at http://iccvam.niehs.nih.gov/methods/immunotox/llna_PeerPanel98.htm). ICCVAM also concluded that the LLNA, when used as an alternative method to the guinea pig maximization test (GPMT) or the Buehler test (BT), could also significantly reduce animal use and improve animal welfare. Based on this evaluation, the U.S. Environmental Protection Agency (EPA 2003), the U.S. Food and Drug Administration, and the U.S. Consumer Product Safety Commission (CPSC) subsequently accepted the method as a valid substitute for the GPMT and BT (http://iccvam.niehs.nih.gov/methods/immunotox/llna_PeerPanel98.htm). The Organisation for Economic Co-operation and Development (OECD) subsequently adopted the LLNA in 2002 as international OECD Test Guideline 429 (OECD, 2002). The International Organization for Standardization (ISO) adopted the LLNA as ISO standard 10993–10 in 2002 (ISO, 2002).

ICCVAM recommended an updated LLNA test method protocol in 2009 that further reduced animal use for each safety test by 20–40% (ICCVAM, 2009). Federal agencies endorsed this updated protocol (75 FR 25866). OECD Test Guideline 429 was subsequently updated in 2010 to incorporate the updated revisions (OECD, 2010a). The ISO standard was also updated in 2010 (ISO, 2010).

Compared to the LLNA, the LLNA: BrdU-ELISA and LLNA: DA do not use

radioactive reagents and therefore provide additional advantages in terms of reduced hazardous waste disposal and broader availability for use by laboratories that cannot use radioactive reagents. ICCVAM concludes that the accuracy and reliability of the LLNA: BrdU-ELISA and LLNA: DA support their use to determine whether substances have the potential to cause ACD. The protocols also include reduced LLNA: BrdU-ELISA and LLNA: DA procedures that should always be considered and used where determined appropriate because they can further reduce animal use by 40% compared to multi-dose procedures. The ICCVAM evaluation and complete recommendations for the LLNA: BrdU-ELISA and LLNA: DA are provided in the *ICCVAM Test Method Evaluation Report on the Murine Local Lymph Node Assay: BrdU-ELISA, A Nonradioactive Alternative Test Method to Assess the Allergic Contact Dermatitis Potential of Chemicals and Products* (NIH Publication No. 10–7552, available at <http://iccvam.niehs.nih.gov/methods/immunotox/llna-ELISA/TMER.htm>) and the *ICCVAM Test Method Evaluation Report on the Murine Local Lymph Node Assay: DA, A Nonradioactive Alternative Test Method to Assess the Allergic Contact Dermatitis Potential of Chemicals and Products* (NIH Publication No. 10–7551, available at <http://iccvam.niehs.nih.gov/methods/immunotox/llna-DA/TMER.htm>). The OECD subsequently adopted the LLNA: BrdU-ELISA and LLNA: DA as international test guidelines (OECD, 2010b, 2010c).

ICCVAM also concluded that available data support the use of the LLNA for safety testing of a broader range of chemicals and products, including pesticide formulations, metals with the exception of nickel, substances in aqueous solutions, and other chemicals and products, unless there are unique physicochemical properties associated with these materials that may interfere with the accuracy of the LLNA. Aqueous solutions should be tested in an appropriate vehicle that maintains sufficient contact of the test article with the skin. The ICCVAM evaluation and complete recommendations for expanded uses of the LLNA are provided in *ICCVAM Test Method Evaluation Report on Using the Murine Local Lymph Node Assay for Testing Pesticide Formulations, Metals, Substances in Aqueous Solutions, and Other Products* (NIH Publication No. 10–7512, available at <http://iccvam.niehs.nih.gov/methods/immunotox/LLNA-app/TMER.htm>).

ICCVAM evaluated the new versions and applications of the LLNA in response to a 2007 nomination from CPSC (http://iccvam.niehs.nih.gov/methods/immunotox/llnadocs/CPSC_LLNA_nom.pdf). The nomination requested that ICCVAM assess (1) the validation status of the LLNA limit dose procedure (*i.e.*, the reduced LLNA); (2) modified LLNA test method protocols that do not require the use of radioactive materials; (3) the use of the LLNA to test mixtures, aqueous solutions, and metals; and (4) the use of the LLNA as a stand-alone assay to determine ACD potency categories for hazard classification. ICCVAM recommendations on an updated LLNA test method protocol that included the reduced LLNA were communicated to Federal agencies and each of the 15 ICCVAM agencies concurred with the ICCVAM recommendations for the reduced LLNA. ICCVAM has completed the evaluation of the LLNA for its validity for potency categorization of chemicals causing ACD in humans. Final ICCVAM recommendations will be forwarded to Federal agencies in 2011.

Agency Responses to ICCVAM Recommendations

In June 2010, ICCVAM forwarded final test method recommendations for the LLNA BrdU-ELISA, LLNA: DA and the expanded uses of the LLNA to U.S. Federal agencies for consideration (74 FR 50212), in accordance with the ICCVAM Authorization Act of 2000 (42 U.S.C. 2851–3(e)(4)). The Act requires agencies to review ICCVAM test method recommendations and notify ICCVAM in writing of their findings no later than 180 days after receipt of recommendations. The Act also requires ICCVAM to make ICCVAM recommendations and agency responses available to the public. Agency responses are to include identification of relevant test methods for which the ICCVAM test method recommendations may be added or substituted, and indicate any revisions or planned revisions to existing guidelines, guidances, or regulations to be made in response to these recommendations.

Federal agency responses include acceptance decisions and agreement with the test method recommendations for the LLNA: BrdU-ELISA, LLNA: DA and the expanded uses of the LLNA. Several agencies also indicated that they would communicate the ICCVAM recommendations to stakeholders and encourage their appropriate use. Agency responses are available at <http://iccvam.niehs.nih.gov/methods/immunotox/llna.htm>.

Background Information on ICCVAM and NICEATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative methods with regulatory applicability and promotes the scientific validation and regulatory acceptance of toxicological and safety-testing methods that more accurately assess the safety and hazards of chemicals and products and that reduce, refine (decrease or eliminate pain and distress), or replace animal use. The ICCVAM Authorization Act of 2000 established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM (42 U.S.C. 285l-3(a)). NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts independent validation studies to assess the usefulness and limitation of new, revised, and alternative test methods. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods applicable to the needs of U.S. Federal agencies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods for validation studies and technical evaluations. Additional information about ICCVAM and NICEATM can be found on the NICEATM-ICCVAM Web site (<http://iccvam.niehs.nih.gov>).

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Dated: January 5, 2011.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2011-669 Filed 1-12-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "Connecting Primary Care Practices with Hard-to-Reach Adolescent Populations." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3520, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by March 14, 2011.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by e-mail at doris.lefkowitz@AHRQ.hhs.gov.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by e-mail at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

Connecting Primary Care Practices With Hard-to-Reach Adolescent Populations

The overall goal of this exploratory project is to improve the quality of adolescent health care. The project will address suboptimal adolescent care with respect to health risk behaviors, which can have serious health consequences. In particular, failure to address health risk behaviors among adolescents (*e.g.*, smoking, substance abuse, poor diets, physical inactivity, and high-risk sexual behavior) contributes significantly to increased morbidity and mortality. Adolescents (11–17 years of age) constitute 17% of the population of the U.S., but they are responsible for only 7% of medical office visits. As a result, primary care providers have relatively less opportunity to evaluate and counsel adolescents in their offices than most other patients. Even when adolescents receive routine health care, open communication with their health care providers may be problematic. A national survey found that the majority of adolescent boys and girls in the U.S. report at least 1 of 8 potential health risks, but most (63%) had not spoken to their doctor about any of these (Klein & Wilson, 2002). Improved engagement and communication between adolescents and their primary care providers could increase the likelihood that effective preventive services and health care are provided. It could also improve the efficiency of health care services for adolescents, in terms of appointments kept and adherence to recommended screening or treatment recommendations.

Technological interventions to improve care may be particularly appropriate for adolescents, since they are typically the early adopters of new technology (Skinner, Biscope, Poland, & Goldberg, 2003). Use of in-office electronic screeners before appointments has proven useful (Olson, Gaffney, Lee, & Star 2008; Salerno, 2008; Yi, Martyn, Salerno, & Darling-Fisher, 2009). Outside of the office, youth have increasingly turned to the internet for health-related information, and have also rapidly adopted mobile technology (Lenhart, Ling, Campbell, & Purcell, 2010) and social media (Lenhart, Purcell, Smith, & Zickuhr, 2010). Health plans (*e.g.*, Kaiser Permanente) and practices (Hawn, 2009) have conducted early work in applying patient-centered web and mobile technologies. These projects have included interventions to decrease patient no-show rates, increase the use of sunscreen, and engage adolescents in diabetes management. Much work remains to be done,

however, in understanding how primary care practices can best embrace advances in communications and information technology to improve health outcomes for adolescent patients.

This project has the following goals:

- (1) Explore the benefits of supplementing an electronic in-office pre-visit screener with a set of web technologies for adolescent outreach and engagement outside of office visits.
 - a. The Rapid Assessment for Adolescent Preventive Services © (RAAPS), as described below, will be used for in-office pre-visit screening
 - b. The web technologies will include
 - (i) a web page for more static content such as information about practices and health-related commentary from practice clinicians and staff, (ii) a Facebook page for social interaction about health topics including topical content that will engage adolescents in conversations about general, not personal, health behaviors and encouraging youth to discuss these issues with their primary care practitioners at clinic visits, and (iii) a Twitter site that will allow youth to use mobile phones with text messaging to subscribe to Facebook posts.
- (2) Increase adolescent visits to primary care and identification of health risks during visits
- (3) Promote healthier behavior in four domains: (1) Diet, (2) physical activity, (3) substance abuse (smoking, alcohol, and use of other recreational drugs), and (4) sexual health
- (4) Develop a manual of best practices for these components in primary care.

This study is being conducted by AHRQ through its contractor, State Network of Colorado Ambulatory Practices and Partners (SNOCAP–USA), a practice-based research network (PBRN) based at the University of Colorado Denver, pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare services and with respect to clinical practice, including primary care and practice-oriented research. 42 U.S.C. 299a(a)(1) and (4).

Method of Collection

This project will be conducted in four primary care practice sites that have a substantial number of adolescent patients. The following activities and data collections will be implemented:

- (1) RAAPS questionnaire. Practices will use the 21-item RAAPS questionnaire for in-office pre-visit screening. RAAPS was developed by the

University of Michigan Regional Alliance for Healthy Schools to elicit information about risky adolescent behaviors that should be addressed, but often are missed, in primary care. It is available in both paper and online forms; the latter will be used in this project. The primary purpose of the RAAPS questionnaire is to improve clinical recognition of risky behaviors so that personal counseling may be provided.

- (2) Process measures for web technologies. For each of the web technologies used (the web page, Facebook page, and Twitter site), data on the number of unique visitors, the frequency of their visits, and their activities (*e.g.* whether they create a new post or "like" postings) will be obtained by the research team. These data will not include personally identifiable information (*e.g.* the user's username, birth date, IP address, *etc.*). OMB clearance is not required for this data collection.

- (3) Extraction of medical record data. Staff members at each practice will use their clinical information systems to extract medical record data for use by the research team. Data to be extracted consist of (a) Contact information for patients seen in the 18 months prior to the start date for implementation of RAAPS and the web technologies. This is the sample frame for the adolescent behavior and communication survey. These data will be used by the project staff to prepare the recruitment mailings. (b) Clinic notes for adolescents seen in the 12 months prior to implementation start date and for adolescents seen in the 12 months following the implementation start date. Clinic notes will be made accessible either by pulling paper charts or printing notes from electronic medical records. The notes will be reviewed and abstracted by the research team to assess whether the intervention had the intended effect of increasing adolescent visits to primary care and the identification of potential health risks during visits.

- (4) Consent-assent form. This is used to obtain consent from the parent or guardian and assent from the adolescent to participate in the adolescent behavior and communication survey.

- (5) Adolescent behavior and communication survey. A questionnaire (by mail, with an online option) will be administered twice to adolescent patients for whom consent-assent has been obtained: Once at baseline and again six months after the intervention. The purpose of this survey is to measure the adolescent's level of comfort with discussing their health with their

clinician and their level of satisfaction with their medical care, and to see how this changes after the intervention.

(6) Post-visit satisfaction survey. Practices will provide adolescents with a brief, post-card sized anonymous questionnaire at every office visit during the study period. The purpose is to assess the perceived utility of the RAAPS questionnaire, and whether the visit was related to the project’s web technologies.

(7) Adolescent focus groups. Eight adolescents (two from each practice) will provide feedback on the web page, Facebook, and Twitter pages. There will be one in-person group meeting preimplementation, followed by a series of 3 additional asynchronous group discussions conducted via the web at three-month intervals. These provide a process for user-centered design and refinement of the of web technologies.

(8) Adolescent “think-aloud” sessions. These sessions, which will be conducted near the end of the study period, will involve a set of eight adolescent patients (two from each practice) that did not participate in the focus groups. Subjects will come to the practice for individual sessions in which they will be asked to say aloud what they are thinking about the Web technologies as they navigate them as they typically would. The purpose is to assess the perceived utility of the components of the Web, Facebook, and Twitter pages.

(9) Clinician semi-structured interviews. At each site, individual interviews will be conducted with two clinicians (eight clinicians total). The purpose is to assess clinician perceptions of the effects of the RAAPS questionnaire and the Web technologies on the clinical encounter and the care they provide.

(10) Administrator-staff semi-structured interviews. At each site, semi-structured interviews will be conducted with the practice manager and a front-desk staff member. The purpose is to assess the effect of the interventions on the check in process and other business processes.

(11) Semi-structured interviews for the draft manual. The draft manual of best practices in primary care for adoption of Web and assessment technologies (such as the RAAPS questionnaire) developed by the research team will be sent to the practice manager and the practice director (lead clinician) of each site. Their feedback will be solicited by telephone roughly two weeks later. This “member checking” enhances the validity of the manual’s conclusions and recommendations.

The results from this exploratory project will be used to inform development of a manual to assist primary care practices in adopting interventions to improve the effectiveness of their outreach to and interactions with adolescent patients. In addition, information collected in the RAAPS questionnaire may be used by clinicians to improve clinical care.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents’ time to participate in this research. Among the 776 adolescent patients across the 4 participating practices, 310 are expected to complete the RAAPS questionnaire, which takes about 15 minutes to complete, at each office visit (on average there will be an estimated 1.25 office visits per patient). Practice staff members will perform the extraction of medical record data pre-implementation, and again post-

implementation, for 50 patients. This task is estimated to require 4 hours per practice (slightly less than 5 minutes per patient record).

The consent-assent form for participation in the adolescent behavior and communication survey will be sent to the homes of all adolescents in the practice’s panels. The estimated average time for reading and responding to the form is 15 minutes. The adolescent behavior and communication survey will be completed twice, pre- and post-intervention, by 233 adolescent patients and requires 15 minutes to complete. The post-visit satisfaction survey will be completed by each of the 310 participating adolescent patients after each office visit and will take 5 minutes to complete.

A series of four focus groups will be held with 8 adolescent patients over the course of the study period with each session lasting about 1.5 hours. In addition to the focus groups one “think-aloud” session will be held with a group of 8 adolescent patients and will also take 1.5 hours.

Feedback from the practice staff and the clinicians will be obtained through 3 different semi-structured interviews. Two staff members from each of the 4 practices will participate in these interviews. The clinician and administrator-staff semi-structured interviews will each last 30 minutes. Semi-structured interviews for the draft manual will require about one hour total (30 minutes to review the manual and 30 minutes to participate in the interview). The total annualized burden is estimated to be 548 hours.

Exhibit 2 shows the estimated annualized cost burden associated with the respondents’ time to participate in this research. The total annual cost burden is estimated to be \$8,601.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Activity/data collection	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
RAAPS questionnaire	310	1.25	15/60	97
Extraction of medical record data	4	2	4	32
Consent-assent form	776	1	15/60	194
Adolescent behavior and communication survey	233	2	15/60	117
Post-visit satisfaction survey	310	1.25	5/60	32
Adolescent focus groups	8	4	1.5	48
Adolescent “think-aloud” sessions	8	1	1.5	12
Clinician semi-structured interviews	4	2	30/60	4
Administrator-staff semi-structured interviews	4	2	30/60	4
Semi-structured interviews for the draft manual	4	2	1	8
Total	1,661	na	na	548

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Activity/data collection	Number of respondents	Total burden hours	Average hourly wage rate ¹	Total cost burden
RAAPS questionnaire	310	97	\$9.01 ²	\$874
Extraction of medical record data	4	32	18.15 ³	581
Consent-assent form	776	194	22.11 ⁴	4,289
Adolescent behavior and communication survey	233	117	9.01 ²	1,054
Post-visit satisfaction survey	310	32	9.01 ²	288
Adolescent focus groups	8	48	9.01 ²	432
Adolescent “think-aloud” sessions	8	12	9.01 ²	108
Clinician semi-structured interviews	4	4	84.53 ⁵	338
Administrator-staff semi-structured interviews	4	4	29.63 ⁶	119
Semi-structured interviews for the draft manual	4	8	64.75 ⁷	518
Total	1,661	548	na	8,601

¹ Mean hourly and wage costs for Colorado were derived from the Bureau of Labor and Statistics National Compensation Survey for May 2009 (http://www.bls.gov/oes/current/oes_co.htm).

² Hourly rate for an entry level worker (occupation code 3 5–0000) estimates the cost of time for adolescents, although many will not be employed.

³ Hourly rate for medical records and health information technician (29–2071).

⁴ Hourly rate for the mean for all occupations (00–0000) estimates the cost of time for the parent or guardian of the adolescent.

⁵ Average of hourly rates for a family medicine practitioner (29–1062) and a general internist (29–1063).

⁶ Average of (1) the hourly rate for a medical and health services manager (11–9111) and (2) the average of the hourly rates for a receptionist (43–4171) and a medical assistant (31–9092).

⁷ Average of (1) the hourly rate for a medical and health services manager (11–9110) and (2) the average of the hourly rates for a family medicine practitioner (29–1062) and a general internist (29–1063).

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the estimated total and annualized cost to the Federal Government for conducting this

research. These estimates include the costs associated with the project such as the preparation of survey administration procedures, labor costs, administrative expenses, costs associated with copying, postage, and telephone expenses, data

management and analysis, and preparation of final reports. The annualized and total costs are identical since the data collection period will last for one year. The total cost is estimated to be \$436,524.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

Cost component	Total cost	Annualized cost
Project Development	\$72,364	\$72,364
Data Collection Activities	48,904	48,904
Data Processing and Analysis	73,937	73,937
Publication of Results	21,890	21,890
Project Management	75,733	75,733
Overhead	143,696	143,696
Total	436,524	436,524

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ’s information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ’s estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of

automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency’s subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: January 4, 2011.
Carolyn M. Clancy,
Director.
 [FR Doc. 2011–408 Filed 1–12–11; 8:45 am]
BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–11–0338]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington,

DC or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Annual Submission of the Ingredients Added to, and the Quantity of Nicotine Contained in, Smokeless Tobacco Manufactured, Imported, or Packaged in the U.S. (OMB No. 0920-0338, exp. 4/30/2011)—Extension—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC), Office on Smoking and Health (OSH) has the primary responsibility for the Department of Health and Human Services (HHS) smoking and health program. HHS's overall goal is to reduce death and disability resulting from the use of smokeless tobacco products and other forms of tobacco use through programs of information, education and research.

Since 1994, as required by the Comprehensive Smokeless Tobacco Education Act of 1986 (CSTHEA, 15 U.S.C. 4401 *et seq.*, Pub. L. 99-252), CDC has collected information about the ingredients used in smokeless tobacco products and their nicotine content. Respondents are commercial smokeless tobacco product manufacturers, packagers, or importers (or their representatives), who are required by the CSTHEA to submit ingredient reports to HHS on an annual basis.

Respondents are not required to submit specific forms; however, they are required to meet reporting guidelines and to submit the ingredient report by chemical name and Chemical Abstract Service (CAS) Registration Number, consistent with accepted reporting practices for other companies currently required to report ingredients added to other consumer products. Typically, respondents submit a summary report to CDC with the ingredient information for multiple products, or a statement that

there are no changes to their previously submitted ingredient report.

Ingredient reports for new products are due at the time of first importation. Thereafter, ingredient reports are due annually on March 31. Information is submitted to OSH by mailing a written report on the respondent's letterhead, by CD, three-inch floppy disk, or thumb drive. Electronic mail submissions are not accepted.

Upon receipt and verification of the annual ingredient and nicotine data reports, OSH issues a Certificate of Compliance to the respondent. OSH also uses the information to report to the Congress (as deemed appropriate) discussing the health effects of these ingredients.

In this Extension request, there no changes to the estimated number of respondents, the estimated burden per response, or the information collection methods. There are no costs to respondents other than their time. The total estimated annualized burden hours are 18,843.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Smokeless Tobacco Manufacturers, Packagers, and Importers	11	1	1,713

Dated: January 6, 2011.
Carol E. Walker,
Acting Reports Clearance Officer, Centers for Disease Control and Prevention.
 [FR Doc. 2011-470 Filed 1-12-11; 8:45 am]
BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Evaluation of the Head Start Safe Families Safe Homes Training Curriculum.

OMB No.: New Collection.
Description: The purpose of this collection is to examine the implementation of the Head Start Safe Families Safe Homes domestic violence training curriculum. The Office of Head Start, within the Administration for Children and Families (ACF) of the Department of Health and Human Services (HHS), is partnering with the Division of Family Violence Prevention of the Family and Youth Services Bureau of the Administration on Children, Youth and Families, also located within ACF, in an effort to expand the knowledge base of Head Start staff and build stronger partnerships with domestic violence service providers in local communities.

Teams of trainers in each of five states will lead training sessions for 50 participants. The follow-up evaluation will examine implementation of the training curriculum; changes in participant knowledge and changes in communication; collaboration; and service delivery related to domestic violence. All participants in the local trainings will be asked to complete several brief surveys, which will be conducted online or by phone. A subsample of participants will also be asked to complete a semi-structured phone interview.

Respondents: Head Start staff.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Knowledge of Domestic Violence Survey	250	1	.25	63
Collaboration Quality Survey	250	1	.25	63
Services & Referrals Survey	250	1	.125	31
Domestic Violence Knowledge, Attitudes, and Practices: Semi-Structured Interview	20	1	.5	10

Estimated Total Annual Burden Hours: 167.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, ACE is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Office of Planning, Research and Evaluation, ACE, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. *E-mail address:*

OPREinfocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments 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; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: January 6, 2011.

Steven M. Hanmer,

Reports Clearance Officer.

[FR Doc. 2011-412 Filed 1-12-11; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0019]

Agency Information Collection Activities; Proposed Collection; Comment Request; Customer/Partner Service Surveys

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the

Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on voluntary customer satisfaction service surveys to implement Executive Order 12862.

DATES: Submit either electronic or written comments on the collection of information by March 14, 2011.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3794, Jonnalynn.capezzuto@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether

the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Customer/Partner Service Surveys (OMB Control Number 0910-0360)—Extension

Under section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393), FDA is authorized to conduct research and public information programs about regulated products and responsibilities of the agency. Executive Order 12862, entitled, "Setting Customer Service Standard," directs Federal agencies that "provide significant services directly to the public" to "survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services." FDA is seeking OMB clearance to conduct a series of surveys to implement Executive Order 12862. Participation in the surveys is voluntary. This request covers customer/partner service surveys of regulated entities, such as food processors; cosmetic drug, biologic and medical device manufacturers; consumers; and health professionals. The request also covers "partner" (State and local governments) customer service surveys.

FDA will use the information from these surveys to identify strengths and weaknesses in service to customers/partners and to make improvements. The surveys will measure timeliness, appropriateness and accuracy of information, courtesy and problem resolution in the context of individual programs.

FDA estimates conducting 15 customer/partner service surveys per year, each requiring an average of 15 minutes for review and completion. We estimate respondents to these surveys to be between 100 and 10,000 customers. Some of these surveys will be repeats of earlier surveys for purposes of monitoring customer/partner service and developing long-term data.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Type of survey	Number of respondents	Annual frequency per response	Hours per response	Total hours
Mail, telephone, web-based	20,000	1	0.25	5,000

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 7, 2011.
Leslie Kux,
Acting Assistant Commissioner for Policy.
 [FR Doc. 2011-532 Filed 1-12-11; 8:45 am]
BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0016]

Agency Information Collection Activities; Proposed Collection; Comment Request; Recordkeeping and Records Access Requirements for Food Facilities

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection provisions of FDA's recordkeeping and records access requirements for food facilities.

DATES: Submit either electronic or written comments on the collection of information by March 14, 2011.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Recordkeeping and Records Access Requirements for Food Facilities—21 CFR 1.337, 1.345, and 1.352 (OMB Control Number 0910-0560)—Extension

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) added section 414 of the Federal Food, Drug, and Cosmetic Act (the FD & C Act) (21 U.S.C. 350c), which requires that persons who manufacture, process, pack, hold, receive, distribute, transport, or import food in the United States establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food. Sections 1.326 to 1.363 (21 CFR 1.326 to 1.363) of FDA's regulations set forth the requirements for recordkeeping and records access. The requirement to establish and maintain records improves FDA's ability to respond to, and further contain, threats of serious adverse health consequences or death to humans or animals from accidental or deliberate contamination of food.

Description of respondents: Persons that manufacture, process, pack, hold, receive, distribute, transport, or import food in the United States are required to establish and maintain records, including persons that engage in both interstate and intrastate commerce.

FDA's regulations require that records for nontransporters include the name and full contact information of sources, recipients, and transporters, an adequate description of the food, including the quantity and packaging, and the receipt and shipping dates (§§ 1.337 and 1.345). Required records for transporters include the names of consignor and consignee, points of origin and destination, date of shipment, number of packages, description of freight, route of movement and name of each carrier participating in the transportation, and transfer points through which shipment moved (§ 1.352). Existing records may be used if they contain all of the required information and are retained for the required time period.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR section	Number of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
1.337, 1.345, and 1.352 (Records maintenance)	379,493	1	379,493	13.228	5,020,000
1.337, 1.345, and 1.352 (Learning for new firms)	18,975	1	18,975	4.790	90,890
Total					5,110,890

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

This estimate is based on FDA's estimate of the number of facilities affected by the final rule entitled "Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002," published in the **Federal Register** of December 9, 2004 (69 FR 71562 at 71630). With regard to records maintenance, FDA estimates that approximately 379,493 facilities will spend 13.228 hours collecting, recording, and checking for accuracy the limited amount of additional information required by the regulations, for a total of 5,020,000 hours annually. In addition, FDA estimates that new firms entering the affected businesses will incur a burden from learning the regulatory requirements and understanding the records required for compliance. In this regard, the Agency estimates the number of new firms entering the affected businesses to be 5 percent (5%) of 379,493, or 18,975 firms. Thus, FDA estimates that approximately 18,975 facilities will spend 4.790 hours learning about the recordkeeping and records access requirements, for a total of 90,890 hours annually. Therefore, the total annual recordkeeping burden is estimated to be 5,110,890 hours.

Dated: January 10, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-592 Filed 1-12-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Menthol Report Subcommittee of the Tobacco Products Scientific Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee

of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Menthol Report Subcommittee of the Tobacco Products Scientific Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 11, 2011, from 9 a.m. to 5 p.m.

Location: Center for Tobacco Products, 9200 Corporate Blvd, Rockville, MD, 20850. The telephone number is 1-877-287-1373.

Contact Person: Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd, Rockville, MD 20850, 1-877-287-1373 (choose Option 4), e-mail: TPSAC@fda.hhs.gov or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On February 11, 2011, the subcommittee will receive presentations and discuss the timelines and structure of the Tobacco Products Scientific Advisory Committee's required report to the Secretary of Health and Human Services regarding the impact of use of menthol in cigarettes on the public health.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee

meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before January 28, 2011. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon on February 11, 2011. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 20, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 21, 2011.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Caryn Cohen at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/>

ucm111462.htm for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 6, 2011.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011-635 Filed 1-12-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Tobacco Products Scientific Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Tobacco Products Scientific Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 10, 2011, from 8 a.m. until 5 p.m.

Location: Center for Tobacco Products, 9200 Corporate Blvd., Rockville, MD 20850. The phone number is 1-877-287-1373.

Contact Person: Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1-877-287-1373 (choose Option 4), e-mail: TPSAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On February 10, 2011, the Committee will continue to do the following: (1) Receive updates from the Menthol Report Subcommittee and (2) receive and discuss presentations regarding the data requested by the Committee at the March 30 through 31, 2010, meeting of the Tobacco Products Scientific Advisory Committee.

FDA intends to make redacted background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: On February 10, 2011, from 1 p.m. to 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before January 27, 2011. Oral presentations from the public will be scheduled between approximately 3 p.m. and 4 p.m. on February 10, 2011. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 19, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 20, 2011.

Closed Committee Deliberations: On January 10, 2011, from 9 a.m. to 12 noon, the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)). This portion of the meeting must be closed because the Committee will be discussing trade secret and/or confidential data provided by the Federal Trade Commission and the tobacco industry.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Caryn Cohen at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 10, 2011.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011-634 Filed 1-12-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; California Health Interview Survey Cancer Control Module (CHIS-CCM) 2011 (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on November 15, 2010 (75 FR 69681) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health 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.

Proposed Collection: Title: California Health Interview Survey Cancer Control Module (CHIS-CCM) 2011. *Type of*

Information Collection Request: Revision. *Need and Use of Information Collection:* The NCI has sponsored four Cancer Control Modules in the California Health Interview Survey (CHIS), and will be sponsoring a sixth to be administered in 2011. CHIS is a telephone survey that collects population-based, standardized health-related data to assess California's progress in meeting Healthy People 2010 objectives for the nation and the State. The CHIS sample is designed to provide statistically reliable estimates statewide, for California counties, and for California's ethnically and racially diverse population. Initiated by the UCLA Center for Health Policy

Research, the California Department of Health Services, and the California Public Health Institute, the survey is funded by a number of public and private sources. It was first administered in 2001 to 55,428 adults and subsequently in 2003 to 42,043 adults, in 2005 to 43,020 adults, and in 2007 to 48,150 adults. These adults are a representative sample of California's non-institutionalized population living in households. CHIS 2011 is planned for continual administration to 48,000 adult Californians. This study will allow NCI to examine patterns and trends in cancer screening and follow-up, as well as to study other cancer-related topics such as tobacco control, diet, physical

activity, obesity, and human papillomavirus. Additionally, CHIS is designed to be comparable to the National Health Interview Survey (NHIS) data in order to conduct comparative analyses. CHIS provides enhanced estimates for cancer risk factors and screening among racial/ethnic minority populations. *Frequency of Response:* Once. *Affected public:* Individuals. *Types of Respondents:* U.S. adults and adolescents (persons 12 years of age and older). The total annual burden hours requested are 2,177 (see Table 1). There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

TABLE 1—ESTIMATES OF ANNUALIZED HOUR BURDEN

Type of respondent	Form type	Number of respondents	Frequency of response	Average time per response (hours)	Annual hour burden
Adults	Adult Pilot	50	1	8/60	6.67
	Adult Survey	16,000	1	8/60	2,133.33
Adolescents	Adolescent Pilot	6	1	2/60	.20
	Adolescent Survey	1,100	1	2/60	36.67
Total		17,156			2,176.87

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proposed performance of the function 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 collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Attention: NIH Desk Officer, Office of Management and Budget, at *OIRA_submission@omb.eop.gov* or by fax to 202-395-6974. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Nancy Breen, Ph.D., Project Officer, National

Cancer Institute, EPN 4005, 6130 Executive Boulevard MSC 7344, Bethesda, Maryland 20852-7344, or call non-toll free number 301-496-4675 or e-mail your request, including your address to: *breen@mail.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: January 9, 2011.

Vivian Horovitch-Kelley,
NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2011-661 Filed 1-12-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial

property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Motor Function, Speech and Rehabilitation.

Date: January 28, 2011.

Time: 2 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call.)

Contact Person: Dana Jeffrey Plude, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3176, MSC 7848, Bethesda, MD 20892. 301-435-2309. *pluded@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Biological Chemistry and Macromolecular Biophysics.

Date: February 2-3, 2011.

Time: 11 a.m. to 10 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting.)

Contact Person: Donald L. Schneider, PhD, Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5160, MSC 7842, Bethesda, MD 20892. (301) 435-1727. schneidd@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Selected Topics in Transfusion Medicine.

Date: February 7–8, 2011.

Time: 11 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting.)

Contact Person: Bukhtiar H. Shah, DVM, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4120, MSC 7802, Bethesda, MD 20892. (301) 301 806–7314. shahb@csr.nih.gov.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group, Cellular Aspects of Diabetes and Obesity Study Section.

Date: February 10–11, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Robert Garofalo, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6156, MSC 7892, Bethesda, MD 20892. 301–435–1043. garofalors@csr.nih.gov.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group, Neurotransmitters, Receptors, and Calcium Signaling Study Section.

Date: February 10, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn San Francisco Fisherman's Wharf, 1300 Columbus Avenue, San Francisco, CA 94133.

Contact Person: Peter B Guthrie, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4182, MSC 7850, Bethesda, MD 20892. (301) 435–1239. guthriep@csr.nih.gov.

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group, Gastrointestinal Mucosal Pathobiology Study Section.

Date: February 10, 2011.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Peter J Perrin, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2180, MSC 7818, Bethesda, MD 20892. (301) 435–0682. perrinp@csr.nih.gov.

Name of Committee: Vascular and Hematology Integrated Review Group, Hypertension and Microcirculation Study Section.

Date: February 10–11, 2011.

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Mayflower Hotel, 1127 Connecticut Avenue, NW., Washington, DC 20036.

Contact Person: Ai-Ping Zou, MD, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892. 301–435–1777. zouai@csr.nih.gov.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group, Electrical Signaling, Ion Transport, and Arrhythmias Study Section.

Date: February 10, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westin Long Beach Hotel, 333 East Ocean Boulevard, Long Beach, CA 90802.

Contact Person: Lawrence E Boerboom, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4130, MSC 7814, Bethesda, MD 20892. (301) 435–8367. boerboom@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, PAR–10–169: Academic Industrial Partnerships.

Date: February 10, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Crowne Plaza International Airport Hotel, 5985 Century Boulevard, Los Angeles, CA 90045.

Contact Person: Antonio Sastre, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5215, MSC 7412, Bethesda, MD 20892. (301) 435–2592. sastrea@csr.nih.gov.

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group, Clinical Research and Field Studies of Infectious Diseases Study Section.

Date: February 10–11, 2011.

Time: 8 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: Marina del Rey Hotel, 1354 Bali Way, Marina del Rey, CA 90292.

Contact Person: Soheyla Saadi, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3211, MSC 7808, Bethesda, MD 20892. (301) 435–0903. saadisoh@csr.nih.gov.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group, Infectious Diseases, Reproductive Health, Asthma and Pulmonary Conditions Study Section.

Date: February 10–11, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Guest Suites Santa Monica, 1707 Fourth Street, Santa Monica, CA 90401.

Contact Person: Valerie Durrant, PhD, Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3148, MSC 7770, Bethesda, MD 20892. (301) 827–6390. durravn@csr.nih.gov.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group, Clinical Neuroscience and Neurodegeneration Study Section.

Date: February 10–11, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westin St. Francis, 335 Powell Street, San Francisco, CA 94102.

Contact Person: Samuel C Edwards, PhD, Chief, Brain Disorders and Clinical Neuroscience, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892. (301) 435–1246. edwardss@csr.nih.gov.

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group, Biostatistical Methods and Research Design Study Section.

Date: February 10–11, 2011.

Time: 8 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance M Street Hotel, 1143 New Hampshire Avenue, NW., Washington, DC 20037.

Contact Person: Tomas Drgon, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3152, MSC 7770, Bethesda, MD 20892. (301) 435–1017. tdrgon@csr.nih.gov.

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group, Pathobiology of Kidney Disease Study Section.

Date: February 10–11, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Atul Sahai, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2188, MSC 7818, Bethesda, MD 20892. (301) 435–1198. sahaia@csr.nih.gov.

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group, Genetic Variation and Evolution Study Section.

Date: February 10–11, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The River Inn, 924 25th Street, NW., Washington, DC 20037.

Contact Person: Cheryl M Corsaro, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2204, MSC 7890, Bethesda, MD 20892. (301) 435–1045. corsaroc@csr.nih.gov.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group, Neural Oxidative Metabolism and Death Study Section.

Date: February 10, 2011.

Time: 8 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westin St. Francis, 335 Powell Street, San Francisco, CA 94102.

Contact Person: Carol Hamelink, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7850, Bethesda, MD 20892. (301) 213-9887. hamelinc@csr.nih.gov.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group, Cellular and Molecular Biology of Glia Study Section.

Date: February 10, 2011.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westin St. Francis, 335 Powell Street, San Francisco, CA 94102.

Contact Person: Toby Behar, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4136, MSC 7850, Bethesda, MD 20892. (301) 435-4433. behart@csr.nih.gov.

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group, Synthetic and Biological Chemistry A Study Section.

Date: February 10–11, 2011.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Palomar Hotel, 2121 P Street, NW., Washington, DC 20037.

Contact Person: Mike Radtke, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4176, MSC 7806, Bethesda, MD 20892. 301-435-1728. rادتke@csr.nih.gov.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group, Cardiovascular and Sleep Epidemiology Study Section.

Date: February 10–11, 2011.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: J Scott Osborne, PhD, MPH, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4114, MSC 7816, Bethesda, MD 20892. (301) 435-1782. osbornes@csr.nih.gov.

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group, Genetics of Health and Disease Study Section.

Date: February 10–11, 2011.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Richard Panniers, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2212, MSC 7890, Bethesda, MD 20892. (301) 435-1741. pannierr@csr.nih.gov.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review

Group, Cognition and Perception Study Section.

Date: February 10–11, 2011.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Sir Francis Drake Hotel, 450 Powell Street at Sutter, San Francisco, CA 94102.

Contact Person: Dana Jeffrey Plude, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3176, MSC 7848, Bethesda, MD 20892. (301) 435-2309. pluded@csr.nih.gov.

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group, Dissemination and Implementation Research in Health Study Section.

Date: February 10, 2011.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance M Street Hotel, 1143 New Hampshire Avenue, NW., Washington, DC 20037.

Contact Person: Jacinta Bronte-Tinkew, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3164, MSC 7770, Bethesda, MD 20892. (301) 806-0009. brontetinkewjm@csr.nih.gov.

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group, Virology—B Study Section.

Date: February 10–11, 2011.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street, NW., Washington, DC 20036.

Contact Person: John C Pugh, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1206, MSC 7808, Bethesda, MD 20892. (301) 435-2398. pughjohn@csr.nih.gov.

Names of Committee: Center for Scientific Review Special Emphasis Panel, Cellular Physiology Studies.

Date: February 10–11, 2011.

Time: 11 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting.)

Contact Person: Raya Mandler, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217, MSC 7840, Bethesda, MD 20892. 301-402-8228. rayam@csr.nih.gov.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group, Musculoskeletal Rehabilitation Sciences Study Section.

Date: February 10–11, 2011.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westin Long Beach, 333 East Ocean Boulevard, Long Beach, CA 90802.

Contact Person: Jo Pelham, BA, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge

Drive, Room 4102, MSC 7814, Bethesda, MD 20892. (301) 435-1786. pelham@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 7, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-629 Filed 1-12-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel. Mentoring Networks to Enhance Diversity.

Date: February 9, 2011.

Time: 12 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call).

Contact Person: Megan Libbey, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6148, MSC 9609, Rockville, MD 20852-9609. 301-402-6807. libbeym@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel. Treatment Development for Eating Disorders.

Date: March 1, 2011.

Time: 2:30 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call).

Contact Person: David I. Sommers, PhD, Scientific Review Officer, Division of

Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Room 6154, MSC 9606, Bethesda, MD 20892-9606. 301-443-7861. dsommers@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: January 6, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-628 Filed 1-12-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these

documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Project: Emergency Response Grants Regulations—42 CFR part 51—(OMB No. 0930-0229)—Extension

This rule implements section 501(m) of the Public Health Service Act (42 U.S.C. 290aa), which authorizes the Secretary to make noncompetitive grants, contracts or cooperative agreements to public entities to enable such entities to address emergency substance abuse or mental health needs in local communities. The rule establishes criteria for determining that a substance abuse or mental health emergency exists, the minimum content for an application, and reporting requirements for recipients of such funding. SAMHSA will use the information in the applications to make a determination that the requisite need exists; that the mental health and/or substance abuse needs are a direct result of the precipitating event; that no other local, State, Tribal or Federal funding are sources available to address the need; that there is an adequate plan of services; that the applicant has appropriate organizational capability; and, that the budget provides sufficient justification and is consistent with the documentation of need and the plan of services. Eligible applicants may apply to the Secretary for either of two types of substance abuse and mental health emergency response grants: Immediate

awards and Intermediate awards. The former are designed to be funded up to \$50,000, or such greater amount as determined by the Secretary on a case-by-case basis, and are to be used over the initial 90-day period commencing as soon as possible after the precipitating event; the latter awards require more documentation, including a needs assessment, other data and related budgetary detail. The Intermediate awards have no predefined budget limit. Typically, Intermediate awards would be used to meet systemic mental health and/or substance abuse needs during the recovery period following the Immediate award period. Such awards may be used for up to one year, with a possible second year supplement based on submission of additional required information and data. This program is an approved user of the PHS-5161 application form, approved by OMB under control number 0920-0428. The quarterly financial status reports in 51d.10(a)(2) and (b)(2) are as permitted by 45 CFR 92.41(b); the final program report, financial status report and final voucher in 51d.10(a)(3) and in 51d.10(b)(3-4) are in accordance with 45 CFR 92.50(b). Information collection requirements of 45 CFR part 92 are approved by OMB under control number 0990-0169. The following table presents annual burden estimates for the information collection requirements of this regulation.

42 CFR citation	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Immediate award application:				
51d.4(a) and 51d.6(a)(2)	3	1	3	9*
51d.4(b) and 51d.6(a)(2)				
Immediate Awards	3	1	10	30*
51d.10(a)(1)-Immediate awards- mid-program report if applicable	3	1	2	6*
Final report content for both types of awards:				
51d.10(c)	6	1	3	18
Total	6			18

* This burden is carried under OMB No. 0920-0428.

Written comments and recommendations concerning the proposed information collection should be sent by February 14, 2011 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202-395-6974.

Dated: January 5, 2010.

Elaine Parry

Director, Office of Management, Technology and Operations.

[FR Doc. 2011-685 Filed 1-12-11; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2009-0384]

Maritime Security Directive 104-6 (Rev 5); Guidelines for U.S. Vessels Operating in High Risk Waters

AGENCY: Coast Guard, DHS.

ACTION: Notice of Availability.

SUMMARY: The Coast Guard announces the release of Maritime Security

(MARSEC) Directive 104-6 (Rev 5). This Directive only applies to U.S. flagged vessels subject to the Maritime Transportation Security Act (MTSA) on international voyages through or in designated high risk waters, and provides additional counter-piracy guidance and mandatory measures for these vessels operating in these areas where acts of piracy and armed robbery against ships are prevalent. MARSEC Directive 104-6 (Rev 5) also includes an annex that provides specific direction for vessels operating around the Horn of Africa. MARSEC Directives are designated Sensitive Security Information (SSI) and are not subject to public release.

DATES: MARSEC Directive 104-6 (Rev 5) is available on January 13, 2011. MARSEC Directive 104-6 (Rev 4) is no longer valid after this date.

ADDRESSES: The latest MARSEC Directives are available at your local Captain of the Port (COTP) office. Phone numbers and addresses for your local COTP office can be found in the Port Directory at <http://homeport.uscg.mil>.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call LCDR James T. Fogle, Office of Vessel Activities, Coast Guard, telephone 202-372-1038, e-mail James.T.Fogle@uscg.mil. If you have questions on viewing material on the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Background and Purpose

Somali pirates operate along a 2,300 mile coast and in 2.5 million square miles of ocean. Given the size and complexity of the affected area, a combination of domestic and international efforts has been necessary to curb piratical activities. The combination of piracy and weak rule of law in the region offers a potential breeding ground for other transnational threats. Accordingly, the U.S. uses existing statutory authority to develop security standards designed to protect U.S.-flagged vessels and continues to work with international partners to prevent piracy.

On February 10, 2006, the Coast Guard announced the release of MARSEC Directive 104-6 (71 FR 7054) for those owners and operators of vessels subject to 33 CFR parts 101 and 104 to provide direction to U.S. flagged vessels operating in high risk areas where acts of piracy and armed robbery against ships is prevalent.

MARSEC Directive 104-6 has been revised five times. MARSEC Directive

104-6 (REV 1) provided an updated list of the high risk waters based on a biennial review of global piracy and terrorism threats.

MARSEC Directive 104-6 (Rev 2) provided additional counter-piracy guidance to U.S. flagged vessels operating in high risk waters where acts of piracy and armed robbery against ships are prevalent. It also provided a listing of additional high risk waters, updated from the previous version of the Directive.

MARSEC Directive 104-6 (Rev 3) encouraged the use of industry best management practices that have proven to be successful in thwarting pirate attacks and incorporates lessons-learned since the issuance of Revision 2.

MARSEC Directive 104-6 (Rev 4) provided clarification for U.S. flagged vessels berthed or anchored in high risk waters. Vessels at anchor should operate in a manner consistent with vessels that transit through high risk waters. Whether at anchor or underway, the vessels are subjected to the same type of threats from attacking pirates. Vessels berthed in high risk waters should implement enhanced security measures as described in the MARSEC Directive.

MARSEC Directive 104-6 (Rev 5), the Directive that is the subject of this notice of availability, addresses the expanding operating area of Somali pirates and provides U.S. flagged vessels additional guidance for operations in the Indian Ocean. With the issuance of (Rev 5), MARSEC Directive 104-6 (Rev 4) is no longer valid.

To support the issuance of MARSEC Directive 104-6 (series), we developed piracy-related Port Security Advisories (PSAs) to provide further guidance and direction to U.S. flagged vessels operating in high risk waters to help facilitate compliance with this directive. The PSAs can be found at <http://homeport.uscg.mil/piracy>, including a non-SSI version of this MARSEC Directive in PSA (2-09) (Rev 3).

Procedural

COTPs and District Commanders can access all MARSEC directives on Homeport by logging in and going to Missions > Maritime Security > Maritime Transportation Security Act (MTSA) > Policy. Owners and operators of U.S. flagged vessels that travel on international voyages must contact their local COTP, cognizant District Commander or the Office of Vessel Activities to acquire a copy of MARSEC Directive 104-6 (Rev 5). COTPs or cognizant District Commanders may provide this MARSEC Directive to appropriate vessel owners and operators

via mail or fax in accordance with SSI handling procedures.

Pursuant to 33 CFR 101.405, we consulted with the Department of State, Office of the Secretary of Defense, Joint Chiefs of Staff, Department of Transportation/Maritime Administration, Office of Naval Intelligence, Department of Commerce, Department of Justice, Military Sealift Command, Global Maritime Situational Awareness, Overseas Security Advisory Council, United States Agency for International Development, Naval Criminal Investigative Service, Customs and Border Protection, Transportation Security Administration, U.S. Africa Command, U.S. Central Command, and U.S. Transportation Command prior to issuing these Directives.

All MARSEC Directives issued pursuant to 33 CFR 101.405 are marked as SSI in accordance with 49 CFR Part 1520. COTPs and District Commanders will require individuals requesting a MARSEC Directive to prove that they meet the standards for a "covered person" under 49 CFR 1520.7, have a "need to know" the information, as defined in 49 CFR 1520.11, and that they will safeguard the SSI in MARSEC Directive 104-6 (Rev 5) as required in 49 CFR 1520.9.

Dated: January 7, 2011.

Kevin S. Cook, USCG,

Director of Prevention Policy.

[FR Doc. 2011-578 Filed 1-12-11; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Customs and Border Protection

Agency Information Collection Activities: Ship's Store Declaration

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-Day Notice and request for comments; Extension of an existing collection of information: 1651-0018.

SUMMARY: As part of its continuing effort to reduce paperwork and respondent burden, CBP invites the general public and other Federal agencies to comment on an information collection requirement concerning the Ship's Stores Declaration (CBP Form 1303). This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13).

DATES: Written comments should be received on or before March 14, 2011, to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs and Border Protection, Attn: Tracey Denning, Regulations and Rulings, Office of International Trade, 799 9th Street, NW., 5th Floor, Washington, DC 20229-1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 799 9th Street, NW., 5th Floor, Washington, DC 20229-1177, at 202-325-0265.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual costs burden to respondents or record keepers from the collection of information (a total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document CBP is soliciting comments concerning the following information collection:

Title: Ship's Stores Declaration.

OMB Number: 1651-0018.

Form Number: CBP Form 1303.

Abstract: CBP Form 1303, Ship's Stores Declaration, is used by the carriers to declare articles to be retained on board the vessel, such as sea stores, ship's stores, controlled narcotic drugs, bunker coal, or bunker oil in a format that can be readily audited and checked by CBP. The form was developed as a single international standard ship's stores declaration form to replace the different forms used by various countries for the entrance and clearance of vessels. CBP Form 1303 collects

information about the ship, the ports of arrival and departure, and the articles on the ship. It is pursuant to the provisions of section 432, Tariff Act of 1930 and provided for by 19 CFR 4.7, 4.7a, 4.81, 4.85, and 4.87. This form is accessible at http://forms.cbp.gov/pdf/CBP_Form_1303.pdf.

Current Actions: CBP proposes to extend the expiration date of this information collection with no change to the burden hours or to the information being collected.

Type of Review: Extension (without change).

Affected Public: Businesses.

Estimated Number of Respondents: 8,000.

Estimated Number of Responses per Respondent: 13.

Estimated Number of Total Annual Responses: 104,000.

Estimated Total Annual Burden Hours: 26,000.

Dated: January 10, 2010.

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

[FR Doc. 2011-673 Filed 1-12-11; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOMELAND SECURITY

Customs And Border Protection

Quarterly IRS Interest Rates Used in Calculating Interest on Overdue Accounts and Refunds on Customs Duties

AGENCY: Customs and Border Protection, Department of Homeland Security.

ACTION: General notice.

SUMMARY: This notice advises the public of the quarterly Internal Revenue Service interest rates used to calculate interest on overdue accounts (underpayments) and refunds (overpayments) of customs duties. For the calendar quarter beginning January 1, 2011, the interest rates for overpayments will be 2 percent for corporations and 3 percent for non-corporations, and the interest rate for underpayments will be 3 percent. This notice is published for the convenience of the importing public and Customs and Border Protection personnel.

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

FOR FURTHER INFORMATION CONTACT: Ron Wyman, Revenue Division, Collection and Refunds Branch, 6650 Telecom Drive, Suite #100, Indianapolis, Indiana 46278; telephone (317) 614-4516.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to 19 U.S.C. 1505 and Treasury Decision 85-93, published in the **Federal Register** on May 29, 1985 (50 FR 21832), the interest rate paid on applicable overpayments or underpayments of customs duties must be in accordance with the Internal Revenue Code rate established under 26 U.S.C. 6621 and 6622. Section 6621 was amended (at paragraph (a)(1)(B) by the Internal Revenue Service Restructuring and Reform Act of 1998, Public Law 105-206, 112 Stat. 685) to provide different interest rates applicable to overpayments: One for corporations and one for non-corporations.

The interest rates are based on the Federal short-term rate and determined by the Internal Revenue Service (IRS) on behalf of the Secretary of the Treasury on a quarterly basis. The rates effective for a quarter are determined during the first-month period of the previous quarter.

In Revenue Ruling 2010-31, the IRS determined the rates of interest for the calendar quarter beginning January 1, 2011, and ending on March 31, 2011. The interest rate paid to the Treasury for underpayments will be the Federal short-term rate (1%) plus two percentage points (2%) for a total of three percent (3%). For corporate overpayments, the rate is the Federal short-term rate (1%) plus one percentage point (1%) for a total of two percent (2%). For overpayments made by non-corporations, the rate is the Federal short-term rate (1%) plus two percentage points (2%) for a total of three percent (3%). These interest rates are subject to change for the calendar quarter beginning April 1, 2011, and ending June 30, 2011.

For the convenience of the importing public and Customs and Border Protection personnel the following list of IRS interest rates used, covering the period from before July of 1974 to date, to calculate interest on overdue accounts and refunds of customs duties, is published in summary format.

Beginning date	Ending date	Under-payments (percent)	Over-payments (percent)	Corporate overpayments (eff. 1-1-99) (percent)
070174	063075	6	6	
070175	013176	9	9	
020176	013178	7	7	
020178	013180	6	6	
020180	013182	12	12	
020182	123182	20	20	
010183	063083	16	16	
070183	123184	11	11	
010185	063085	13	13	
070185	123185	11	11	
010186	063086	10	10	
070186	123186	9	9	
010187	093087	9	8	
100187	123187	10	9	
010188	033188	11	10	
040188	093088	10	9	
100188	033189	11	10	
040189	093089	12	11	
100189	033191	11	10	
040191	123191	10	9	
010192	033192	9	8	
040192	093092	8	7	
100192	063094	7	6	
070194	093094	8	7	
100194	033195	9	8	
040195	063095	10	9	
070195	033196	9	8	
040196	063096	8	7	
070196	033198	9	8	
040198	123198	8	7	
010199	033199	7	7	6
040199	033100	8	8	7
040100	033101	9	9	8
040101	063001	8	8	7
070101	123101	7	7	6
010102	123102	6	6	5
010103	093003	5	5	4
100103	033104	4	4	3
040104	063004	5	5	4
070104	093004	4	4	3
100104	033105	5	5	4
040105	093005	6	6	5
100105	063006	7	7	6
070106	123107	8	8	7
010108	033108	7	7	6
040108	063008	6	6	5
070108	093008	5	5	4
100108	123108	6	6	5
010109	033109	5	5	4
040109	123110	4	4	3
010111	033111	3	3	2

Dated: January 7, 2011.

Alan Bersin,

Commissioner, U.S. Customs and Border Protection.

[FR Doc. 2011-676 Filed 1-12-11; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR 5481-N-01]

Notice of Proposed Information Collection: Brownfield Economic Development Initiative (BEDI)

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* March 14, 2011.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to

the proposal by name and/or OMB Control Number and should be sent to: LaRuth Harper, Department of Housing Urban and Development, 451 7th Street, SW., Room 7233, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT:

Nikki Bowser at telephone number 202-402-4395 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35 as Amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Brownfield Economic Development Initiative (BEDI).

OMB Control Number: 2506-0153.

Description of the need for the Information and proposed use: The Brownfield Economic Development Initiative is authorized pursuant to Section 108(q), Title I of the Housing and Community Development Act of 1974. BEDI is designed to help local governments redevelop brownfields, defined in the past NOFA as abandoned, idled, or underutilized real property, including industrial and commercial facilities, where expansion or redevelopment is complicated by the presence or potential presence of environmental contamination. This information collection effort is used to evaluate the quality of the proposed project or activities, and the applicant's capacity and commitment to use the BEDI funds in accordance with the purposes of the Act.

Agency form numbers, if applicable: HUD 40123, Brownfields Economic Development Application; SF-LLL, Disclosure of Lobbying Activities; SF-

424, Application for Federal Assistance; SF-424 Supplement, Survey for Ensuring Equal Opportunities; HUD-40122, State Certifications Related to Non entitlements; HUD-96010, Logic Model; HUD-2880, Applicant/Recipient Disclosure Update Report; HUD-2991, Certification of Consistency with Consolidated; SF-1199A, Direct Deposit Sign Up Form; HUD 27054, LOCCS Voice Response System Access Authorization; SF 425A, Federal Financial Report; HUD 27061, Racial & Ethnic Data Reporting Form; HUD 60002, Economic Opportunity for Low & Very Low-Income Persons In Connection with Assisted Projects; Federal Funding Accountability and Transparency Act Subrecipient Reporting Form (FFATA); Federal Awardee Performance and Integrity Information System Reporting Form (FAPIIS), Consolidated Annual Performance Evaluation Report (CAPER).

Members of affected public: Community Development Block Grant (CDBG) entitlement units of general local government and non-entitlement units of general local government eligible to receive loan guarantees under 24 CFR part 570, subpart M.

Estimation of the total numbers of hours needed to prepare the Information collection including number of respondents, frequency of response, and hours of response: Approximately 25 applicants submit application package during a given BEDI program year. A BEDI application package includes a 15 page narrative, and other HUD forms that consist of approximately 40 hours to complete. Approximately 13 grantees out of the 25 applicants will be required to complete additional HUD forms for fund withdrawals and program evaluation which is estimated at 20 hours to complete. The total estimate of burden hours is 1,260 hours.

Status of the proposed information collection: This notice precedes a continuation of the existing burden hour request. It is a proposed reduction from the prior approved request of 2,000. This proposed decrease is due primarily to the decrease of program applicants and grantees.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: January 6, 2011.

Mercedes Márquez,

Assistant Secretary for Community Planning and Development.

[FR Doc. 2011-656 Filed 1-12-11; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5495-N-01]

Notice of Proposed Information Collection: Comment Request Sustainable Communities Regional Grant Program

AGENCY: Office of Sustainable Housing and Communities, Office of the Deputy Secretary HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date: March 14, 2011.*

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Reports Liaison Officer, Department of Housing and Urban Development, 451 7th Street, SW., Washington, DC 20410, Room 9120 or the number for the Federal Information Relay Service (1-800-877-8339).

FOR FURTHER INFORMATION CONTACT: Zuleika Morales-Romero, Grants Division Director, Office of Sustainable Housing and Communities, Department of Housing and Urban Development, 451 7th Street, SW., Washington, DC 20410, telephone (202) 402-7683 (this is not a toll free number) for copies of the proposed forms and other available information.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated

collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Rating Factor Form, Sustainable Communities Regional Planning Grant Program.

OMB Control Number, if applicable: 2501-0024.

Description of the need for the information and proposed use: In FY2011, the Office of Sustainable Housing and Communities intends to offer its Notice of Funding Availability for the Sustainable Communities Regional Planning Grant Program. In FY2010 45 grants were made totaling \$98 million to consortia committed to metropolitan and multijurisdictional planning efforts that integrate housing, land use, economic and workforce development, transportation, and infrastructure investments in a manner that empowers jurisdictions to consider the interdependent challenges of: (1) Economic competitiveness and revitalization; (2) social equity, inclusion, and access to opportunity; (3) energy use and climate change; and (4) public health and environmental impact. The Rating Factor Form is an important data collection tool that contributes to the reviewers' understanding of the context of the region.

Agency form numbers, if applicable: HUD Form 2010.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: The number of burden hours is estimated to be 3,000. In FY2010 there were 225 applicants to the program filling in the five sections of the Rating Factor form. The anticipated number of responses is 300, and the burden hour per response is estimated at 10 hours.

Status of the proposed information collection: This is a new collection.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C., Chapter 35, as amended.

Dated: January 7, 2011.

Shelley R. Poticha.

Director, Office of Sustainable Housing and Communities.

[FR Doc. 2011-657 Filed 1-12-11; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5415-N -21]

Notice of Availability: HUD's Fiscal Year (FY) 2010 NOFA for the Capital Fund Education and Community Facilities Program—Technical Correction and Extension of Deadline Date

AGENCY: Office of the Chief Human Capital Officer, HUD.

ACTION: Notice.

SUMMARY: On October 18, 2010, HUD posted on <http://www.Grants.gov> its Notice of Funding Availability (NOFA) for the Fiscal Year (FY) 2010 Capital Fund Education and Community Facilities (CFCF) Program. The NOFA made available approximately \$35 million in assistance for development of facilities to provide early childhood education, adult education, and/or job training programs for public housing residents. Today's **Federal Register** publication announces that HUD has posted on <http://www.Grants.gov> a technical correction that makes several corrections and clarification to NOFA. Specifically, the corrected NOFA clarifies that Public Housing Agencies (PHAs) may submit multiple applications, but each application must include only one site. HUD has also revised the NOFA to specify tie breaking criteria. Further, in order to provide applicants with sufficient time to submit new or revised applications that incorporate the corrections and clarifications to the NOFA, HUD has extended the application deadline to February 3, 2011.

Potential applicants should review carefully the corrected NOFA to best determine whether to submit an updated application which incorporates the corrections and clarifications related to this notice. Applicants who submitted their applications prior to the technical correction notice can choose to submit an updated application that reflects the corrections and clarifications, but are not required to if they determine no changes are needed for their application. Applicants are reminded that if they submitted any portion of their application by fax with their initial application submission and choose to submit a revised application, then they will have to refax the materials after they submit the revised application to HUD. Please refer to the General Section for instructions regarding materials that are faxed and how HUD matches faxes to applications. For each site for which a PHA submits an application, the last version of the

application received by <http://www.Grants.gov> by the deadline date, in accordance with the timely receipt requirements, will be the application that is reviewed and rated.

The revised NOFA can be found and downloaded from <http://www.Grants.gov>, using the CFDA number for that program, 14.890.

DATES: The revised application deadline date is February 3, 2011. Applications must be received by Grants.gov by 11:59:59 p.m. eastern time on the deadline date. See the General Section for timely receipt requirements. All information required to complete the application is in the General Section and this NOFA. Applicants may download the application and instructions from the Grants.gov Web site at http://www07.grants.gov/applicants/apply_for_grants.jsp. Please carefully read the Notice of HUD's Fiscal Year (FY) 2010 Notice of Funding Availability (NOFA) Policy Requirements and General Section to HUD's FY 2010 NOFAs for Discretionary Programs, posted on Grants.gov on June 7, 2010. Applicants need to be aware that following receipt, applications go through a validation process in which the application may be accepted or rejected. Please allow time for this process to ensure that you meet the timely receipt requirements.

FOR FURTHER INFORMATION CONTACT:

Questions regarding specific program requirements may be directed to the agency contact identified in Section VII of the NOFA. Please send an e-mail message to PIHOCI@hud.gov or call Jeffrey Riddell at (202) 708-1640.

Questions regarding the 2010 General Section may be directed to the Office of Departmental Grants Management and Oversight at 202-708-0667 (this is not a toll-free number) or the NOFA Information Center at 800-HUD-8929 (toll-free). Persons with hearing or speech impairments may access these numbers via TTY by calling the Federal Information Relay Service at 800-877-8339. The NOFA Information Center is open between the hours of 10 a.m. and 6:30 p.m. eastern time, Monday through Friday, except Federal holidays.

Dated: January 7, 2011.

Barbara S. Dorf,

Director, Office of Departmental Grants, Management and Oversight, Office of the Chief Human Capital Officer.

[FR Doc. 2011-658 Filed 1-12-11; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF THE INTERIOR**Fish and Wildlife Service**

[FWS-R9-IA-2011-N002; 96300-1671-0000-P5]

Endangered Species; Marine Mammals; Receipt of Applications for Permit**AGENCY:** Fish and Wildlife Service, Interior.**ACTION:** Notice of Receipt of Applications for permit.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct certain activities with endangered species, marine mammals, or both. With some exceptions, the Endangered Species Act (ESA) and Marine Mammal Protection Act (MMPA) prohibit activities with listed species unless a Federal permit is issued that allows such activities. Both laws require that we invite public comment before issuing these permits.

DATES: We must receive comments or requests for documents on or before February 14, 2011. We must receive requests for marine mammal permit public hearings, in writing, at the address shown in the **ADDRESSES** section by February 14, 2011.

ADDRESSES: Brenda Tapia, Division of Management Authority, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 212, Arlington, VA 22203; fax (703) 358-2280; or e-mail DMAFR@fws.gov.

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, (703) 358-2104 (telephone); (703) 358-2280 (fax); DMAFR@fws.gov (e-mail).

SUPPLEMENTARY INFORMATION:**I. Public Comment Procedures***A. How do I request copies of applications or comment on submitted applications?*

Send your request for copies of applications or comments and materials concerning any of the applications to the contact listed under **ADDRESSES**. Please include the **Federal Register** notice publication date, the PRT-number, and the name of the applicant in your request or submission. We will not consider requests or comments sent to an e-mail or address not listed under **ADDRESSES**. If you provide an e-mail address in your request for copies of applications, we will attempt to respond to your request electronically.

Please make your requests or comments as specific as possible. Please confine your comments to issues for

which we seek comments in this notice, and explain the basis for your comments. Include sufficient information with your comments to allow us to authenticate any scientific or commercial data you include.

The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) Those that include citations to, and analyses of, the applicable laws and regulations. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**) or comments delivered to an address other than those listed above (see **ADDRESSES**).

B. May I review comments submitted by others?

Comments, including names and street addresses of respondents, will be available for public review at the address listed under **ADDRESSES**. The public may review documents and other information applicants have sent in support of the application unless our allowing viewing would violate the Privacy Act or Freedom of Information Act. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

II. Background

To help us carry out our conservation responsibilities for affected species, the Endangered Species Act of 1973, section 10(a)(1)(A), as amended (16 U.S.C. 1531 *et seq.*), and our regulations in the Code of Federal Regulations (CFR) at 50 CFR 17, the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), and our regulations in the Code of Federal Regulations (CFR) at 50 CFR 18 require that we invite public comment before final action on these permit applications. Under the MMPA, you may request a hearing on any MMPA application received. If you request a hearing, give specific reasons why a hearing would be appropriate. The holding of such a hearing is at the discretion of the Service Director.

III. Permit Applications*A. Endangered Species*

Applicant: U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, College Park, MD; PRT-30984A

The applicant requests a permit to import biological specimens from hawksbill sea turtle (*Eretmochelys imbricata*), that were obtained from the wild in Thailand for the purpose of scientific research.

Applicant: Zoological Society of Escondido, CA; PRT-31183A

The applicant requests a permit to import one captive born female dhole (*Cuon alpinus*), from the Toronto Zoo, Toronto, Ontario, Canada, for the purpose of enhancement of the survival of the species.

Applicant: Zoo New England, Boston, MA; PRT-31106A

The applicant requests a permit to import one captive-bred female snow leopard (*Uncia uncia*), from the Toronto Zoo, Toronto, Ontario, Canada, for the purpose of enhancement of the survival of the species.

Applicant: Virginia Aquarium & Marine Science Center, Virginia Beach, VA; PRT-27787A

The applicant requests a permit to export one captive-hatched female Komodo monitor (*Varanus komodoensis*), to the Toronto Zoo, Toronto, Ontario, Canada, for the purpose of enhancement of the survival of the species.

Multiple Applicants

The following applicants each request a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*), culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Gary Bartels, St. Elmo, IL; PRT-31829A

Applicant: William Minore, Loves Park, IL; PRT-25354A

B. Endangered Marine Mammals and Marine Mammals

Applicant: Floragenex, Inc., Eugene, OR; PRT-28829A

The applicant requests a permit to import an unlimited number of biological specimens obtained from wild polar bears (*Ursus maritimus*), in Canada for the purpose of scientific

research. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Texas A&M University, Dr. Randall Davis, Galveston, TX; PRT-078744

The applicant requests renewal of a permit to authorize take by harassment, behavior monitoring, and photo-identification activities of up to 200 wild northern sea otters (*Enhydra lutris kenyoni*), and opportunistic salvage and necropsy of sea otter carcasses, for the purpose of scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Concurrent with publishing this notice in the **Federal Register**, we are forwarding copies of the above applications to the Marine Mammal Commission and the Committee of Scientific Advisors for their review.

Dated: January 7, 2011.

Brenda Tapia,

Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2011-654 Filed 1-12-11; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Proclaiming Certain Lands, Lots 15 and 16 Acquisition, as an Addition to the Bay Mills Indian Reservation for the Bay Mills Indian Community of Michigan

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of Reservation Proclamation.

SUMMARY: This notice informs the public that the Assistant Secretary—Indian Affairs proclaimed approximately 2 acres, more or less, to be added to the Bay Mills Indian Reservation for the Bay Mills Indian Community of Michigan.

FOR FURTHER INFORMATION CONTACT: Ben Burshia, Bureau of Indian Affairs, Division of Real Estate Services, Mail Stop 4639-MIB, 1849 C Street, NW., Washington, DC 20240, telephone (202) 208-7737.

SUPPLEMENTARY INFORMATION: This Notice is published in the exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by part 209 of the Departmental Manual.

A proclamation was issued according with Section 7 of the Act of June 18, 1934 (48 Stat. 986; 25 U.S.C. 467), for

the land described below. The land was proclaimed to be an addition to the Bay Mills Indian Reservation and part of the Bay Mills Indian Community of Michigan for the exclusive use of Indians on that Reservation who are entitled to reside at the Reservation by enrollment or tribal membership.

Bay Mills Indian Community Reservation, Lots 15 and 16 Acquisition, Township of Bay Mills, Chippewa County, State of Michigan. Lots 15 and 16, Spectacle Lake Subdivision, Part of Government Lot 1, Section 13, Township 47 North, Range 3 West, Bay Mills Township, Chippewa County, Michigan, according to the recorded Plat thereof, as recorded in Liber 9 of Plats, Page 19, Chippewa County records.

The above-described lands contain a total of 2 acres, more or less, which are subject to all valid rights, reservations, rights-of-way, and easements of record.

This proclamation does not affect title to the land described above, nor does it affect any valid existing easements for public roads and highways, public utilities and for railroads and pipelines and any other rights-of-way or reservations of record.

Dated: September 22, 2010.

Larry Echo Hawk,

Assistant Secretary—Indian Affairs.

[FR Doc. 2011-614 Filed 1-12-11; 8:45 am]

BILLING CODE 4310-W7-P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Proclaiming Certain Lands, Golf Course Acquisition, as an Addition to the Bay Mills Indian Reservation for the Bay Mills Indian Community of Michigan

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of Reservation Proclamation.

SUMMARY: This notice informs the public that the Assistant Secretary—Indian Affairs proclaimed approximately 40 acres, more or less, to be added to the Bay Mills Indian Reservation for the Bay Mills Indian Community of Michigan.

FOR FURTHER INFORMATION CONTACT: Ben Burshia, Bureau of Indian Affairs, Division of Real Estate Services, Mail Stop 4639-MIB, 1849 C Street, NW., Washington, DC 20240, telephone (202) 208-7737.

SUPPLEMENTARY INFORMATION: This Notice is published in the exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—

Indian Affairs by part 209 of the Departmental Manual.

A proclamation was issued according with Section 7 of the Act of June 18, 1934 (48 Stat. 986; 25 U.S.C. 467), for the land described below. The land was proclaimed to be an addition to the Bay Mills Indian Reservation and part of the Bay Mills Indian Community of Michigan for the exclusive use of Indians on that Reservation who are entitled to reside at the Reservation by enrollment or tribal membership.

Bay Mills Indian Community Reservation, Golf Course Acquisition, Michigan Meridan, Superior Township, Chippewa County, Michigan. Southeast One Quarter (SE ¼) of the Northwest One Quarter (NW ¼) of Section 6, Township 46 North, Range 2 West, Michigan (40 acres).

The above-described lands contain a total of 40 acres, more or less, which are subject to all valid rights, reservations, rights-of-way, and easements of record.

This proclamation does not affect title to the land described above, nor does it affect any valid existing easements for public roads and highways, public utilities and for railroads and pipelines and any other rights-of-way or reservations of record.

Larry Echo Hawk,

Assistant Secretary—Indian Affairs.

[FR Doc. 2011-616 Filed 1-12-11; 8:45 am]

BILLING CODE 4310-W7-P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Proclaiming Certain Lands, Lot 32 Acquisition, as an Addition to the Bay Mills Indian Reservation for the Bay Mills Indian Community of Michigan

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of Reservation Proclamation.

SUMMARY: This notice informs the public that the Assistant Secretary—Indian Affairs proclaimed approximately 1 acre, more or less, to be added to the Bay Mills Indian Reservation for the Bay Mills Indian Community of Michigan.

FOR FURTHER INFORMATION CONTACT: Ben Burshia, Bureau of Indian Affairs, Division of Real Estate Services, Mail Stop 4639-MIB, 1849 C Street, NW., Washington, DC 20240, telephone (202) 208-7737.

SUPPLEMENTARY INFORMATION: This Notice is published in the exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—

Indian Affairs by part 209 of the Departmental Manual.

A proclamation was issued according with Section 7 of the Act of June 18, 1934 (48 Stat. 986; 25 U.S.C. 467), for the land described below. The land was proclaimed to be an addition to the Bay Mills Indian Reservation and part of the Bay Mills Indian Community of Michigan for the exclusive use of Indians on that Reservation who are entitled to reside at the Reservation by enrollment or tribal membership.

Bay Mills Indian Community

Reservation, Lot 32 Acquisition, Michigan Meridian, Township of Bay Mills, Chippewa County, Michigan.

Lot 32, Spectacle Lake Subdivision, Part of Government Lot 1, Section 13, Township 47 North, range 3 West, Bay Mills Township, Chippewa County, according to the recorded Plat thereof, as recorded in Liber 9 of Plats, page 19, Chippewa County records.

The above-described land contains a total of 1 acre, more or less, which is subject to all valid rights, reservations, rights-of-way, and easements of record.

This proclamation does not affect title to the land described above, nor does it affect any valid existing easements for public roads and highways, public utilities and for railroads and pipelines and any other rights-of-way or reservations of record.

Dated: September 22, 2010.

Larry Echo Hawk,

Assistant Secretary—Indian Affairs.

[FR Doc. 2011-612 Filed 1-12-11; 8:45 am]

BILLING CODE 4310-W7 -P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLOR9320000-L10200000.PH0000; HAG11-0053]

Call for Nominations for Advisory Groups

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Resource Advisory Council Call for Nominations.

SUMMARY: The Secretary of the Interior requests public nominations for persons to serve on Oregon/Washington Bureau of Land Management (BLM) Resource Advisory Councils, Committees, and Boards. Citizens who serve on these groups provide advice and recommendations to the BLM on land use planning and management of the National System of Public Lands within their geographic areas, the selection and prioritization of projects funded under

Title II of the Secure Rural Schools and Community Self-Determination Act, and management options for specific National Landscape Conservation System (NLCS) sites. The BLM will accept public nominations for 30 days after the publication of this notice.

DATES: All nominations must be received no later than February 14, 2011.

ADDRESSES: For the addresses of councils seeking nominations, please refer to the section titled

SUPPLEMENTARY INFORMATION.

FOR FURTHER INFORMATION CONTACT: Pam Robbins, Public Affairs Specialist, Bureau of Land Management, Oregon State Office, Division of Communications, 333 SW. First Avenue, Portland, Oregon 97204, (503) 808-6306.

SUPPLEMENTARY INFORMATION: The Federal Land Policy and Management Act (FLPMA) (43 U.S.C. 1739) directs the Secretary of the Interior to involve the public in planning and issues related to management of lands administered by the BLM. Section 309 of FLPMA directs the Secretary to establish citizen-based advisory councils that are consistent with the Federal Advisory Committee Act (FACA). As required by FACA, council membership must be balanced and representative of the various interests concerned with the management of public lands. The rules governing advisory committees are found at 43 CFR subpart 1784.

Regional Resource Advisory Councils (RAC) seek nominations in three categories:

Category One—Holders of Federal grazing permits, representatives of organizations associated with energy and mineral development, timber industry, transportation or rights-of-way, developed outdoor recreation, off-highway vehicle use, and commercial recreation;

Category Two—Representatives of nationally or regionally recognized environmental organizations; archaeological and historic organizations, dispersed recreation activities, and wild horse and burro organizations, and;

Category Three—Representatives of state, county, or local elected office; representatives and employees of a state agency responsible for management of natural resources; representatives of Indian tribes within or adjacent to the area for which the council is organized; representatives of academia who are employed in natural sciences; and the public-at-large.

The National Historic Oregon Trail Interpretive Center Advisory Board seeks representatives of: Federal, county, and local governments; trail advocacy groups; the local business community; and the public-at-large.

The Steens Mountain Advisory Council seeks a member of the Burns Paiute Tribe.

County Payment RACs seek nominations for these three categories:

Category One—Representatives of organized labor or non-timber forest product harvester groups; commercial or developed outdoor recreation activities or off-highway vehicle users; energy and mineral development interests or commercial or recreational fishing interests; commercial timber industry; or holders of Federal grazing permits or other land permits, or nonindustrial private forest land owners within the area for which the committee is organized.

Category Two—Representatives of nationally, regionally or locally recognized environmental organizations; dispersed recreational activities; archaeological and historical interests; or nationally or regionally recognized wild horse and burro interest groups, wildlife or hunting organizations, or watershed associations.

Category Three—Persons who hold State elected office (or a designee); hold county or local elected office; represent American Indian tribes within or adjacent to the committee area; represent the affected public-at-large; or area school officials or teachers.

Individuals may nominate themselves or others. Nominees must be residents of the state or region in which the council has jurisdiction. The BLM will evaluate nominees based on their education, training, experience, and knowledge of the geographical area of the council. Nominees should demonstrate a commitment to collaborative resource decision-making. A Presidential Memorandum prohibits individuals who are currently Federally-registered lobbyists from being appointed to any FACA or non-FACA boards, committees, or councils. All nominations must include: (1) Letters of reference from the stakeholder interest area to be represented; (2) a completed background information nomination form; and (3) other information that addresses the nominee's qualifications.

The BLM Oregon/Washington State Office will issue press releases providing additional information for submitting nominations, with specifics about the number and categories of member positions available for each council. Nominations should be sent to

the appropriate BLM offices listed below:

Regional RACs Oregon/Washington

Eastern Washington RAC: John Day-Snake RAC; Southeast Oregon RAC

Pam Robbins, Oregon State Office, BLM, 333 SW. First Avenue, Portland, Oregon 97204, (503) 808-6306.

County Payment RACs

Coos Bay District: Glenn Harkleroad, 1300 Airport Lane, North Bend, Oregon 97459, (541) 756-0100;

Eugene District: Pat Johnston, 3106 Pierce Parkway, Suite E, Springfield, Oregon 97477, (541) 683-6600;

Medford District: Jim Whittington, 3040 Biddle Road, Medford, Oregon 97504, (541) 618-2200;

Roseburg District: Jake Winn, 777 NW Garden Valley Blvd., Roseburg, Oregon 97470, (541) 440-4930; and

Salem District: Richard Hatfield, 1717 Fabry Road SE., Salem, Oregon 97306, (503) 375-5657.

Steens Mountain Advisory Council

Christi West, BLM Burns District, 28910 Highway 20 West, Hines, Oregon 97738, (541) 573-4400.

National Historic Oregon Trail Interpretive Center Advisory Board

Pam Robbins, Oregon State Office, BLM, 333 SW. First Avenue, Portland, Oregon 97204, (503) 808-6306.

Certification Statement: I hereby certify that the BLM Resource Advisory Councils are necessary and in the public interest in connection with the Secretary's responsibilities to manage the lands, resources, and facilities administered by the BLM.

Cathy L. Harris,

Associate Deputy State Director, Oregon/Washington.

[FR Doc. 2011-607 Filed 1-12-11; 8:45 am]

BILLING CODE 4310-33-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA-030-1210-BE]

Notice of Designation of Elkhorn Ridge Wilderness, California

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: This notice implements Section 6 of the Northern California Coastal Wild Heritage Wilderness Act (Act) (Pub. L. 109-362). The Act designates the 11,271 acre Elkhorn

Ridge Potential Wilderness Area and requires that this area "shall be designated as wilderness and as a component of the National Wilderness Preservation System, on the earlier of— (1) the date on which the Secretary publishes in the **Federal Register** notice that the conditions in the potential wilderness area that are incompatible with the Wilderness Act (16 U.S.C. 1131 *et seq.*) have been removed; or (2) the date that is 5 years after the date of enactment of this Act."

The Secretary of the Interior has determined that the conditions of the Elkhorn Ridge Potential Wilderness Area that were incompatible have been removed, and therefore the area is now suitable for wilderness designation.

DATES: The Elkhorn Ridge Potential Wilderness Area shall become the Elkhorn Ridge Wilderness on January 13, 2011.

ADDRESSES: Bureau of Land Management, Arcata Field Office, 1695 Heindon Road, Arcata, California 95521. Detailed information concerning this action is available for review at this address.

FOR FURTHER INFORMATION CONTACT: Bob Wick, Bureau of Land Management, at the above address or at (707) 825-2321.

SUPPLEMENTARY INFORMATION: Section 6(b) of the Act provides that the 11,271 acre Elkhorn Ridge Potential Wilderness Area be managed as wilderness except as necessary for ecological restoration and subject to valid existing rights until its designation as wilderness. Section 6(c) of the Act allows the Bureau of Land Management (BLM) to use motorized equipment and mechanized transport for ecological restoration within the potential wilderness area, but requires that restoration to the maximum extent practicable be undertaken through the "minimum tool or administrative practice necessary * * * with the least amount of adverse impact on wilderness character and resources."

The Elkhorn Ridge area's designation as a potential wilderness was intended to provide the Secretary of the Interior, through the BLM, time to assess and, if necessary, restore 1,565 acres of previously logged private in-holdings acquired shortly before the Act's passage.

After designation of the Elkhorn Ridge Potential Wilderness Area, the BLM's Arcata Field Office assessed the in-holdings to determine their condition relative to the Act and the BLM wilderness inventory criteria. Through this assessment, the BLM determined that impacts from past activities are successfully recovering through natural

rehabilitation and are compatible with the Act's requirements and with wilderness designation. The Elkhorn Ridge Potential Wilderness Area appears to have been affected primarily by the forces of nature and exhibits outstanding opportunities for solitude and primitive and unconfined recreation. Although some traces of past logging operations and associated road construction remain, the BLM has determined that the benefits of mechanized restoration are outweighed by the adverse impacts of such mechanized restoration on wilderness character. The BLM has determined that additional restoration actions would not be beneficial or necessary prior to wilderness designation and would not further the purposes of the Act.

As provided for under section 6(d) and 6(e) of the Act, the Elkhorn Ridge Potential Wilderness Area shall become wilderness on January 13, 2011. The area shall be known as the Elkhorn Ridge Wilderness and administered in accordance with section 4 of the Wilderness Act (16 U.S.C. 1131 *et seq.*). As the Elkhorn Ridge Potential Wilderness Area has been managed as wilderness pursuant to section 6(b) of the Act, the designation of this area as wilderness will not change any public uses of the area. The BLM will take this designation of the Elkhorn Ridge Wilderness into account as it moves forward with its long term planning and management.

Authority: Sec. 6, Pub. L. 109-362.

Sylvia V. Baca,

Deputy Assistant Secretary, Land and Minerals Management.

[FR Doc. 2011-606 Filed 1-12-11; 8:45 am]

BILLING CODE 4310-40-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLID933000.L1430000.FR0000; IDI-011668, IDI-15305, IDI-15304]

Expiration of Withdrawals and Opening of Lands; Idaho

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management announces the expiration of two withdrawals established by two Secretarial Orders and one Public Land Order and modified by two Public Land Orders affecting 62,025.42 acres of public lands in Ada, Adams, Boise, Canyon, Gem, Payette, and Washington Counties withdrawn for stock driveway

purposes. This action opens the lands to the operation of the public land laws. The lands have been and will remain open to mining and mineral leasing.

DATES: *Effective Date:* February 14, 2011.

FOR FURTHER INFORMATION CONTACT:

Laura Bingham, Bureau of Land Management, Idaho State Office, 1387 South Vinnell Way, Boise, Idaho 83709, 208-373-3866.

SUPPLEMENTARY INFORMATION: Copies of the expired orders describing the lands involved are available at the Bureau of Land Management Idaho State Office (address above). All of the lands have been and will remain open to mining and mineral leasing.

1. The withdrawal established by the Secretarial Order of May 17, 1918, and Public Land Order No. 3398, (29 FR 6686 (May 22, 1964)), as modified by Public Land Order No. 6436 (48 FR 33711 (July 25, 1983)), which withdrew 60,744.74 acres public lands from the operation of the public land laws for a period of 20 years for stock driveway purposes, expired on July 24, 2003.

2. The withdrawal established by the Secretarial Order of July 17, 1918, as modified by Public Land Order No. 6518 (49 FR 5924 (February 16, 1984)), which withdrew 1,280.68 acres public lands from the operation of the public land laws for a period of 20 years for stock driveway purposes, expired on March 16, 2004.

3. In accordance with 43 CFR 2091.6, at 8:30 a.m. on February 14, 2011, the lands withdrawn by the orders listed in Paragraphs 1 and 2 above will be opened to the operation of the public land laws generally, subject to valid existing rights, the provisions of existing withdrawals, other segregations of record, and the requirements of applicable law. All valid applications received at or prior to 8:30 a.m. on February 14, 2011, shall be considered as simultaneously filed at that time.

Those received thereafter shall be considered in the order of filing.

Authority: 43 CFR 2091.6.

Jerry L. Taylor,

Chief, Branch of Lands, Minerals and Water Rights, Resource Services Division.

[FR Doc. 2011-608 Filed 1-12-11; 8:45 am]

BILLING CODE 4310-GG-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCONO3000.L1610000.DSO000]

Notice of Intent To Amend the Grand Junction Resource Management Plan, Prepare an Environmental Assessment, and Notice of Realty Action, Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Intent and Notice of Realty Action.

SUMMARY: The Grand Junction, Colorado, Regional Airport Authority has requested the Bureau of Land Management (BLM) Grand Junction Field Office (GJFO) to consider the transfer of title to approximately 720 acres of public land for airport improvements, including relocation and construction of the main runway for the Grand Junction Regional Airport. Public Land Order No. 7027 (59 FR 3000 January 20, 1994) withdrew these lands from mining claim location in anticipation of a need for future airport expansion. The BLM's consideration of the Grand Junction Regional Airport Authority's (Airport Authority) request initiates a BLM Notice of Intent to initiate a public scoping process to amend the BLM GJFO 1987 Resource Management Plan (RMP) and prepare an Environmental Analysis (EA). The request also initiates a Notice of Realty Action (NORA) to assist the BLM in determining whether granting the requested title conveyance is consistent with the needs of the Department of the Interior. This notice initiates the public scoping process and concurrent opportunity for submission of public comments for the EA, RMP Amendment, and NORA.

DATES: Comments on this project, the NORA, or the proposed transfer of title to the Airport Authority may be submitted in writing until February 28, 2011. The date(s) and location(s) of scoping meetings will be announced at least 15 days in advance through local media, newspapers and the BLM Web site at: <http://www.blm.gov/co/st/en/fo/gjfo.html>. In order to be included in the EA, all comments must be received prior to the close of the scoping period or 45 days after the last public meeting, whichever is later.

ADDRESSES: Written comments should be sent to the Grand Junction Field Office, Bureau of Land Management, 2815 H. Road, Grand Junction, Colorado 81506, or via fax at (970) 244-3083. E-mail comments may be sent to

GJFO_mail@blm.gov. Comments, including names and addresses of respondents, will be available for public review at the BLM GJFO, during regular business hours 7:30 a.m. through 4:30 p.m., Monday-Friday, except holidays.

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.

FOR FURTHER INFORMATION CONTACT: For further information and/or to have your name added to our mailing list contact Robin Lacy, Project Manager, telephone (970) 244-3028. Project documents may be reviewed on the BLM GJFO Web site at <http://www.blm.gov/co/st/en/fo/gjfo>.

SUPPLEMENTARY INFORMATION: The purpose of the public scoping process is to identify those issues that should be considered in the EA and to initiate public participation in the planning process. BLM and Airport Authority personnel will be present at scoping meetings to explain the proposed action and other requirements for preparing the EA. Interested parties can request notification of any encumbrances or other claims relating to the land. Customary Federal Aviation Administration (FAA) conditions, in draft, that are proposed to be included in a land patent from the United States to the Airport Authority will also be available for review. The public lands requested for title transfer are within the jurisdiction of the BLM GJFO adjacent to the Grand Junction Regional Airport in the North Desert and are described as follows:

Ute Principal Meridian

T. 1 N., R. 1 W.,
 Sec. 23, S $\frac{1}{2}$ NE $\frac{1}{4}$;
 Sec. 24, S $\frac{1}{2}$ NE $\frac{1}{4}$, N $\frac{1}{2}$ SE $\frac{1}{4}$, and SE $\frac{1}{4}$ SE $\frac{1}{4}$;
 T. 1 N., R. 1 E.,
 Sec. 19, lots 3 and 4, and E $\frac{1}{2}$ SW $\frac{1}{4}$;
 Sec. 29, SW $\frac{1}{4}$ NW $\frac{1}{4}$;
 Sec. 30, lot 1, NE $\frac{1}{4}$, and NE $\frac{1}{4}$ NW $\frac{1}{4}$.

The areas described contain approximately 720 acres in Mesa County.

These are public lands administered by the BLM GJFO and do not include any private, State, tribal trust or Federal lands not administered by the BLM, the lands proposed for the title transfer to the Airport Authority are currently withdrawn from the United States mining laws by Public Land Order No.

7027 (59 FR 3000 (1994)), and are not intended for further segregation.

The EA will fulfill the needs and obligations set forth by the National Environmental Policy Act and associated Council of Environmental Quality Regulations (40 CFR 1500). The EA will also fulfill requirements of the Federal Land Policy and Management Act of 1976 (FLPMA), 43 U.S.C. 1701, Section 516 of the Airport and Airway Improvement Act of 1982 (49 U.S.C. 2215), Airport Grant regulations at 43 CFR 2640, applicable planning regulations at 43 CFR 1600, and BLM management policies.

The purpose of the proposed land title transfer from the United States to the Airport Authority is to fulfill the BLM's intent to make such lands available to the Airport Authority for a beneficial public use as described in the 1991 Memorandum of Understanding between the BLM and the Airport Authority. As authorized through the FLPMA, these lands will also be considered for title transfer to the Airport Authority in an amendment to the Grand Junction RMP. The BLM will determine whether or not to transfer title to the lands based on the EA, and the assessed environmental impacts of transferring title to the lands.

The purpose of the runway relocation is to comply with the FAA design standards by correcting deficiencies related to runway and taxiway gradients and to eliminate intersecting runways at the airport. The need for the proposed runway relocation is to increase safety at the Grand Junction Regional Airport, which is one of the few commercial service airports in the State of Colorado that still has a geometric runway layout consisting of an intersecting crosswind runway. The runway intersection increases the potential for runway incursions, which are defined by the FAA as "any occurrence at an aerodrome involving the incorrect presence of an aircraft, vehicle or person on the protected area of a surface designated for the landing and takeoff of aircraft." Increasing runway safety has been made a high priority in recent years and the FAA has published guidance on improving runway safety through airfield configuration. Also, several design components of the runway at Grand Junction Regional Airport do not meet the FAA design standards, including the following:

Runway 11/29 Transverse Gradient. Portions of the runway exceed the maximum recommended design standard of 1.5 percent;

Runway 11/29 Longitudinal Gradient. A portion of the runway near the approach end of Runway 29 exceeds the maximum recommended design standard of 0.8 percent;

Runway 11/29 Connecting Taxiway Gradient. A number of the connecting taxiways between Runway 11/29 and parallel Taxiway "A" exceed the maximum recommended design standard of 1.5 percent; and

Runway 11/29 and Runway 4/22 Runway Visibility Zone (RVZ). Numerous structures obstruct line of sight between runway mid-points.

The BLM seeks resource information and data for other public land values [i.e., air quality, cultural and historic resources, fire and fuels, fisheries, forestry, lands and realty, non-energy minerals and geology, oil and gas (including coalbed methane), paleontology, rangeland management, recreation, soil, water, and wildlife] in the BLM GJFO planning area. The purpose of this request is to assure that the planning effort has sufficient information to consider a reasonable range of resource uses, management options, and alternatives for the public lands involved.

Proprietary data marked as confidential may be submitted in response to this call for coal, oil and gas, and other resource information. Please submit all proprietary information submissions to the address listed above. The BLM will treat submissions marked as "Confidential" in accordance with the laws and regulations governing the confidentiality of such information.

The BLM GJFO will work collaboratively with interested parties to identify the management actions and decisions that are best suited to local, regional, and national needs. Potential issues that have been identified to date include, but are not limited to the following general categories: Wildlife (including birds); vegetation (including weeds and invasive plant species); threatened, endangered, and sensitive species; public access; visual concerns; cultural resources; tribal concerns; rangeland resources; geology and soils; hydrology; recreation resources; hazardous materials; air quality; noise; and socio-economics. The BLM has established a 45-day scoping period during which affected tribes, landowners, concerned citizens, special interest groups, local governments, and any other interested parties are invited to comment on the scope of the EA. Scoping will help the BLM identify the full range of issues that should be addressed in the EA.

Authority: Airport and Airway Improvement Act of September 3, 1982 (49

U.S.C. 4761, 49 U.S.C. 47101 *et seq.*, 3 CFR 2640 *et seq.*).

Helen M. Hankins,
State Director.

[FR Doc. 2011-556 Filed 1-12-11; 8:45 am]

BILLING CODE 4310-JB-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMTC0400.L14300000.
EU0000;SDM101126]

Notice of Realty Action: Direct Sale of Public Land in Lawrence County, SD

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Realty Action.

SUMMARY: The Bureau of Land Management (BLM), South Dakota Field Office, proposes to sell a parcel of public land consisting of 0.03 acres in Lawrence County, South Dakota, to Keith Sauls for the appraised fair market value of \$183.

DATES: Comments regarding the proposed sale must be received by the BLM on or before February 28, 2011.

ADDRESSES: Written comments concerning the proposed sale should be sent to the Field Manager, BLM, South Dakota Field Office, 310 Roundup Street, Belle Fourche, South Dakota 57717.

FOR FURTHER INFORMATION CONTACT: Charles Berdan, Realty Specialist, BLM, South Dakota Field Office, 310 Roundup Street, Belle Fourche, South Dakota 57717 or phone (605) 892-7000.

SUPPLEMENTARY INFORMATION: The following described public land is being proposed for direct sale to Keith Sauls 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);

Black Hills Meridian

T. 5 N., R. 3 E.,
Sec. 26, Lot 16.

The area described contains 0.03 acres, more or less, in Lawrence County.

The BLM proposes to sell this land to Keith Sauls for the appraised fair market value of \$183. The public land is identified as suitable for disposal in the BLM's 1986 South Dakota Resource Area Management Plan, as amended, and is not needed for any other Federal purpose.

The public land proposed for sale consists of a tiny lot on which a corner of a home was built. The BLM is proposing a direct sale to the homeowner, in accordance with 43 CFR

2711.3–3, to resolve inadvertent unauthorized use or occupancy of the land. A competitive sale is, therefore, not appropriate and the public interest would be best served by a direct sale. The public land proposed for sale adjoins a larger parcel of public land. The BLM proposes not to convey the Federal mineral interests. The BLM completed a leasable mineral and surface interference report which concluded disposal of the land would not interfere with operations under the Mineral Leasing Act. The land has been examined in accordance with the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, 120(h), 40 CFR 373, and BLM policy. No evidence of hazardous substances, petroleum products, or recognized environmental conditions was found.

On January 13, 2011, the above described land will be segregated from appropriation under the public land laws, including the mining laws, except for the sale provisions of FLPMA. Until completion of the sale, the BLM will no longer accept land use applications affecting the identified public land. The segregation terminates upon issuance of a patent, publication in the **Federal Register** of a termination of the segregation, or on January 14, 2013, unless extended by the BLM State Director in accordance with 43 CFR 2711.1–2 prior to the termination date. The land would not be sold until at least March 14, 2011. Any patent issued would contain the following terms, conditions, and reservations:

1. A reservation of a right-of-way 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 mineral rights to the United States;

3. The parcel will be subject to all valid existing rights of record at the time of conveyance; and

4. An appropriate indemnification clause protecting the United States from claims arising out of the patentee's use, occupancy or operations on the patented lands.

Detailed information concerning the proposed land sale, including the appraisal, planning and environmental documents, is available for review at the location identified in **ADDRESSES** above.

Public comments regarding the proposed sale may be submitted in writing to the attention of the BLM South Dakota Field Manager (see **ADDRESSES** above) on or before February 28, 2011. Comments received in electronic form, such as e-mail or fax,

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).

Theresa M. Hanley,

Deputy State Director, Division of Resources.

[FR Doc. 2011–550 Filed 1–12–11; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCOS06000.L12200000.XG0000.
LKSIOVHD0000]

Notice of Relocation of the Bureau of Land Management's Gunnison Field Office in Gunnison, CO

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of relocation.

SUMMARY: The Bureau of Land Management's (BLM) Gunnison Field Office moved from 216 North Colorado Street in Gunnison to a new location at 650 South 11th Street in Gunnison, Colorado 81230. The BLM officially closed the office located on Colorado Street at 12 p.m., November 24, 2010, and reopened at the new office December 6, 2010. The new telephone number is (970) 642–4940. Directions to the new office: From State Highway 50, turn east on Rio Grande Boulevard, continue approximately ½ mile, then turn left on 11th Street. The new office is located on the northeast corner of Rio Grande Boulevard and 11th Street.

FOR FURTHER INFORMATION CONTACT: Brian St. George, BLM Gunnison Field Office, (970) 642–4940.

Helen M. Hankins,
State Director.

[FR Doc. 2011–551 Filed 1–12–11; 8:45 am]

BILLING CODE 4310–BJ–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNM932000 14300000.ES0000; OKNM
68880]

Termination of a Recreation and Public Purposes Classification and Opening Order in Comanche County, OK

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: This order terminates a Bureau of Land Management (BLM) Recreation and Public Purposes (R&PP) Act classification and will open the public land to the operation of the public land laws generally. The classification termination and opening order will affect 8.45 acres of public land within Medicine Park, Oklahoma.

DATES: The classification termination and opening order is effective February 14, 2011.

FOR FURTHER INFORMATION CONTACT: Gilda Fitzpatrick, Realty Specialist, at the above address or by phone at (505) 954–2197, or Bureau of Land Management, New Mexico State Office, 301 Dinosaur Trail, Santa Fe, New Mexico 87508.

SUPPLEMENTARY INFORMATION: By virtue of the authority vested in the Secretary of the Interior by the R&PP Act of June 14, 1926, as amended (43 U.S.C. 869 *et seq.*), it is ordered as follows:

1. Pursuant to the regulations in 43 CFR 2091.7–1(b)(1) and the authority delegated by 43 CFR 2400.0–3(f), the classification decision of January 11, 1989, which classified 8.45 acres of public land as suitable for R&PP under the Act of June 14, 1926, as amended (43 U.S.C. 896 *et seq.*), under Serial Number OKNM 68880, is hereby revoked as to the following described land:

Indian Meridian

T. 3 N., R. 12 W.,

Sec. 19, that portion of the N½NE¼, in Comanche County, Oklahoma being more particularly described by metes bounds as follows: Beginning at a point being the intersection of the north boundary line of said Section 19 with the center line of Medicine Bluff Creek, said point being 1820 feet west of the Northeast corner of said

Section 19, N89°46'28" W; Thence southeastwardly with the center line of said Creek N40°34'08" E a distance of 779.20 feet to its intersection with the North right-of-way line of Oklahoma State Highway No. 49; Thence northwestwardly with said right-of-way line N83°59'09" W a distance of 271.57 feet; Thence continuing northwestwardly with said right-of-way line on a curve to the right having a radius of 1372.69 feet for a distance of 863.68 feet; Thence continuing northeastwardly with said right-of-way line N42°03'51" E a distance of 20.00 feet; Thence continuing northwestwardly with said right-of-way line N47°56'09" W a distance of 306.74 feet to the north line of said Section 19; Thence east with said north line S89°46'28" E a distance of 753.48 feet to the point of beginning.

The area described contains 8.45 acres, more or less, in Comanche County.

2. At 8 a.m. on February 14, 2011 the land described in Paragraph 1 will be opened to the operation of the public land laws generally, subject to valid existing rights, the provisions of existing withdrawals, other segregations of record, and the requirements of applicable law. All valid applications received at or prior to 8 a.m. on February 14, 2011 shall be considered as simultaneously filed at that time. Those received thereafter shall be considered in the order of filing.

William Merhege,

Deputy State Director.

[FR Doc. 2011-603 Filed 1-12-11; 8:45 am]

BILLING CODE 4310-FB-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 332-522]

Advice Concerning Possible Modifications to the U.S. Generalized System of Preferences, 2010 Review of Competitive Need Limitation Waivers

AGENCY: United States International Trade Commission.

ACTION: Institution of investigation and scheduling of hearing.

SUMMARY: Following receipt of a request on December 22, 2010, from the United States Trade Representative (USTR) under section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)), the U.S. International Trade Commission (Commission) instituted investigation No. 332-522, *Advice Concerning Possible Modifications to the U.S. Generalized System of Preferences, 2010 Review of Competitive Need Limitation Waivers*.

DATES:

January 28, 2011: Deadline for filing requests to appear at the public hearing.

February 4, 2011: Deadline for filing pre-hearing briefs and statements.

February 17, 2011: Public hearing.

February 24, 2011: Deadline for filing post-hearing briefs and statements and other written submissions.

April 11, 2011: Transmittal of classified report to the United States Trade Representative.

ADDRESSES: All Commission offices, including the Commission's hearing rooms, are located in the United States International Trade Commission Building, 500 E Street, SW., Washington, DC. All written submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street, SW., Washington, DC 20436. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <http://www.usitc.gov/secretary/edis.htm>.

FOR FURTHER INFORMATION CONTACT:

Information specific to this investigation may be obtained from Shannon Gaffney, Project Leader, Office of Industries (202-205-3316 or shannon.gaffney@usitc.gov) or Alberto Goetzl, Deputy Project Leader, Office of Industries (202-205-3323 or alberto.goetzl@usitc.gov). For information on the legal aspects of these investigations, contact William Gearhart of the Commission's Office of the General Counsel (202-205-3091 or william.gearhart@usitc.gov). The media should contact Margaret O'Laughlin, Office of External Relations (202-205-1819 or margaret.olaughlin@usitc.gov). Hearing-impaired individuals may obtain information on this matter by contacting the Commission's TDD terminal at 202-205-1810. General information concerning the Commission may also be obtained by accessing its Internet server (<http://www.usitc.gov>). Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-205-2000.

Background: The Commission, as requested by the USTR under the authority delegated by the President, pursuant to section 332(g) of the Tariff Act of 1930 and in accordance with section 503(d)(1)(A) of the Trade Act of 1974 (1974 Act) (19 U.S.C. 2463(d)(1)(A)), will provide advice on whether any industry in the United States is likely to be adversely affected by a waiver of the competitive need limitations specified in section 503(c)(2)(A) of the 1974 Act for the

following countries and articles provided for in the noted subheadings of the Harmonized Tariff System (HTS): Brazil for HTS subheading 2922.41.00 (lysine and esters); Sri Lanka for HTS subheading 4011.93.80 (pneumatic tires); Thailand for HTS subheading 4015.19.10 (rubber gloves); and Argentina for HTS subheading 7202.99.20 (calcium silicon ferroalloys). As requested, the Commission will also provide advice as to the probable economic effect on U.S. industries producing like or directly competitive articles, on total U.S. imports, and on U.S. consumers, by a waiver of such limitations. In addition, as requested, the Commission will provide information as to whether like or directly competitive products were being produced in the United States on January 1, 1995. As requested, for purposes of section 503(c)(2)(A)(i)(I) of the 1974 Act, the Commission will use the dollar value limit of \$145,000,000.

As requested by the USTR, the Commission will provide its advice by April 11, 2011. The USTR indicated that the portions of the Commission's report and its working papers which relate to the Commission's advice will be classified as "confidential," and that USTR considers the Commission's report to be an inter-agency memorandum that will contain pre-decisional advice and be subject to the deliberative process privilege.

Public Hearing: A public hearing in connection with this investigation will be held at the U.S. International Trade Commission Building, 500 E Street, SW., Washington, DC, beginning at 9:30 a.m. on February 17, 2011. Requests to appear at the public hearing should be filed with the Secretary no later than 5:15 p.m. on January 28, 2011. Any pre-hearing briefs and other statements relating to the hearing should be filed with the Secretary not later than 5:15 p.m. on February 4, 2011, and all post-hearing briefs and statements and any other written submissions should be filed with the Secretary not later than 5:15 p.m. on February 24, 2011. All requests to appear and pre- and post-hearing briefs and statements must be filed in accordance with the requirements in the "Written Submissions" section below. In the event that, as of the close of business on January 28, 2011, no witnesses are scheduled to appear at the hearing, the hearing will be canceled. Persons interested in learning whether the hearing has been canceled should call the Office of the Secretary after January 28, 2011, at 202-205-2000.

Written Submissions: In lieu of or in addition to participating in the hearing,

interested parties are invited to file written submissions concerning this investigation. All such submissions should be addressed to the Secretary and should be received not later than 5:15 p.m. on February 24, 2011 (see earlier dates for filing requests to appear and for filing pre-hearing briefs and statements). All written submissions must conform with the provisions of section 201.8 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.8). Section 201.8 requires that a signed original (or a copy so designated) and fourteen (14) copies of each document be filed. In the event that confidential treatment of a document is requested, at least four (4) additional copies must be filed in which the confidential information must be deleted (see the following paragraph for further information regarding confidential business information). The Commission's rules authorize filing submissions with the Secretary by facsimile or electronic means only to the extent permitted by section 201.8 of the rules (see Handbook for Electronic Filing Procedures, http://www.usitc.gov/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 submissions that contain confidential business information must also conform with the requirements of section 201.6 of the *Commission's Rules of Practice and Procedure* (19 CFR 201.6). Section 201.6 of the rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the "confidential" or "non-confidential" version, and that the confidential business information be clearly identified by means of brackets. All written submissions, except for confidential business information, will be made available in the Office of the Secretary to the Commission for inspection by interested parties. The Commission may include some or all of the confidential business information submitted in the course of the investigation in the report it sends to the USTR.

As requested by the USTR, the Commission will publish a public version of the report, which will exclude portions of the report that the USTR has classified as well as any confidential business information.

Issued: January 7, 2011.

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 2011-553 Filed 1-12-11; 8:45 am]

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

[OMB Number 1190-0008]

Civil Rights Division, Federal Coordination and Compliance Section; Agency Information Collection Activities Under Review

ACTION: 30-Day Notice of Information Collection Under Review: Federal Coordination and Compliance Section Complaint Form.

The Department of Justice, Civil Rights Division, Federal Coordination and Compliance Section, will be submitting the following information collection request to the Office of Management and Budget for review and approval in accordance with the Paperwork Reduction Act of 1995. The information collection extension is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 75, Number 210, page 67116, on November 1, 2010 allowing for a 60-day public comment period.

The purpose of this notice is to allow an additional 30 days for public comment. Comments are encouraged and will be accepted until February 14, 2011. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions are requested from the public and affected agencies concerning the proposed collection of information. Your comments should address one or more of the following four points:

(1) Evaluate whether the collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the collection of information;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (e.g., permitting electronic submission of responses).

To ensure that comments on the information are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* DOJ Desk Officer, FAX: 202-395-7285, or e-mailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number, *i.e.* (1140-XXXX). Also include the DOJ docket number found in brackets in the heading of this document.

Overview of this information collection is listed below:

(1) *Type of information collection:* Extension of Currently Approved Collection.

(2) *The title of the form/collection:* Federal Coordination and Compliance Section, Complaint Form.

(3) *The agency form number and applicable component of the Department sponsoring the collection:* No form number. Federal Coordination and Compliance Section, Civil Rights Division, U.S. Department of Justice.

(4) *Affected public who will be asked to respond, as well as a brief abstract:*

Primary: Individuals alleging discrimination by public and private entities based on race, color, national origin, sex, religion, age, or other bases. Federal Coordination and Compliance Section serves as a clearinghouse for receipt, review and referral of citizen complaints. FCS also investigates complaints against recipients of Federal financial assistance from the U.S. Department of Justice. Under Title VI of the Civil Rights Act of 1964 and other Federal civil rights statutes, an individual who believes that he or she has been subjected to discrimination on the basis of race, color, national origin, sex, religion, age, or other bases by a public or private entity may, by himself or herself or by an authorized representative, file a complaint. Any Federal agency that receives a complaint alleging discrimination by a public or private entity is required to review the complaint to determine whether it has jurisdiction under Title VI or other Federal civil rights statutes. If the agency does not have jurisdiction, it can refer the complaint to the Federal Coordination and Compliance Section, Civil Rights Division, U.S. Department of Justice, for review and referral to the appropriate Federal agency or other action deemed appropriate.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 4,000 respondents per year at 30 minutes per complaint form.

(6) *An estimate of the total public burden (in hours) associated with the*

collection: 2,000 hours annual burden hours associated with this collection.

If Additional Information is Required

Contact: Lynn Murray, Department Clearance Officer, United States Department of Justice, Policy and Planning Staff, Justice Management Division, Two Constitution Square, 145 N Street, NE., Suite 2E-502, Washington, DC 20530.

Dated: January 6, 2011.

Lynn Murray,

Department Clearance Officer, PRA, United States Department of Justice.

[FR Doc. 2011-478 Filed 1-12-11; 8:45 am]

BILLING CODE 4410-13-P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA-2010-0056]

OSHA-7 Form ("Notice of Alleged Safety and Health Hazards"); Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning its proposal to extend OMB approval of the information collection requirements specified in the OSHA-7 Form.

DATES: Comments must be submitted (postmarked, sent, or received) by March 14, 2011.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at <http://www.regulations.gov>, which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693-1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit your comments and attachments to the OSHA Docket Office, OSHA Docket No. OSHA-2010-0056, U.S. Department of Labor, Occupational Safety and Health Administration, Room N-2625, 200 Constitution Avenue, NW., Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Department of Labor's and Docket Office's normal

business hours, 8:15 a.m. to 4:45 p.m., e.t.

Instructions: All submissions must include the Agency name and OSHA docket number for the Information Collection Request (ICR) (OSHA-2010-0056). All comments, including any personal information you provide, are placed in the public docket without change, and may be made available online at <http://www.regulations.gov>. For further information on submitting comments see the "Public Participation" heading in the section of this notice titled **SUPPLEMENTARY INFORMATION**.

Docket: To read or download comments or other material in the docket, go to <http://www.regulations.gov> or the OSHA Docket Office at the address above. All documents in the docket (including this **Federal Register** notice) are listed in the <http://www.regulations.gov> index; 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. You may also contact Todd Owen at the address below to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT:

Todd Owen, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, Room N-3609, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693-2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent (*i.e.*, workers filing occupational safety or health complaints) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (the OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act

also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of efforts in obtaining information (29 U.S.C. 657).

Under paragraphs (a) and (c) of 29 CFR § 1903.11 ("Complaints by employees") workers and their representatives may notify the OSHA area director or an OSHA compliance officer of safety and health hazards regulated by the Agency that they believe exist in their workplaces at any time. These provisions state further that this notification must be in writing and "shall set forth with reasonable particularity the grounds for the notice, and shall be signed by the employee or representative of the employee."

In addition to providing specific hazard information to the Agency, paragraph (a) permits workers/worker representatives to request an inspection of the workplace. Paragraph (c) also addresses situations in which workers/worker representatives may provide the information directly to the OSHA compliance officer during an inspection. An employer's former workers may also submit complaints to the Agency.

To address the requirements of paragraphs (a) and (c), especially the requirement that the information be in writing, the Agency developed the OSHA-7 Form; this form standardized and simplified the hazard reporting process. For paragraph (a), they may complete an OSHA-7 Form obtained from the Agency's Web site and then send it to OSHA online, or deliver a hardcopy of the form to the OSHA area office by mail or facsimile, or by hand. They may also write a letter containing the information and hand deliver it to the area office, or send it by mail or facsimile. In addition, they may provide the information orally to the OSHA area office or another party (e.g., a Federal safety and health committee for Federal workers), in which case the area office or other party completes the hardcopy version of the form. For the typical situation addressed by paragraph (c), a worker/worker representative informs an OSHA compliance officer orally of the alleged hazard during an inspection, and the compliance officer then completes the hardcopy version of the OSHA-7 Form; occasionally, the worker/worker representative provides the compliance officer with the information on the hardcopy version of the OSHA-7 Form.

The information in the hardcopy version of the OSHA-7 Form includes information about the employer and alleged hazards, including: the

establishment's name; the site's address and telephone and facsimile numbers; the name and telephone number of the management official; the type of business; a description and the specific location of the hazards, including the approximate number of workers exposed or threatened by the hazards; and whether or not the worker/worker representative informed another government agency about the hazards (and the name of the agency if so informed).

Additional information on the hardcopy version of the form concerns the complainant including: whether or not the complainant wants OSHA to reveal their name to the employer; whether the complainant is a worker or a worker representative, or for information provided orally, a member of a Federal safety and health committee or another party (with space to specify the party); the complainant's name, telephone number, and address; and the complainant's signature attesting that they believe a violation of an OSHA standard exists at the named establishment; and the date of the signature. A worker representative must also provide the name of the organization they represent and their title.

The information contained in the online version of the OSHA-7 Form is similar to the hardcopy version. However, the online version requests the complainant's e-mail address, and does not ask for the site's facsimile number or the complainant's signature and signature date.

The Agency uses the information collected on the OSHA-7 Form to determine whether reasonable grounds exist to conduct an inspection of the workplace. The description of the hazards, including the number of exposed workers, allows the Agency to assess the severity of the hazards and the need to expedite the inspection. The completed form also provides the employer with notice of the complaint and may serve as the basis for obtaining a search warrant if the employer denies the Agency access to the workplace.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;

- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on workers who must comply; for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

OSHA is requesting that OMB extend its approval of the information collection requirements relating to the OSHA-7 Form. The Agency is requesting an increase in burden hours from 12,775 to 13,414 (a total increase of 639 burden hours). The Agency will summarize the comments submitted in response to this notice and will include this summary in the request to OMB to extend the approval of the information collection requirements.

Type of Review: Extension of a currently approved collection.

Title: Notice of Alleged Safety and Health Hazards, OSHA-7 Form.

OMB Number: 1218-0064.

Affected Public: Individuals or households.

Number of Respondents: 50,715.

Total Responses: 50,715.

Frequency of Recordkeeping: On occasion.

Average Time per Response: Varies from 15 minutes (.25 hour) to communicate the required information orally to the Agency to 25 minutes (.42 hour) to provide the information in writing and send it to OSHA.

Total Burden Hours Requested: 13,414.

Estimated Cost (Operation and Maintenance): \$1,116.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) Electronically at <http://www.regulations.gov>, which is the Federal eRulemaking Portal; (2) by facsimile (fax); or (3) by hard copy. All comments, attachments, and other material must identify the Agency name and the OSHA docket number for the ICR (Docket No. OSHA-2010-0056). You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled **ADDRESSES**). The additional materials must clearly identify your electronic comments by your name, date, and the docket number so the Agency can attach them to your comments.

Because of security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693-2350, (TTY) (877) 889-5627).

Comments and submissions are posted without change at <http://www.regulations.gov>. Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and date of birth. Although all submissions are listed in the <http://www.regulations.gov> index, some information (e.g., copyrighted material) is not publicly available to read or download through this Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the <http://www.regulations.gov> Web site to submit comments and access the docket is available at the Web site's "User Tips" link. Contact the OSHA Docket Office for information about materials not available through the Web site, and for assistance in using the Internet to locate docket submissions.

V. Authority and Signature

David Michaels, PhD, MPH, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 4-2010 (75 FR 55355).

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

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2011-602 Filed 1-12-11; 8:45 am]

BILLING CODE 4510-26-P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA-2010-0055]

Proposed Information Collection Request Submitted for Public Comment and Recommendations; Recording and Reporting Occupational Injuries and Illnesses (1218-0176)

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comment.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA 95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and impact of collection requirements on respondents can be properly assessed. The Occupational Safety and Health Administration (OSHA) is soliciting comments concerning the proposed extension of approval for the current paperwork requirements of 29 CFR part 1904, Recording and Reporting Occupational Injuries and Illnesses. A copy of the proposed information collection request can be obtained by contacting the office listed below in the address section of this notice.

DATES: Comments must be submitted (postmarked, sent, or received) by March 14, 2011.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at <http://www.regulations.gov>, which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693-1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit three copies of your comments and attachments to the OSHA Docket Office, Docket No. OSHA-2010-0055, U.S. Department of Labor, Occupational Safety and Health Administration, Room N-2625, 200 Constitution Avenue, NW., Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m. to 4:45 p.m., e.t.

Instructions: All submissions must include the Agency name and OSHA docket number for the ICR (OSHA-2010-0055). All comments, including any personal information you provide, are placed in the public docket without change, and may be made available

online at <http://www.regulations.gov>. For further information on submitting comments see the "Public Participation" heading in the section of this notice titled **SUPPLEMENTARY INFORMATION**.

Docket: To read or download comments or other material in the docket, go to <http://www.regulations.gov> or the OSHA Docket Office at the address above. All documents in the docket (including this **Federal Register** notice) are listed in the <http://www.regulations.gov> index; 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. You may also contact Rex Tingle at the address below to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT: Rex Tingle at Office of Statistical Analysis, Occupational Safety and Health Administration, U.S. Department of Labor, Room N3507, 200 Constitution Avenue, NW., Washington, DC 20210, telephone: (202) 693-1926, or Todd Owen, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, Room N-3609, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693-2222.

SUPPLEMENTARY INFORMATION:

I. Background

The OSH Act and 29 CFR part 1904 prescribe that certain employers maintain records of job-related injuries and illnesses. The injury and illness records are intended to have multiple purposes. One purpose is to provide data needed by OSHA to carry out enforcement and intervention activities to provide workers a safe and healthy work environment. The data are also needed by the Bureau of Labor Statistics to report on the number and rate of occupational injuries and illnesses in the country. The data also provides information to employers and employees of the kinds of injuries and illnesses occurring in the workplace and their related hazards. Increased employer awareness should result in the identification and voluntary correction of hazardous workplace conditions. Likewise, employees who are provided information on injuries and illnesses will be more likely to follow safe work practices and report workplace hazards. This would generally raise the overall level of safety and health in the workplace. OSHA currently has approval from the Office of Management and Budget (OMB) for information collection requirements contained in 29

CFR part 1904. That approval will expire on [February 29, 2011] unless OSHA applies for an extension of the OMB approval. This notice initiates the process for OSHA to request an extension of the current OMB approval. This notice also solicits public comment on OSHA's existing paperwork burden estimates from those interested parties and seeks public responses to several questions related to the development of OSHA's estimates. Interested parties are requested to review OSHA's estimates, which are based upon the most current data available, and to comment on their accuracy or appropriateness in today's workplace situation.

II. Current Actions

OSHA is requesting that OMB extend its approval of the information collection requirements contained in the Standard 29 CFR part 1904, Recording and Reporting Occupational Injuries and Illnesses.

The Agency is requesting to reduce its current burden hour estimate associated with this Standard from 3,072,978 to 2,967,237 hours for a total reduction of 105,741 hours. The Agency will summarize the comments submitted in response to this notice and will include this summary in the request to OMB.

Type of Review: Extension of a currently approved collection.

Title: 29 CFR part 1904, Recording and Reporting Occupational Injuries and Illnesses (1218-0176).

OMB Number: 1218-0176.

Affected Public: Business or other for-profits; farms; not-for-profit institutions; State and local government.

Cite/Reference/Form/etc.: 29 CFR part 1904; OSHA Form 300; OSHA Form 300A; OSHA Form 301.

Number of Respondents: 1,585,374.

Frequency: On occasion.

Average Time per Response: 2 hours to complete based on the information required.

Estimated Total Burden Hours: 2,967,237.

Estimated Cost (Operation and Maintenance): \$136,753,120.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) Electronically at <http://www.regulations.gov>, which is the Federal eRulemaking Portal; (2) by facsimile (FAX); or (3) by hard copy. All comments, attachments, and other material must identify the Agency name and the OSHA docket number for the ICR (Docket No. OSHA-2010-0055). You may supplement electronic

submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (*see* the section of this notice titled **ADDRESSES**). The additional materials must clearly identify your electronic comments by your name, date, and the docket number so the Agency can attach them to your comments.

Because of security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693-2350 (TTY (877) 889-5627).

Comments and submissions are posted without change at <http://www.regulations.gov>. Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and date of birth. Although all submissions are listed in the <http://www.regulations.gov> index, some information (*e.g.*, copyrighted material) is not publicly available to read or download through this Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the <http://www.regulations.gov> Web site to submit comments and access the docket is available at the Web site's "User Tips" link. Contact the OSHA Docket Office for information about materials not available through the Web site, and for assistance in using the Internet to locate docket submissions.

V. Authority and Signature

David Michaels, PhD, MPH, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 4-2010 (75 FR 55355).

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

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2011-601 Filed 1-12-11; 8:45 am]

BILLING CODE 4510-26-P

DEPARTMENT OF LABOR

Veterans' Employment and Training Service

Agency Information Collection Activities: Extension of Existing Information Collection; Comment Request

AGENCY: Veterans' Employment and Training Service.

ACTION: 60-Day Notice of Information Collection for Review; Federal Contractor Veterans' Employment Reports VETS-100 and VETS-100A; OMB Control No. 1293-0005.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Veterans' Employment and Training Service (VETS) is soliciting comments concerning the proposed extension of the currently approved information collection request for the "Federal Contractor Veterans' Employment Report VETS-100" and the "Federal Contractor Veterans' Employment Report VETS-100A." A copy of the proposed information collection request can be obtained by contacting the office listed below in the ADDRESSES section of this Notice. There have been no changes to the current VETS-100 and the VETS-100A Reports. Each report has the same number of reporting elements.

DATES: Written comments must be submitted to the office listed in the **ADDRESSES** section below on or before March 14, 2011.

ADDRESSES: Comments are to be submitted to Robert Wilson, Director for the Division of Investigation and Compliance, VETS, U.S. Department of Labor, Room S-1316, 200 Constitution Avenue, NW., Washington, DC 20210. Electronic transmission is the preferred method for submitting comments. E-mail may be sent to FCP-PRA-04-VETS@dol.gov. Include "VETS-100A" in the subject line of the message. Written

comments of 10 pages or fewer also may be transmitted by facsimile to (202) 693-4755 (this is not a toll free number). Receipt of submissions, whether by U.S. Mail, e-mail or FAX transmittal, will not be acknowledged; however, the sender may request confirmation that a submission has been received, by telephoning VETS at (202) 693-4719 (VOICE) (this is not a toll-free number) or (202) 693-4753 (TTY/TDD).

SUPPLEMENTARY INFORMATION:

I. Background

The Vietnam Era Veterans' Readjustment Assistance Act of 1974 ("VEVRAA"), 38 U.S.C. 4212(d), requires Federal contractors and subcontractors subject to the Act's affirmative action provisions in 38 U.S.C. 4212(a) to track and report annually to the Secretary of Labor the number of employees in their workforces, by job category and hiring location, who belong to the specified categories of covered veterans. VETS maintains two sets of regulations to implement the reporting requirements under VEVRAA, and uses two different forms for providing the required information on the employment of covered veterans.

The regulations set forth in 41 CFR part 61-250 require contractors that have a Government contract of \$25,000 or more entered into before December 1, 2003, to use the Federal Contractor Veterans' Employment Report VETS-100 ("VETS-100 Report") form for reporting information on the number of covered veterans in their workforces.

The regulations set forth in 41 CFR part 61-300 implement amendments to the reporting requirements under VEVRAA that were made by the Jobs for Veterans Act (JVA) (Pub. L. 107-288) enacted in 2002. The JVA amended VEVRAA by: (1) Increased from \$25,000 to \$100,000, the dollar amount of the contract that subjects a Federal contractor to the requirement to report on veterans' employment; and (2) changed the categories of covered veterans under VEVRAA, and thus the categories of veterans that contractors are required to track and report on annually.

The regulations in 41 CFR part 61-300 require contractors with a Government contract entered into or modified on or after December 1, 2003, in the amount of \$100,000 or more to use the Federal Contractor Veterans' Employment Report VETS-100A for reporting information on their employment of covered veterans under VEVRAA.

Both the VETS-100 and VETS-100A Reports are currently approved under OMB No. 1293-0005.

II. Desired Focus of Comments

Currently VETS is soliciting comments concerning a request to extend the currently approved information collection request. The Department of Labor is particularly interested in comments which:

- * Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

- * Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

- * Enhance the quality, utility and clarity of the information to be collected; and

- * Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

III. Current Actions

The Department of Labor seeks approval of the extension of the currently approved information collection request in order to carry out its responsibilities to administer and enforce compliance with the contractor reporting requirements under VEVRAA, as amended by the JVA.

Type of Review: Extension without change of currently approved collection.

Agency: Veterans' Employment and Training Service.

Title: Federal Contractor Veterans' Reports VETS-100 and VETS-100A.

OMB Number: 1293-0005.

Affected Public: Government contractors and subcontractors with a contract of \$25,000 or more entered into before December 1, 2003, and Government contractors and subcontractors with a contract of \$100,000 or more entered into or modified on or after December 1, 2003, that are required to comply with the affirmative action provisions of the Vietnam Era Veterans' Readjustment Assistance Act.

Total Respondents: 20,700.

Total Annual responses: 387,900.

Average Time per Response:

Electronic Submission—30 minutes;

Paper Submission—one hour.

Total Burden Hours: 202,100.

Frequency: Annually.

Total Burden Cost (capital/startup): \$0.

Total Burden Cost (operating/maintaining): \$0—The information contractors report about their veterans' employment is collected and maintained in the normal course of business. There are no requirements for contractors to have any kind of equipment to be able comply with this collection of information.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

John M. McWilliam,

Deputy Assistant Secretary for Operations and Management, Veterans' Employment and Training.

[FR Doc. 2011-638 Filed 1-12-11; 8:45 am]

BILLING CODE 4510-79-P

DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

Proposed Extension of Existing Collection; Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Office of Workers' Compensation Programs is soliciting comments concerning the proposed collection: Rehabilitation Plan and Award (OWCP-16). A copy of the proposed information collection request can be obtained by contacting the office listed below in the addresses section of this Notice.

DATES: Written comments must be submitted to the office listed in the addresses section below on or before March 14, 2011.

ADDRESSES: Mr. Vincent Alvarez, U.S. Department of Labor, 200 Constitution Ave., NW., Room S-3201, Washington, DC 20210, telephone (202) 693-0372, fax (202) 693-1378, E-mail

Alvarez.Vincent@dol.gov. Please use only one method of transmission for comments (mail, fax, or E-mail).

SUPPLEMENTARY INFORMATION:

I. Background

The Office of Workers' Compensation Programs (OWCP) is the agency responsible for administration of the Longshore and Harbor Workers' Compensation Act (LHWCA), 33 U.S.C. 901 *et seq.*, and the Federal Employees' Compensation Act (FECA), 5 U.S.C. 8101 *et seq.* Both of these Acts authorize OWCP to pay for approved vocational rehabilitation services to eligible workers with work-related disabilities. In order to decide whether to approve a rehabilitation plan, OWCP must receive a copy of the plan, supporting vocational testing materials and the estimated cost to implement the plan, broken down to show the fees, supplies, tuition and worker maintenance payments that are contemplated. OWCP also must receive the signatures of the worker and the rehabilitation counselor to show that the worker agrees to follow the proposed plan, and that the proposed plan is appropriate. Form OWCP-16 is the standard format for the collection of this information. The regulations implementing these statutes allow for the collection of information needed for OWCP to determine if a rehabilitation plan should be approved and payment of any related expenses should be authorized. This information collection is currently approved for use through May 31, 2011.

II. Review Focus

The Department of Labor is particularly interested in comments which:

- * Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

- * Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

- * Enhance the quality, utility and clarity of the information to be collected; and

- * Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

III. Current Actions

The Department of Labor seeks approval for the extension of this currently approved information collection in order to determine if a rehabilitation plan should be approved and payment of any related expenses authorized.

Type of Review: Extension.

Agency: Office of Workers' Compensation Programs.

Title: Rehabilitation Plan and Award.

OMB Number: 1240-0045.

Agency Number: OWCP-16.

Affected Public: Individual or households; Businesses or other for-profit.

Total Respondents: 5,500.

Total Responses: 5,500.

Time per Response: 30 minutes.

Estimated Total Burden Hours: 2,750.

Total Burden Cost (capital/startup): \$0.

Total Burden Cost (operating/maintenance): \$2,585.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: January 7, 2011.

Vincent Alvarez,

Agency Clearance Officer, Office of Workers' Compensation Programs, U.S. Department of Labor.

[FR Doc. 2011-631 Filed 1-12-11; 8:45 am]

BILLING CODE 4510-CR-P

MERIT SYSTEMS PROTECTION BOARD

Merit Systems Protection Board (MSPB) Provides Notice of Opportunity To File Amicus Briefs in the Matter of Jeffrey Denton v. Department of Agriculture, MSPB Docket Number DC-3330-09-0696-I-1

AGENCY: Merit Systems Protection Board.

ACTION: Notice.

SUMMARY: Pursuant to 5 U.S.C. 1204(e)(1)(A), the MSPB has requested an advisory opinion from the Director of the Office of Personnel Management (OPM) concerning an appeal currently pending before the Board, *Jeffrey Denton v. Department of Agriculture*, MSPB Docket Number DC-3330-09-0696-I-1. The MSPB is also providing an opportunity to other interested parties to file amicus briefs concerning the appeal. The legal questions set forth in the *Denton* appeal, which were posed in the request for an advisory opinion to the Director of OPM, are set forth below.

The agency employs the appellant in the position of Animal Health Program Assistant, GS-5. The agency announced the position of Veterinary Program Assistant ("VPA"), GS-0303-5/6/7, under both case exam (announcement 24VS-2009-0130) and merit promotion (announcement 6VS-2009-0132) procedures. The appellant applied under both vacancy announcements and submitted his DD-214, showing his eligibility for veterans' preference. The appellant made the certificate at the GS-7 level on the case exam announcement. The maximum score an applicant could receive was 100, except when veterans' preference points were added. The appellant had 10 points added to his score of 99.68 to reflect his veterans' preference, and he was thus listed on the top of the certificate of 6 candidates with a score of 109.68 as "CPS," which is a 30% or more disabled veteran. The appellant also made the GS-6 level on the merit promotion certificate, and he was referred to the selecting official. The agency made no selection from either the case exam or merit promotion certificate. Rather, the agency cancelled both vacancy announcements and filled the VPA position through an alternative hiring authority, the Student Career Experience Program (SCEP).

The appellant filed a complaint with the Department of Labor (DOL) alleging that his rights to veterans' preference as a 30% disabled veteran were violated because the agency filled the position through SCEP instead of filling the position from either the merit promotion or case exam certificate. The DOL informed the appellant that it had completed its investigation into the appellant's claim and had determined that the evidence did not support a finding that the appellant's veterans' preference rights were violated. The DOL provided the appellant with notice of appeal rights to the MSPB.

After exhausting his remedy with DOL, the appellant timely filed an appeal with the MSPB pursuant to the Veterans Employment Opportunities Act (VEOA) alleging that his veterans' preference rights were violated when the agency used SCEP to fill the VPA position and did not select him for that position. The appellant essentially argued that the agency had engaged in a sham. The assigned administrative judge determined that the MSPB has VEOA jurisdiction over the appeal, but issued an initial decision on the merits finding that the appellant did not establish a VEOA violation.

The appellant filed a petition for review with the MSPB challenging the initial decision of the administrative judge. This appeal raises significant

issues regarding whether the agency's use of SCEP improperly circumvented the competitive examination process, allowing the agency to avoid its obligations regarding veterans' preference and a veteran's right to compete for positions. The material issues are similar in many respects to the issues raised regarding the Federal Career Intern Program (FCIP) in the MSPB's recent decisions in the appeals of *Dean v. Office of Personnel Management*, AT-3330-10-0534-I-1 and *Evans v. Department of Veterans Affairs*, AT-3330-09-0953-I-1, 2010 MSPB 213 (November 2, 2010). The Board determined that appellants Dean and Evans had established the FCIP program as conducted violated their veterans' preference rights because FCIP was inconsistent with 5 U.S.C. 3302(1) by: (1) Allowing agencies to invoke an appointing authority reserved for positions for which it is not practicable to hold a competitive examination after holding a competitive examination yielding highly-qualified preference-eligible candidates; and (2) not requiring agencies to justify placement of positions in the excepted service.

The SCEP program is covered by OPM's regulations at 5 CFR 213.3202(b) and is authorized by Executive Order 12015 (as amended by Executive Order 13024). The FCIP positions are also Schedule B, excepted-service positions but are addressed at 5 CFR 213.3202(o) and Executive Order 13162. The SCEP allows agencies to hire students currently enrolled in specified educational programs in Schedule B, excepted-service positions, and noncompetitively convert them to term, career or career-conditional appointments upon satisfactory completion of the educational program and accumulation of 640 hours of agency work experience.

Questions to be resolved:

1. Does the SCEP program violate veterans' preference rights because it allows agencies to invoke an appointing authority reserved for positions for which it is not practicable to hold a competitive examination after holding a competitive examination yielding highly-qualified preference-eligible candidates?

2. Does the SCEP program violate veterans' preference rights because it does not require agencies to justify placement of positions in Schedule B of the excepted service?

3. What impact, if any, does the Executive Order dated December 27, 2010, entitled "Recruiting and Hiring Students and Recent Graduates," have on the appellant's appeal or any other appeals based on the SCEP hiring

occurring before Executive Order 12015 is revoked?

DATES: All briefs submitted in response to this notice shall be filed with the Clerk of the Board on or before February 7, 2011.

ADDRESSES: All briefs shall be captioned “*Jeffrey Denton v. Department of Agriculture*,” and entitled “Amicus Brief.” Only one copy of the brief need be submitted. Briefs must be filed with the Office of the Clerk of the Board, Merit Systems Protection Board, 1615 M Street, NW., Washington, DC 20419.

FOR FURTHER INFORMATION CONTACT: Matthew Shannon, Merit Systems Protection Board, Office of the Clerk of the Board, 1615 M Street, NW., Washington, DC 20419; (202) 653-7200; mspb@mspb.gov.

William D. Spencer,
Clerk of the Board.

[FR Doc. 2011-633 Filed 1-12-11; 8:45 am]

BILLING CODE 7400-01-P

MILLENNIUM CHALLENGE CORPORATION

[MCC FR 11-01]

Report on the Selection of Eligible Countries for Fiscal Year 2011

AGENCY: Millennium Challenge Corporation.

ACTION: Notice.

SUMMARY: This report is provided in accordance with section 608(d)(1) of the Millennium Challenge Act of 2003, Public Law 108-199, Division D, (the “Act”), 22 U.S.C. 7708(d)(1).

Report on the Selection of Eligible Countries for Fiscal Year 2011

Summary

This report is provided in accordance with section 608(d)(1) of the Millennium Challenge Act of 2003, Public Law 108-199, Division D, (the “Act”) (22 U.S.C. 7707(d)(1)).

The Act authorizes the provision of Millennium Challenge Account (“MCA”) assistance under section 605 of the Act (22 U.S.C. 7704) to countries that enter into compacts with the United States to support policies and programs that advance the progress of such countries in achieving lasting economic growth and poverty reduction, and are in furtherance of the Act. The Act requires the Millennium Challenge Corporation (“MCC”) to determine the countries that will be eligible to receive MCA assistance during the fiscal year, based on their demonstrated commitment to just and democratic governance,

economic freedom, and investing in their people, as well as on the opportunity to reduce poverty and generate economic growth in the country. The Act also requires the submission of reports to appropriate congressional committees and the publication of notices in the **Federal Register** that identify, among other things:

1. The countries that are “candidate countries” for MCA assistance during fiscal year 2011 (“FY11”) based on their per-capita income levels and their eligibility to receive assistance under U.S. law, and countries that would be candidate countries but for specified legal prohibitions on assistance (section 608(a) of the Act (22 U.S.C. 7707(a)));

2. The criteria and methodology that the Board of Directors of MCC (the “Board”) will use to measure and evaluate the policy performance of the “candidate countries” consistent with the requirements of section 607 of the Act in order to select “MCA eligible countries” from among the “candidate countries” (section 608(b) of the Act (22 U.S.C. 7707(b))); and

3. The list of countries determined by the Board to be “MCA eligible countries” for FY11, with justification for eligibility determination and selection for compact negotiation, including with which of the MCA eligible countries the Board will seek to enter into MCA compacts (section 608(d) of the Act (22 U.S.C. 7707(d))).

This is the third of the above-described reports by MCC for FY11. It identifies countries determined by the Board to be eligible under section 607 of the Act (22 U.S.C. 7706) for FY11 and countries with which the Board will seek to enter into compacts under section 609 of the Act (22 U.S.C. 7708), as well as the justification for such decisions.

Eligible Countries

The Board met on January 5, 2011, to select countries that will be eligible for MCA compact assistance under section 607 of the Act (22 U.S.C. 7706) for FY11. The Board selected the following countries as eligible for such assistance for FY11: Cape Verde, Georgia, Ghana, Indonesia, Malawi, and Zambia.

In accordance with the Act and with the “Report on the Criteria and Methodology for Determining the Eligibility of Candidate Countries for Millennium Challenge Account Assistance in Fiscal Year 2011” formally submitted to the Congress on September 30, 2010, selection was based primarily on a country’s overall performance in three broad policy categories: *Ruling Justly*, *Encouraging Economic Freedom*,

and *Investing in People*. As a basis for determining which countries would be eligible for MCA compact assistance, the Board relied, to the maximum extent possible, upon 17 transparent and independent indicators to assess countries’ policy performance and demonstrated commitment in these three broad policy areas. The Board compared countries’ performance on the indicators relative to their income-level peers, evaluating them in comparison to either the group of low income countries (“LIC”) or the group of lower-middle income countries (“LMIC”). In particular, the Board considered if a country performed above the median in relation to its peers on at least three indicators in each of the *Ruling Justly*, *Investing in People*, and *Encouraging Economic Freedom* policy categories, and above the median on the *Control of Corruption* indicator. Scorecards reflecting each country’s performance on the indicators are available on MCC’s Web site at <http://www.mcc.gov>.

The Board also considered whether any adjustments should be made for data gaps, data lags, or recent events since the indicators were published, as well as strengths or weaknesses in particular indicators. Where appropriate, the Board took into account additional quantitative and qualitative information, such as evidence of a country’s commitment to fighting corruption and promoting democratic governance, and its effective protection of human rights. For countries that graduated from the LIC group to the LMIC group within the last two years, due to an increase in their per capita gross national income, the Board also took into account supplemental information that showed how the new LMIC countries would have performed in comparison to the LIC group. This is consistent with a 2009 congressional decision to allow MCC to fund as LICs a set of countries that had recently transitioned to the LMIC category. Finally, the Board considered the opportunity to reduce poverty and promote economic growth in a country, in light of the overall context of the information available, as well as the availability of appropriated funds.

This was the second year the Board considered the eligibility of countries for subsequent compacts, as permitted under section 609(k) of the Act (22 U.S.C. 7708(k)). In determining subsequent compact eligibility, the Board considered—in addition to the criteria outlined above—the country’s performance implementing its first compact, including the nature of the country partnership with MCC, the degree to which the country has

demonstrated a commitment and capacity to achieve program results, and the degree to which the country has implemented the compact in accordance with MCC's core policies and standards. Using this higher bar to measure eligibility, Ghana and Georgia were selected as eligible for MCA assistance for a second compact under section 607 of the Act (22 U.S.C. 7706).

As a candidate country under section 606(a) of the Act (22 U.S.C. 7705(a)), Ghana consistently performs well on the MCC indicator criteria. Its continued track record of democratic governance is demonstrated by its regular ranking among the top LIC performers in the *Ruling Justly* category. Implementation of Ghana's Compact is on track to achieve its objectives, and the investment is managed by a strong Ghanaian-led and staffed team. The Ghana Compact has also already generated tangible interest from the private sector. MCC believes that a second compact offers opportunities for deeper investment in a low income country that not only has a demonstrated commitment to a positive policy environment and effective program implementation, but is also considered a regional economic anchor in West Africa.

As a candidate country under section 606(b) of the Act (22 U.S.C. 7705(b)), Georgia performs well on the MCC indicator criteria, even after having transitioned from the LIC group to the more competitive LMIC group two years ago. Georgia is widely recognized as an investment climate reformer and is regularly among the top performers in the *Encouraging Economic Freedom* category for all MCC candidate countries. Although Georgia does not meet the formal indicator criteria in the *Investing in People* category this year, supplemental information, including analysis from the World Health Organization, describes a situation in which the performance on MCC's *Immunization Rates* indicator can be largely attributed to a temporary shortage of one vaccine and the introduction of alternative, private vaccination facilities that were not captured in 2010 data. As a result, MCC does not have policy concerns in this category. The government of Georgia has demonstrated commitment to the ongoing Georgia Compact and the Georgian-led implementation unit is effectively managing the compact through its final months. MCC sees a subsequent compact in Georgia as an opportunity to support growth and poverty reduction in a country with a track record of rigorous policy reform

and a desire to foster private sector investment in its own development.

Country partners that are developing or implementing compacts must also show a commitment to maintaining and improving their policy performance. While MCC's indicators work well as a transparent way of identifying those countries that are most committed to sound development policies and for discerning trends over the medium-term, they are not as well-suited for tracking incremental progress from year-to-year. Countries may be generally maintaining performance but not meet the criteria in a given year due to factors such as:

- Graduation from the LIC category to the LMIC category,
- Data improvements or revisions,
- MCC's introduction of two new indicators in fiscal year 2008 and the accompanying requirement that countries pass three of the five indicators in the *Investing in People* category,
- Increases in peer-group medians for some indicators, and
- Slight declines in performance.

Four of the countries selected as eligible for MCA compact assistance in FY11 were previously selected as eligible last year. Because they have not yet signed a compact agreement, they needed to be reselected as eligible for FY11 to continue compact development and receive funding from this fiscal year. Two of these countries are in the LIC category: Malawi and Zambia. Two countries, Indonesia and Cape Verde, are in the LMIC category.

The Board reselected these countries based on their continued good performance since their prior selection. The Board determined that since their fiscal year 2010 selection, there has been no material change in their performance on the indicator criteria that indicates a serious decline in policy performance. This includes the two countries—Cape Verde and Indonesia—that do not meet the formal indicator criteria this year. Although the data available at the time of the publication of the scorecards suggested that Cape Verde did not meet the *Investing in People* criteria this year, after the publication of the scorecards, revised data for FY11 were received from UNESCO. The revised data for the expenditures on primary education indicator indicate that Cape Verde would have passed this indicator, and the *Investing in People* category, had the revised figures been available at the time of scorecard publication. Additionally, Cape Verde's progress in achieving high levels of primary education attainment is widely

recognized by third party experts.

Indonesia transitioned to the more competitive LMIC category last year and fares less well against the higher standards, but would have continued to meet MCC's indicator criteria as an LIC. Last year, Congress granted MCC authority that allows Indonesia to be funded as a LIC for up to three years.

The Board also reviewed the policy performance of countries that are implementing compacts. However, these countries do not need to be reselected each year in order to continue implementation. Once MCC makes a commitment to a country through a compact agreement, MCC will not consider the country for reselection on an annual basis during the term of its compact. MCC will continue to work with a country—even if it does not meet the indicator criteria each year—as long as the country has not demonstrated a pattern of actions inconsistent with the eligibility criteria. If it is determined that a country has demonstrated a significant policy reversal, MCC can hold it accountable by applying MCC's Suspension and Termination Policy.

The Board emphasized the need for all partners to continue to improve their policy environment and, if they do not meet the criteria, to demonstrate their ongoing commitment by informing MCC of actions they are undertaking. Countries participating in this policy improvement process may work with MCC to develop and implement a forward-looking action plan that outlines the steps they plan to take to improve performance on certain policy criteria, including key areas of governance (e.g., public financial management), or provide periodic reports on government efforts to improve performance on specific indicators. MCC recognizes that there are cases in which countries that do not meet the indicator criteria have not demonstrated a significant policy reversal.

Finally, a number of countries that performed well on the quantitative elements of the selection criteria (*i.e.*, on the policy indicators) were not chosen as eligible countries for FY11. As discussed above, the Board considered a variety of factors in addition to the country's performance on the policy indicators in determining whether it was an appropriate candidate for assistance (e.g., the country's commitment to fighting corruption and promoting democratic governance; the availability of appropriated funds; and where MCC would likely have the best opportunity to reduce poverty and generate economic growth).

Selection To Initiate the Compact Process

The Board also authorized MCC to invite Ghana and Georgia to submit a proposal for a second compact, as described in section 609 of the Act (22 U.S.C. 7708).

Submission of a proposal is not a guarantee that MCC will finalize a compact with an eligible country. Any MCA assistance provided under section 605 of the Act (22 U.S.C. 7704) will be contingent on the successful negotiation of a mutually agreeable compact between the eligible country and MCC, approval of the compact by the Board, and the availability of funds.

Dated: January 7, 2011.

Melvin F. Williams, Jr.,

VP/General Counsel and Corporate Secretary, Millennium Challenge Corporation.

[FR Doc. 2011-609 Filed 1-12-11; 8:45 am]

BILLING CODE 9211-03-P

NATIONAL SCIENCE FOUNDATION

National Science Board; Sunshine Act Meetings; Notice

The National Science Board's Task Force on Merit Review, pursuant to NSF regulations (45 CFR Part 614), the National Science Foundation Act, as amended (42 U.S.C. 1862n-5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of a meeting held by teleconference for the transaction of National Science Board business and other matters specified, as follows:

DATE AND TIME: January 19, 2011, 11 a.m. to 12 p.m. EST.

SUBJECT MATTER: Chairman's remarks and a discussion of Section 526 of the FY10 America Competes Reauthorization Act (Broader Impacts Review Criterion).

STATUS: Open.

LOCATION: This meeting will be held by teleconference at the National Science Board Office, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. A room will be available for the public to listen-in to this meeting held by teleconference. All visitors must contact the Board Office at least 24 hours prior to the meeting held by teleconference to arrange for a visitor's badge and to obtain the room number. Call 703-292-7000 or send an e-mail message to nationalsciencebrd@nsf.gov with your name and organizational affiliation to request the room number and your badge, which will be ready for pick-up

at the visitor's desk the day of the meeting. All visitors must report to the NSF visitor desk located in the lobby at the 9th and N. Stuart Streets entrance to receive your visitor's badge on the day of the teleconference.

UPDATES AND POINT OF CONTACT: Please refer to the National Science Board Web site <http://www.nsf.gov/nsb> for additional information and schedule updates (time, place, subject matter or status of meeting) may be found at <http://www.nsf.gov/nsb/notices/>. Point of contact for this meeting is: Kim Silverman, National Science Board Office, 4201 Wilson Blvd., Arlington, VA 22230. Telephone: (703) 292-7000.

Daniel A. Lauretano,

Counsel to the National Science Board.

[FR Doc. 2011-705 Filed 1-11-11; 11:15 am]

BILLING CODE 7555-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2009-0263]

Draft Regulatory Guide: Reissuance and Availability

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of Reissuance and Availability of Draft Regulatory Guide (DG)-1229.

FOR FURTHER INFORMATION CONTACT:

Aaron Szabo, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: 301-415-1985 or e-mail: Aaron.Szabo@nrc.gov.

SUMMARY: DG-1229 was previously issued for public comment in June 2009, and the Commission approved RG 1.159 subject to changes which are spelled out in a Staff Requirements Memorandum dated October 25, 2010 (ML1029805650). Because of the nature of the changes, the draft guide is being reissued for comment, and during that period, NRR will hold a public workshop to solicit comments from stakeholders and other relevant experts on the use of the net present value method for parent guarantees in license transfer cases.

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment a draft guide in the agency's "Regulatory Guide" series. This series was developed to describe and make available to the public such information as methods that are acceptable to the NRC staff for implementing specific

parts of the NRC's regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff needs in its review of applications for permits and licenses.

The draft regulatory guide (DG), entitled, "Assuring the Availability of Funds for Decommissioning Nuclear Reactors," is temporarily identified by its task number, DG-1229, which should be mentioned in all related correspondence. DG-1229 is proposed Revision 2 of Regulatory Guide 1.159, dated October 2003.

The general requirements for applications for license termination and decommissioning nuclear power, research, and test reactors appear in Title 10, Part 50, "Domestic Licensing of Production and Utilization Facilities," of the *Code of Federal Regulations* (10 CFR Part 50). Subsequent to the original publication of this regulatory guide in August 1990, the NRC promulgated amendments to 10 CFR Part 50 in the **Federal Register** on September 22, 1998 (63 FR 50465). Various amendments modified 10 CFR 50.33(k), 10 CFR 50.75, "Reporting and Recordkeeping for Decommissioning Planning," and 10 CFR 50.82(b), which require operating license applicants and existing licensees to submit information on how reasonable assurance will be provided that funds are available to decommission the facility. The NRC promulgated additional amendments to 10 CFR 50.75 on December 24, 2002, in the **Federal Register** (67 FR 78332). As amended, 10 CFR 50.75 establishes requirements for indicating how this assurance will be provided; namely, the amount of funds that must be provided, including updates; the methods to be used for assuring funds; and provisions contained in trust agreements for safeguarding decommissioning funds. This document provides guidance to applicants and licensees of nuclear power, research, and test reactors concerning methods acceptable to the staff of the NRC for complying with requirements in the rules regarding the amount of funds for decommissioning. It also provides guidance on the content and form of the financial assurance mechanisms in those rule amendments.

II. Further Information

The NRC staff is soliciting comments on DG-1229. Comments may be accompanied by relevant information or supporting data and should mention DG-1229 in the subject line. Comments submitted in writing or in electronic form will be made available to the public in their entirety through the

NRC's Agencywide Documents Access and Management System (ADAMS).

ADDRESSES: You may submit comments by any one of the following methods. Please include Docket ID NRC-2009-0263 in the subject line of your comments. Comments submitted in writing or in electronic form will be posted on the NRC website and on the Federal rulemaking website 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.

Federal Rulemaking Website: Go to <http://www.regulations.gov> and search for documents filed under Docket ID NRC-2009-0263. Address questions about NRC dockets to Carol Gallagher 301-492-3668; e-mail Carol.Gallagher@nrc.gov.

Mail comments to: Cindy K. 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, or by fax to RDB at 301-492-3446.

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 copy 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. The Regulatory Analysis is available electronically under ADAMS Accession Number ML103350166.

Comments would be most helpful if received by March 14, 2011. Comments received after that date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Although a time limit is given, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time.

Electronic copies of DG-1229 are available through the NRC's public Web site under Draft Regulatory Guides in the "Regulatory Guides" collection of the NRC's Electronic Reading Room at <http://www.nrc.gov/reading-rm/doc-collections/>. Electronic copies are also available in ADAMS (<http://www.nrc.gov/reading-rm/adams.html>), under Accession No. ML103350136.

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Dated at Rockville, Maryland, this 6th day of January, 2011.

For the Nuclear Regulatory Commission.

Harriet Karagiannis,

Acting Chief, Regulatory Guide, Development Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2011-611 Filed 1-12-11; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[Docket Numbers 50-498, 50-499; NRC-2010-0375]

Notice of Acceptance for Docketing of the Application and Notice of Opportunity for Hearing Regarding Renewal of Facility Operating License Numbers NPF-76 and NPF-80 for an Additional 20-Year Period, STP Nuclear Operating Company, South Texas Project, Units 1 and 2

The U.S. Nuclear Regulatory Commission (NRC or the Commission) is considering an application for the renewal of operating licenses NPF-76 and NPF-80, which authorizes STP Nuclear Operating Company (STPNOC), to operate the South Texas Project STP, Unit 1, at 3853 megawatts thermal and Unit 2 at 3853 megawatts thermal, respectively. The renewed licenses would authorize the applicant to operate STP, Units 1 and 2, for an additional 20 years beyond the period specified in the current licenses. STP, Units 1 and 2, are located near Wadsworth, TX; the current operating license for Unit 1 expires on August 20, 2027, and Unit 2 expires on December 15, 2028.

STPNOC submitted the application dated October 25, 2010, pursuant to Title 10, Part 54, of the *Code of Federal Regulations* (10 CFR Part 54), to renew operating licenses NPF-76 and NPF-80 for STP, Units 1 and 2. A notice of receipt and availability of the license renewal application (LRA) was published in the **Federal Register** on December 9, 2010 (75 FR 76757).

The NRC staff has determined that STPNOC has submitted sufficient information in accordance with 10 CFR Sections 54.19, 54.21, 54.22, 54.23, and 51.53(c), to enable the staff to undertake a review of the application, and that the application is therefore acceptable for docketing. The current Docket Numbers 50-498 and 50-499 for operating licenses NPF-76 and NPF-80, respectively, will be retained. The determination to accept the LRA for docketing does not constitute a determination that a renewed license should be issued, and does not preclude the NRC staff from requesting additional information as the review proceeds.

Before issuance of the requested renewed licenses, the NRC will have made the findings required by the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. In accordance with 10 CFR 54.29, the NRC may issue the renewed licenses on the basis of its review if it finds that actions have been identified and have been or will be taken with respect to: (1) Managing the effects of aging during the period of extended operation on the functionality of structures and components that have been identified as requiring aging management review, and (2) time-limited aging analyses that have been identified as requiring review, such that there is reasonable assurance that the activities authorized by the renewed licenses will continue to be conducted in accordance with the current licensing basis (CLB) and that any changes made to the plant's CLB will comply with the Act and the Commission's regulations.

Additionally, in accordance with 10 CFR 51.95(c), the NRC will prepare an environmental impact statement that is a supplement to the Commission's NUREG-1437, "Generic Environmental Impact Statement for License Renewal of Nuclear Power Plants," dated May 1996. In considering the LRA, the Commission must find that the applicable requirements of Subpart A of 10 CFR Part 51 have been satisfied, and that matters raised under 10 CFR 2.335 have been addressed. Pursuant to 10 CFR 51.26, and as part of the environmental scoping process, the staff intends to hold a public scoping meeting. Detailed information regarding

the environmental scoping meeting will be the subject of a separate **Federal Register** notice.

Within 60 days after the date of publication of this **Federal Register** notice, any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene with respect to the renewal of the license. Requests for a hearing or petitions for leave to intervene must be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders" in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.309, which is available at the Commission's Public Document Room (PDR), located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland 20852, and is accessible from the NRC's Agencywide Documents Access and Management System (ADAMS) Public Electronic Reading Room on the Internet at <http://www.nrc.gov/reading-rm/adams.html>. <http://www.nrc.gov/readingrm/adams.html>. Persons who do not have access to the Internet or who encounter problems in accessing the documents located in ADAMS should contact the NRC's PDR reference staff by telephone at 1-800-397-4209, or 301-415-4737, or by e-mail at PDR.RESOURCE@nrc.gov. If a request for a hearing/petition for leave to intervene is filed within the 60-day period, 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 Panel will issue a notice of a hearing or an appropriate order. In the event that no request for a hearing or petition for leave to intervene is filed within the 60-day period, the NRC may, upon completion of its evaluations and upon making the findings required under 10 CFR Parts 51 and 54, renew the license without further notice.

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, taking into consideration the limited scope of matters that may be considered pursuant to 10 CFR Parts 51 and 54. The petition must specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of

the requestor's/petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (3) 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 petitioner/requestor 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 basis for each contention and a concise statement of the alleged facts or the expert opinion that supports the contention 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 requestor/petitioner is aware and on which the requestor/petitioner intends to rely to establish those facts or expert opinion. The requestor/petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact.¹ Contentions shall be limited to matters within the scope of the action under consideration. The contention must be one that, 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.

The Commission requests that each contention be given a separate numeric or alpha designation within one of the following groups: (1) Technical (primarily related to safety concerns); (2) environmental; or (3) miscellaneous.

As specified in 10 CFR 2.309, if two or more requestors/petitioners seek to co-sponsor a contention or propose substantially the same contention, the requestors/petitioners will be required to jointly designate a representative who shall have the authority to act for the requestors/petitioners with respect to that contention.

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

¹ To the extent that the application contains attachments and supporting documents that are not publicly available because they are asserted to contain safeguards or proprietary information, petitioners desiring access to this information should contact the applicant or applicant's counsel to discuss the need for a protective order.

participate fully in the conduct of the hearing. A request for hearing or a petition for leave to intervene must be filed in accordance with the NRC E-Filing rule, which the NRC promulgated in August 2007, 72 FR 49139 (Aug. 28, 2007). The E-Filing process requires participants to submit and serve 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 a waiver 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 requestor/petitioner must contact the Office of the Secretary by e-mail at HEARINGDOCKET@NRC.GOV, or by calling (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/or (2) creation of an electronic docket for the proceeding (even in instances in which the requestor/petitioner (or its counsel or representative) already holds an NRC-issued digital ID certificate). Each requestor/petitioner will need to download the Workplace Forms Viewer™ to access the Electronic Information Exchange (EIE), a component of the E-Filing system. The Workplace Forms Viewer™ is free and is available at <http://www.nrc.gov/site-help/e-submittals/install-viewer.html>. 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>.

Once a requestor/petitioner has obtained a digital ID certificate, had a docket created, and downloaded the EIE viewer, it 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 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 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 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 may seek assistance through the "Contact Us" link located on the NRC Web site at <http://www.nrc.gov/site-help/e-submittals.html> or by calling the NRC technical help line, which is available between 8:30 a.m. and 4:15 p.m., Eastern Time, Monday through Friday. The help line number is 1-800-397-4209 or locally, 301-415-4737.

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: 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.

Non-timely requests and/or petitions and contentions will not be entertained absent a determination by the Commission, the presiding officer, or the Atomic Safety and Licensing Board that the petition and/or request should be granted and/or the contentions should be admitted based on a balancing of the factors specified in 10 CFR 2.309(c)(1)(i)-(viii). To be timely, filings must be submitted no later than 11:59 p.m. Eastern Time on the due date.

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket which is available to the public at http://ehd.nrc.gov/EHD_Proceeding/home.asp, unless excluded pursuant to an order of

the Commission, an Atomic Safety and Licensing Board, or a 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. 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.

Detailed information about the license renewal process can be found under the Nuclear Reactors icon at <http://www.nrc.gov/reactors/operating/licensing/renewal.html> on the NRC's Web site. Copies of the application to renew the operating license for STP, Units 1 and 2, are available for public inspection at the Commission's PDR, located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland 20852-2738, and at <http://www.nrc.gov/reactors/operating/licensing/renewal/applications.html>, the NRC's Web site while the application is under review. The application may be accessed in ADAMS through the NRC's Public Electronic Reading Room on the Internet at <http://www.nrc.gov/reading-rm/adams.html> under ADAMS Accession Number ML103010256. As stated above, persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS may contact the NRC Public Document Room (PDR) Reference staff by telephone at 1-800-397-4209 or 301-415-4737, or by e-mail to PDR.RESOURCE@nrc.gov.

The NRC staff has verified that a copy of the license renewal application is also available to local residents near STP, at the Bay City Public Library, 1100 7th Street, Bay City, TX 77414.

Dated at Rockville, Maryland, this 7th day of January, 2011.

For the Nuclear Regulatory Commission.

Brian E. Holian,

Director, Division of License Renewal, Office of Nuclear Reactor Regulation.

[FR Doc. 2011-610 Filed 1-12-11; 8:45 am]

BILLING CODE 7590-01-P

PRESIDIO TRUST

Notice of Public Meeting

AGENCY: The Presidio Trust.

ACTION: Notice of public meeting.

SUMMARY: In accordance with § 103(c)(6) of the Presidio Trust Act, 16 U.S.C. 460bb appendix, and in accordance with the Presidio Trust's bylaws, notice is hereby given that a public meeting of

the Presidio Trust Board of Directors will be held commencing 6:30 p.m. on Monday, February 7, 2011, at the Golden Gate Club, 135 Fisher Loop, Presidio of San Francisco, California. The Presidio Trust was created by Congress in 1996 to manage approximately eighty percent of the former U.S. Army base known as the Presidio, in San Francisco, California.

The purposes of this meeting are to approve minutes of a previous Board meeting, to provide the Chairperson's report, to provide the Executive Director's report, to provide project updates, and to receive public comment on other matters in accordance with the Trust's Public Outreach Policy.

Individuals requiring special accommodation at this meeting, such as needing a sign language interpreter, should contact Mollie Matull at 415.561.5300 prior to January 31, 2011.

Time: The meeting will begin at 6:30 p.m. on Monday, February 7, 2011.

ADDRESSES: The meeting will be held at the Golden Gate Club, 135 Fisher Loop, Presidio of San Francisco.

FOR FURTHER INFORMATION CONTACT:

Karen Cook, General Counsel, the Presidio Trust, 34 Graham Street, P.O. Box 29052, San Francisco, California 94129-0052, Telephone: 415.561.5300.

Dated: January 5, 2011.

Karen A. Cook,

General Counsel.

[FR Doc. 2011-660 Filed 1-12-11; 8:45 am]

BILLING CODE 4310-4R-P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Request for Public Comment on the Draft National Nanotechnology Initiative Strategy for Nanotechnology-Related Environmental, Health, and Safety Research

AGENCY: White House Office of Science and Technology Policy.

ACTION: Notice: Request for public comment.

SUMMARY: With this notice, the White House Office of Science and Technology Policy and the Nanoscale Science, Engineering, and Technology Subcommittee of the National Science and Technology Council request comments from the public regarding the draft National Nanotechnology Initiative (NNI) Strategy for Nanotechnology-Related Environmental, Health, and Safety Research (hereafter referred to as "draft NNI EHS strategy"). The draft NNI EHS strategy is posted at <http://strategy.nano.gov>. Comments of

approximately one page or less in length (4,000 characters) are requested. This request will be active through January 21, 11:59 pm EST.

DATES: Comments were previously invited through 11:59 p.m. EST on January 6, 2011. This notice extends the period for public comment through January 21, 11:59 pm EST.

ADDRESSES: Respondents are encouraged to register online at the NNI Strategy Portal at <http://strategy.nano.gov> to post their comments (4,000 characters or less) as a response to the request for public comment. Alternatively, comments of one page in length or less may be submitted via e-mail to: nnistrategy@ostp.gov. Any information you provide to us may be posted online. Therefore, do *not* send any information that might be considered proprietary, personal, sensitive, or confidential.

Overview: The National Nanotechnology Initiative Strategy for Nanotechnology-Related Environmental, Health, and Safety Research or “NNI EHS Strategy” helps to facilitate achievement of the National Nanotechnology Initiative vision by laying out guidance for agency leaders, program managers, and the research community regarding planning and implementation of nanotechnology EHS R&D investments and activities.

The NNI is a U.S. Government R&D program of 25 agencies working together toward the common challenging vision of a future in which the ability to understand and control matter at the nanoscale leads to a revolution in technology and industry that benefits society. The combined, coordinated efforts of these agencies have accelerated discovery, development, and deployment of nanotechnology towards agency missions and the broader national interest. Established in 2001, the NNI involves nanotechnology-related activities by the 25 member agencies, 15 of which have requested budgets for nanotechnology R&D for Fiscal Year (FY) 2011.

The NNI is managed within the framework of the National Science and Technology Council (NSTC), the Cabinet-level council that coordinates science and technology across the Federal government and interfaces with other sectors. The Nanoscale Science, Engineering, and Technology (NSET) Subcommittee of the NSTC coordinates planning, budgeting, program implementation, and review of the NNI. The NSET Subcommittee is composed of senior representatives from agencies participating in the NNI (<http://www.nano.gov>). The NSET

Subcommittee and its Nanotechnology Environmental and Health Implications (NEHI) Working Group provide leadership in establishing the NNI environmental, health, and safety research agenda and in communicating data and information related to the environmental and health aspects of nanotechnology between NNI agencies and with the public. NNI activities support the development of the new tools and methods required for the research that will enable risk analysis and assist in regulatory decision-making.

The NSET Subcommittee has solicited multiple streams of input to inform the development of this latest NNI EHS Strategy. Independent reviews of the NNI by the President’s Council of Advisors on Science and Technology and the National Research Council of the National Academies have made specific recommendations for improving the NNI EHS strategy. A series of four NNI workshops took place in 2009–2010 to solicit input for this strategy: 1. Human & Environmental Exposure Assessment of Nanomaterials (details at <http://www.nano.gov/html/meetings/exposure/>), 2. Nanomaterials and the Environment & Instrumentation, Metrology, and Analytical Methods (details at <http://www.nano.gov/html/meetings/environment/>), 3. Nanomaterials and Human Health & Instrumentation, Metrology, and Analytical Methods (details at <http://www.nano.gov/html/meetings/humanhealth/>), and 4. Capstone: Risk Management Methods & Ethical, Legal, and Societal Implications of Nanotechnology (details at <http://www.nano.gov/html/meetings/capstone/>). Additional input has come from the NNI Strategic Planning Stakeholders Workshop (details at <http://www.nano.gov/html/meetings/NNISWorkshop/>) as well as in responses to a Request for Information published in the **Federal Register** on July 6, 2010, and comments posted online in response to challenge questions from July 13–August 15, 2010, at the NNI Strategy Portal (<http://strategy.nano.gov>).

The draft NNI EHS Strategy complements the 2010 NNI Strategic Plan by setting forth the NNI strategy for nanotechnology-related environmental, health, and safety (EHS) research. It describes the NNI vision and goals for Federal EHS research and presents the current NNI EHS research portfolio. The EHS strategy includes a description of the NNI EHS research investment by research need, the state of the science, and an analysis of the gaps and barriers to achieving that research as part of the

NNI’s adaptive management of this strategy. This strategy updates and replaces the NNI EHS Strategy of February 2008. The NNI EHS Strategy aims to ensure the responsible development of nanotechnology by providing guidance to the Federal agencies that produce the scientific information for risk management, regulatory decision-making, product use, research planning, and public outreach. The core research areas providing this critical information are measurement, human exposure assessment, human health, and the environment in order to inform risk assessment and risk management.

Your comments on this draft of the plan must be received by 11:59 p.m. EST on January 21, 2011. Please reference page and line numbers as appropriate, and keep your responses to 4,000 characters or less. You may also e-mail your responses, no more than one page in length, to nnistrategy@ostp.gov. Responses to this notice are not offers and cannot be accepted by the Federal government to form a binding contract or issue a grant. Information obtained as a result of this notice may be used by the Federal government for program planning on a non-attribution basis. Any information you provide to us may be posted online. Therefore, do *not* send any information that might be considered proprietary, personal, sensitive, or confidential.

FOR FURTHER INFORMATION CONTACT: Any questions about the content of this notice should be sent to NNIStrategy@ostp.gov. Questions and responses may also be sent by mail (please allow additional time for processing) to the address: Office of Science and Technology Policy, ATTN: NNI EHS Strategy Comments, Executive Office of the President, 725 17th Street Room 5228, Washington, DC 20502. Phone: (202) 456–7116, Fax: (202) 456–6021.

Ted Wackler,

Deputy Chief of Staff.

[FR Doc. 2011–555 Filed 1–12–11; 8:45 am]

BILLING CODE 3170–W0–P

SECURITIES AND EXCHANGE COMMISSION

[Rule 17a–4(b)(11), SEC File No. 270–449, OMB Control No. 3235–0506, Rule 17a–3(a)(16)]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Investor

Education and Advocacy,
Washington, DC 20549.

Extension:

Rule 17a-4(b)(11), SEC File No. 270-449, OMB Control No. 3235-0506, Rule 17a-3(a)(16).

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. Sec. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") has submitted to the Office of Management and Budget ("OMB") a request for extension of the existing collection of information provided for in the following rule: Rule 17a-4(b)(11) (17 CFR Sec. 240.17a-4(b)(11)) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

Rule 17a-4(b)(11) (17 CFR Sec. 240.17a-4(b)(11)) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) describes the record preservation requirements for those records required to be kept pursuant to Rule 17a-3(a)(16), including how such records should be kept and for how long, to be used in monitoring compliance with the Commission's financial responsibility program and antifraud and antimanipulative rules as well as other rules and regulations of the Commission and the self-regulatory organizations.

It is estimated that respondents will incur a total burden of 2835 hours per year (105 respondents multiplied by 27 burden hours to comply with Rule 17a-3(a)(16). It is estimated that approximately 105 active broker-dealer respondents registered with the Commission will incur a total burden of 315 hours per year to comply with Rule 17a-4(b)(11), (105 respondents multiplied by 3 burden hours per respondent equals 315 total burden hours).

The Commission estimates that an employee of a broker-dealer charged to ensure compliance with Rule 17a-3(a)(16) receives annual compensation of \$238,000. This compensation is the equivalent of \$119 per hour (\$238,000 divided by 2,000 payroll hours per year). Thus, the average cost estimated for each respondent would be \$3,213: Rule 17a-3(a)(16) Recordkeeping requirements 27 hours at \$119/hr = \$3,213.

The Commission estimates that an employee of a broker-dealer charged to ensure compliance with Rule 17a-4(b)(11) receives annual compensation of \$238,000. This compensation is the equivalent of \$119 per hour (\$238,000 divided by 2,000 pay roll hours per year). Thus, the average cost estimated for each respondent would be \$357.00: Rule 17a-4(b)(11) Record preservation requirements 3 hours at \$119/hr = \$357.

Accordingly, the annual aggregated hour burden for each broker-dealer required to comply with Rules 17a-3(a)(16) and 17a-4(b)(11) would be \$3,570: (\$3213 + \$357 = \$3570).

Under Rule 17a-4(a)(11) broker-dealers are required to retain records for a period of not less than three years. Compliance with the rule is mandatory. The required records are available only to the examination staff of the Commission and the self-regulatory organization of which the broker-dealer is a member.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid control number. The public may view the information discussed in this notice at <http://www.reginfo.gov>.

Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an e-mail to: Shagufta_Ahmed@omb.eop.gov; and (ii) Thomas Bayer, Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, VA 22312 or send an e-mail to: PRA_Mailbox@sec.gov. Comments must be submitted to OMB within 30 days of this notice.

Dated: January 10, 2010.

Elizabeth M. Murphy,
Secretary.

[FR Doc. 2011-674 Filed 1-12-11; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-63659; File No. SR-DTC-2010-17]

Self-Regulatory Organizations; the Depository Trust Company; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Fee Revisions

January 6, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ notice is hereby given that on December 28, 2010, The Depository Trust Company ("DTC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II, which Items have been prepared

primarily by DTC. DTC filed the proposed rule change pursuant to Section 19(b)(3)(A)(ii) of the Act² and Rule 19b-4(f)(2)³ thereunder so that the proposal was 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 purpose of this filing is to revise the fees for certain services provided by DTC.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, DTC 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. DTC has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the proposed rule change is to revise the fees for certain services provided by DTC. DTC will increase fees associated with Custody and Asset Servicing, Deposits, Underwriting and Dividend, Book-Entry Delivery, and MMI services in order to realign fees with costs incurred in providing these services and to scale the fees to reflect processing complexity, with the objective of fee simplification and transparency.

DTC will also introduce fees for new capabilities in Asset Services, including a fee to recover costs associated with excluding Treasury Shares of a company from dividend processing.

In addition, DTC will implement or increase certain disincentive fees to discourage behavior that keeps the industry from achieving peak efficiency, including fee increases in Asset Services reject and exception processing relating to Underwriting and Withdrawal activities.

DTC states that the proposed fee revisions are consistent with DTC's overall pricing philosophy of aligning service fees with underlying costs,

² 15 U.S.C. 78s(b)(3)(A)(ii).

³ 17 CFR 240.19b-4(f)(2).

¹ 15 U.S.C. 78s(b)(1).

discouraging manual and exception processing, and encouraging immobilization and dematerialization of securities. Information on specific fee changes is included as Exhibit 5 to DTC's proposed rule filing, which can be viewed at DTC's Web site (http://www.dtcc.com/legal/rule_filings/dtc/2010.php). The effective date for these fee adjustments is January 3, 2011.

DTC states that this rule filing is consistent with the requirements of Section 17A of the Act⁴ and the rules and regulations thereunder because it clarifies and updates DTC's fee schedule. As such, it provides for the equitable allocation of fees among its Participants.

B. Self-Regulatory Organization's Statement on Burden on Competition

DTC does not believe that the proposed rule change will have any impact or impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

DTC has not solicited or received written comments relating to the proposed rule change. DTC will notify the Commission of any comments it receives.

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 Act⁵ and Rule 19b-4(f)(2)⁶ because the proposed rule change establishes or changes a due, fee, or other charge applicable only to a member. 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 No. SR-DTC-2010-17 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC, 20549-1090.

All submissions should refer to File No. SR-DTC-2010-17. 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 filings also will be available for inspection and copying at DTC's principal office and on DTC's Web site at http://www.dtcc.com/legal/rule_filings/dtc/2010.php. 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 submission should refer to File No. SR-DTC-2010-17 and should be submitted on or before February 3, 2011.

For the Commission by the Division of Trading and Markets pursuant to delegated authority.⁷

Elizabeth M. Murphy,
Secretary.

[FR Doc. 2011-663 Filed 1-12-11; 8:45 am]

BILLING CODE 8011-01-P

⁷ 17 CFR 200.30-3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #12320 and #12321]

New Mexico Disaster #NM-00016

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of New Mexico (FEMA-1936-DR), dated 09/13/2010.

Incident: Severe Storms and Flooding.
Incident Period: 07/25/2010 through 08/09/2010.

DATES: *Effective Date:* 01/04/2011.

Physical Loan Application Deadline Date: 11/12/2010.

Economic Injury (EIDL) Loan Application Deadline Date: 06/13/2011.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of NEW MEXICO, dated 09/13/2010, is hereby amended to include the following areas as adversely affected by the disaster. Primary Areas: The Navajo Nation, The Pueblo of Acoma.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2011-649 Filed 1-12-11; 8:45 am]

BILLING CODE 8025-01-P

SMALL BUSINESS ADMINISTRATION

Houston District Office Advisory Committee

AGENCY: U.S. Small Business Administration.

ACTION: Notice of open Federal advisory committee meeting.

SUMMARY: The SBA is issuing this notice to announce the location, date, time, and agenda for the next meeting of the Houston District Office Advisory committee. The meeting will be open to the public.

⁴ 15 U.S.C. 78q-1.

⁵ *Supra* note 2.

⁶ *Supra* note 3.

DATES: The meeting will be held on February 16, 2011 from approximately 11:30 a.m. to 12:30 p.m. Central Standard Time.

ADDRESSES: The meeting will be held at the U.S. Small Business Administration Conference Room, located at 8701 South Gessner, Suite 1200, Houston, TX. 77074.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), SBA announces the meeting of the Houston District Office Advisory Committee. The Houston District Office Advisory Committee is tasked with providing advice and recommendations to the District Director, Regional Administrator, and the SBA Administrator.

The purpose of the meeting is to interact and get feedback from the community stakeholders on how we can better serve our community and to create new networking opportunities with the Houston community. The agenda or topics to be discussed will include: Lender Performance, Small Business Job Act update Guest Speaker: Jacqueline Taylor, Associate Region Director of U of H SBDC, Lender SBA Goals for FY 2010–2011.

FOR FURTHER INFORMATION CONTACT: The meeting is open to the public, however, advance notice of attendance is requested. Anyone wishing to attend and/or make a presentation to the Houston District Office Advisory Committee must contact Sonia Maldonado, Business Development Specialist by February 9, 2011, by fax or e-mail in order to be placed on the agenda. Sonia Maldonado, Business Development Specialist, 8701 S. Gessner Drive, Suite 1200, Houston, TX 77074, Fax 202–481–5617, or e-mail Sonia.maldonado@sba.gov.

Additionally, if you need accommodations because of a disability or require additional information, please contact Sonia Maldonado.

For more information, please visit our Web site at <http://www.sba.gov/tx>.

Dated: January 4, 2011.

Dan Jones,

SBA Committee Management Officer.

[FR Doc. 2011–651 Filed 1–12–11; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[License No. 10/10–0194]

Bancshares Capital, L.P.; Notice of Surrender Under 13 CFR 107.1900

Pursuant to the authority granted to the United States Small Business

Administration under the Small Business Investment Act of 1958, under section 309 of the Act and Section 13 CFR 107.1900 of the Small Business Administration Rules and Regulations Bancshares Capital, L.P., 16118 72nd Avenue West, Edmonds, Washington, 98026 (License number 10/10–0194), licensed September 28, 2000 as a Small Business Investment Company (SBIC), has surrendered; its license is hereby declared null and void.

Date: June 6, 2010.

Sean J. Greene,

Associate Administrator for Investment.

[FR Doc. 2011–650 Filed 1–12–11; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice 7295]

Bureau of Educational and Cultural Affairs (ECA) Request for Grant Proposals: FY2012 Humphrey Fellowship Program

Announcement Type: New Cooperative Agreement.

Funding Opportunity Number: ECA/A/S/U–12–01.

Catalog of Federal Domestic Assistance Number: 19.010.

Application Deadline: April 4, 2011.

Executive Summary: The U.S. Department of State's Bureau of Educational and Cultural Affairs (ECA) announces an open competition to assist in the administration of the FY2012 Hubert H. Humphrey Fellowship Program. Public and private non-profit organizations meeting the provisions described in Internal Revenue Code section 26 U.S.C. 501(c)(3) may submit proposals to cooperate with the Bureau in the administration and implementation of the FY2012 Humphrey Program. The final amount that will be available in FY2012 to fund the Humphrey Program has not yet been determined. Applicants are asked to prepare a budget not to exceed \$13,500,000 for program and administrative costs. Please indicate the number of participants who can be accommodated based on detailed calculations of program and administrative costs. For more information about calculating budget requests, see paragraph IV.3.e.1 of this document. Pending the availability of FY2012 funds, the Agreement should begin on October 1, 2011 and should expire on September 30, 2014.

I. Funding Opportunity Description

Authority

Overall grant making authority for this program is contained in the Mutual Educational and Cultural Exchange Act of 1961, Public Law 87–256, as amended, also known as the Fulbright-Hays Act. The purpose of the Act is “to enable the Government of the United States to increase mutual understanding between the people of the United States and the people of other countries * * *; to strengthen the ties which unite us with other nations by demonstrating the educational and cultural interests, developments, and achievements of the people of the United States and other nations * * * and thus to assist in the development of friendly, sympathetic and peaceful relations between the United States and the other countries of the world.” The funding authority for the program above is provided through legislation.

Purpose

Overview: The Hubert H. Humphrey Fellowship Program was established in 1978. The goal of the Humphrey Program is to strengthen U.S. interaction with professionals from developing and emerging countries who are well placed to address their countries' development needs in key areas including public health, sustainable growth, and democratic institution-building, while providing participants with opportunities to develop professional expertise and leadership skills for public service in their countries. Each year the Humphrey Program brings accomplished professionals from North Africa and the Middle East, Sub-Saharan Africa, East Asia and the Pacific, South and Central Asia, Latin America, the Caribbean, Eastern Europe, and Eurasia to the U.S. for a ten-month stay combining non-degree graduate study, leadership training, and professional development. Candidates for the Humphrey Program are nominated by U.S. Embassies or binational Fulbright Commissions, based on the candidates' professional backgrounds, academic qualifications, and leadership potential. By providing these emerging leaders with opportunities to understand U.S. society and culture and to participate with U.S. colleagues in current approaches to the fields in which they work, the Humphrey Program provides a basis for on-going cooperation between U.S. citizens and their professional counterparts in other countries.

Fellowships are granted competitively to candidates who have a public service orientation, a commitment to their

countries' development, and clear leadership potential. Candidates are recruited from both the public and the private sectors, including non-governmental organizations, in areas that include the following: Agricultural and rural development; communications/journalism; economic development; educational administration, planning, and policy; finance and banking; higher education administration; HIV/AIDS policy, prevention, and treatment; human resource management; law and human rights; natural resource management, environmental policy, and climate change; public health policy and management; public policy analysis and public administration; substance abuse education, treatment, and prevention; teaching of English as a foreign language; technology policy and management; trafficking in persons policy and prevention; and urban and regional planning. Humphrey Fellows typically range in age from the late 20's to the mid-50's; are professionals in leadership positions who have the requisite experience, skills, and commitment to public service to advance in their professions; have a minimum of five years of professional experience; and have an interest in policy issues. English speaking ability is required; to enable the Program to accommodate qualified candidates from under-represented populations, up to 6 months of intensive English instruction is offered in the U.S. to selected Fellows prior to the start of the academic-year program. Outreach to under-represented populations is a major priority of the Bureau, and in recent years more than half of the incoming Humphrey Fellows have undertaken some pre-academic English training.

Seventeen universities are currently serving as Humphrey host institutions: American University (law and human rights); Arizona State University (journalism); Boston University (finance and banking); Cornell University (agricultural and rural development and natural resource management, environmental policy, and climate change); Emory University (public health); Johns Hopkins University (substance abuse prevention and treatment); the Massachusetts Institute of Technology (urban/regional planning); Michigan State University (economic development); Pennsylvania State University (education); Syracuse University (public administration); Tulane University (public health); the University of California, Davis (agricultural and rural development and natural resource management,

environmental policy, and climate change); the University of Maryland, College Park (journalism); the University of Minnesota (two cohorts, one in law and human rights and one in public administration); the University of Washington (public administration); Vanderbilt University (education); and Virginia Commonwealth University (substance abuse prevention and treatment). These institutions are selected to host groups of Humphrey Fellows through a competitive process coordinated by the recipient in consultation with the Bureau. Fellows are placed at one of these Humphrey host institutions in multi-regional professional clusters of approximately ten to fifteen Fellows (*e.g.*, twelve Fellows in law and human rights from twelve different countries would be placed at one university that has applied and been approved to host Fellows in this field). Each field of study is openly competed every five years, a cycle which results in one or two fields of study being openly competed in any given year. The schedule for host campus competitions is provided in the Project Objectives, Goals, and Implementation (POGI) document for this solicitation. The recipient will initially be expected to establish cooperative arrangements with the current host universities for one year. However, proposals should include a strategy for evaluating host campus performance over the course of the year and for organizing and administering a competition to obtain and review applications from a diverse range of institutions to serve as host universities in the fields of study scheduled to be competed in FY2012.

To provide a more diverse U.S. experience for the Humphrey Fellows and to engage a more diverse range of communities in the United States in international exchange programs sponsored by the Department of State, "associate campuses" that might not otherwise have the capacity for graduate-level international programming (including community colleges and rural or minority-serving institutions) now cooperate with Humphrey host universities to engage Humphrey Fellows substantively in projects and events at the associate campuses. The plans for host university competitions should include a requirement that all applicant universities include an associate campus component in their proposals.

Proposals must conform with the Bureau requirements and guidelines outlined in the Solicitation Package, which includes this document (the Request for Grant Proposals, or RFGP);

the Project Objectives, Goals and Implementation (POGI); and the Proposal Submission Instructions (PSI).

The Bureau will work cooperatively and closely with the recipient of this Cooperative Agreement and will maintain a regular dialogue on administrative and program issues and questions as they arise over the duration of the award.

Contingent upon satisfactory performance based on annual reviews and availability of funds in subsequent fiscal years, the Bureau intends to renew this award each year for four additional years, before openly competing it again.

Guidelines

Program Planning and Implementation

Applicant organizations are requested to submit a narrative outlining a comprehensive strategy for the administration and program implementation of the Hubert H. Humphrey Fellowship Program including preparation of participant recruitment guidelines, coordination with U.S. Embassies and binational Fulbright Commissions, selection and placement of participants at host universities, monitoring the Fellows' academic and professional programs, and alumni support. In addition, applicant organizations should outline a plan for a range of enhancement activities that will reinforce one another and build on the core academic and professional program. These activities must include, but are not limited to, a fall program-wide seminar in Washington, DC, professional enhancement workshops on specific topics for those Fellows who share an interest in the topics (for example, sustainable use of resources, climate change, food security, international finance, or conflict resolution), and an end-of-year program-wide workshop focusing on issues related to re-entering the home country environment and to implementing the skills and knowledge gained during the Humphrey year. The comprehensive program strategy should reflect a vision for the Program as a whole, interpreting the goals of the Humphrey Program with creativity and providing innovative ideas and recommendations for the Program. The strategy should include a description of how the various components of the Program will be integrated to build upon and reinforce one another. For example, workshops or seminars should build on the campus-based academic and professional program in support of the Humphrey Program's goal of enabling the Fellows to develop leadership skills in public service.

Applicants should propose a theme for the program-wide seminar and identify by name potential speakers who will stimulate the Fellows to engage in discussions with the speakers and one another in ways that are consistent with the seminar's objectives and the Program's goals.

Applicants should describe how they will provide periodic electronic data uploads for the Bureau's participant database, and how they will ensure that these updates are accurate. Please describe a strategy for maintaining a Humphrey Program Web site and for updating it periodically so that Fellows' achievements and statements, listings of eligible countries, Embassy and Fulbright Commission contacts, and the listing of host universities are current and complete. Applicants should also be prepared to collaborate with the Bureau to create and maintain a Humphrey-specific section of the ECA alumni Web site and help promote this Web site to alumni as well as current participants.

Pending availability of funds, this award should begin on October 1, 2011 and will run through September 30, 2014. This award would include both the administrative and program portions of the Hubert H. Humphrey Fellowship Program such as: The selection and placement of the 2012–2013 class of Fellows and the monitoring of their programs; the administration of creative programs of follow-up support and coordination with Humphrey alumni from all classes in coordination with the Bureau's comprehensive alumni outreach efforts; and the administration and implementation of enhancement activities for the 2012–2013 class such as workshops, seminars, or other activities to be proposed by the applicant organizations.

Funding for administrative expenses under this award, such as salaries and benefits, staff travel, office supplies, postage, communications, and indirect costs will cover only the period October 1, 2011 through September 30, 2012.

Funding for program expenses will cover programmatic needs for the 2012–2013 class of Humphrey Fellows throughout the entire Agreement period (October 1, 2011 through September 30, 2014) according to the work plan approved in the final Cooperative Agreement.

Alumni activities should address the following ECA alumni program goals: To foster U.S. diplomatic mission engagement with exchange alumni; to foster alumni implementation and teaching of the concepts they explored during their exchange programs; to provide training that will foster the

ability of alumni to share and implement these concepts; and to participate in long-term evaluations of the Humphrey Program. Alumni programming may include, but is not limited to, activities such as workshops allowing alumni to share their knowledge with the public, including youth; activities fostering community service, or small grants competitions.

A separate Agreement with the current recipient will cover administrative implementation of the program for academic year 2011–2012 Humphrey Fellows until the conclusion of their U.S. program in the late spring of 2012. For the FY2012 Cooperative Agreement, which this announcement covers, the recipient will have responsibility for selection, placement, and program implementation for the academic year 2012–2013 Fellows and for alumni programming for all program alumni. In FY2012 and subsequent years, if the award is renewed, the recipient would additionally be responsible for overseeing the programs of the Fellows who will be in the U.S. in subsequent years (for example, the programs of academic year 2013–2014 Fellows in FY2013).

Please refer to the POGI for specific program and budget guidelines.

In a Cooperative Agreement, ECA/A/S/U is substantially involved in program activities above and beyond routine grant monitoring. ECA/A/S/U will consult frequently with the recipient on details of program implementation as illustrated in the list below of items for which program office consultation and approval is required. ECA/A/S/U activities and responsibilities for this program are as follows:

- Specific plans for enhancement activities such as workshops, seminars, and retreats including themes, agendas, and speakers;
- Texts for publication;
- Candidate Review Committee members;
- Co-funding initiatives;
- Alumni conference plans and other alumni support initiatives;
- Recommendations of the host campus selection committee;
- Associate host campus partnerships;
- Country eligibility and nomination quotas;
- Formulation of program policy;
- Assignment of recommended candidates to principal or alternate status;
- Program evaluation activities.

II. Award Information

Type of Award: Cooperative Agreement. ECA's level of involvement

in this program is listed under number I above.

Fiscal Year Funds: 2012.

Approximate Total Funding: \$13.5 million.

Approximate Number of Awards: 1.

Approximate Average Award:

Pending availability of funds, \$13.5 million.

Anticipated Award Date: Pending availability of funds, October 1, 2011.

Anticipated Project Completion Date: September 30, 2014.

Additional Information

Pending successful implementation of this program and the availability of funds in subsequent fiscal years, it is ECA's intent to renew this award each year for four additional fiscal years, before openly competing it again.

(III.) Eligibility Information:

III.1. Eligible applicants: Applications may be submitted by public and private non-profit organizations meeting the provisions described in Internal Revenue Code section 26 U.S.C. 501(c)(3).

III.2. Cost Sharing or Matching Funds:

There is no minimum or maximum percentage required for this competition. However, the Bureau encourages applicants to provide maximum levels of cost sharing and funding in support of its programs.

When cost sharing is offered, it is understood and agreed that the applicant must provide the amount of cost sharing as stipulated in its proposal and later included in an approved grant agreement. Cost sharing may be in the form of allowable direct or indirect costs. For accountability, you must maintain written records to support all costs which are claimed as your contribution, as well as costs to be paid by the Federal government. Such records are subject to audit. The basis for determining the value of cash and in-kind contributions must be in accordance with OMB Circular A–110, (Revised), Subpart C.23—Cost Sharing and Matching. In the event you do not provide the minimum amount of cost sharing as stipulated in the approved budget, ECA's contribution will be reduced in like proportion.

III.3. Other Eligibility Requirements:

(a.) Bureau grant guidelines require that organizations with less than four years experience in conducting international exchanges be limited to \$60,000 in Bureau funding. ECA anticipates issuing one award, in an amount up to \$13.5 million to support program and administrative costs required to implement this exchange program. Therefore, organizations with less than four years experience in

conducting international exchanges are ineligible to apply under this competition. The Bureau encourages applicants to provide maximum levels of cost sharing and funding in support of its programs.

(IV.) Application and Submission Information:

Note: Please read the complete announcement before sending inquiries or submitting proposals. Once the RFGP deadline has passed, Bureau staff may not discuss this competition with applicants until the proposal review process has been completed.

IV.1. Contact Information to Request an Application Package: Please contact the Humphrey Fellowships and Institutional Linkages Branch, ECA/A/S/U, SA-5, 4th Floor, U.S. Department of State, 2200 C Street, NW., Washington, DC 20037, *telephone:* (202)632-6331, fax (202)632-9479, *e-mail:* pschelp@state.gov to request a Solicitation Package. Please refer to the Funding Opportunity Number ECA/A/S/U-12-01 when making your request.

Alternatively, an electronic application package may be obtained from grants.gov. Please see section IV.3f for further information.

The Solicitation Package contains the Proposal Submission Instruction (PSI) document which consists of required application forms, and standard guidelines for proposal preparation.

It also contains the Project Objectives, Goals and Implementation (POGI) document, which provides specific information, award criteria and budget instructions tailored to this competition.

Please specify Bureau Program Officer Paul Schelp and refer to Funding Opportunity Number ECA/A/S/U-12-01 on all inquiries and correspondence.

IV.2. To Download a Solicitation Package Via Internet: The entire Solicitation Package may be downloaded from the Bureau's Web site at <http://exchanges.state.gov/grants/open2.html>, or from the Grants.gov Web site at <http://www.grants.gov>.

Please read all information before downloading.

IV.3. Content and Form of Submission: Applicants must follow all instructions in the Solicitation Package. The application should be submitted per the instructions under IV.3f. "Application Deadline and Methods of Submission" section below.

IV.3a. You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the U.S. Government. This number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a

DUNS number is easy and there is no charge. To obtain a DUNS number, access <http://www.dunandbradstreet.com> or call 1-866-705-5711. Please ensure that your DUNS number is included in the appropriate box of the SF-424 which is part of the formal application package.

IV.3b. All proposals must contain an executive summary, proposal narrative and budget.

Please Refer to the Solicitation Package. It contains the mandatory Proposal Submission Instructions (PSI) document and the Project Objectives, Goals and Implementation (POGI) document for additional formatting and technical requirements.

IV.3c. All federal award recipients and sub-recipients must maintain current registrations in the Central Contractor Registration (CCR) database and have a Dun and Bradstreet Data Universal Numbering System (DUNS) number. Recipients and sub-recipients must maintain accurate and up-to-date information in the CCR until all program and financial activity and reporting have been completed. All entities must review and update the information at least annually after the initial registration and more frequently if required information changes or another award is granted.

You must have nonprofit status with the IRS at the time of application. **Please note:** Effective January 7, 2009, all applicants for ECA federal assistance awards must include in their application the names of directors and/or senior executives (current officers, trustees, and key employees, regardless of amount of compensation). In fulfilling this requirement, applicants must submit information in one of the following ways:

(1) Those who file Internal Revenue Service Form 990, "Return of Organization Exempt From Income Tax," must include a copy of relevant portions of this form.

(2) Those who do not file IRS Form 990 must submit information above in the format of their choice.

In addition to final program reporting requirements, award recipients will also be required to submit a one-page document, derived from their program reports, listing and describing their grant activities. For award recipients, the names of directors and/or senior executives (current officers, trustees, and key employees), as well as the one-page description of grant activities, will be transmitted by the State Department to OMB, along with other information required by the Federal Funding Accountability and Transparency Act (FFATA), and will be made available to

the public by the Office of Management and Budget on its USASpending.gov Web site as part of ECA's FFATA reporting requirements.

If your organization is a private nonprofit which has not received a grant or cooperative agreement from ECA in the past three years, or if your organization received nonprofit status from the IRS within the past four years, you must submit the necessary documentation to verify nonprofit status as directed in the PSI document. Failure to do so will cause your proposal to be declared technically ineligible.

IV.3d. Please take into consideration the following information when preparing your proposal narrative:

IV.3d.1. Adherence to all Regulations Governing the J Visa. The Bureau of Educational and Cultural Affairs places critically important emphasis on the security and proper administration of the Exchange Visitor (J visa) Programs and adherence by award recipients and sponsors to all regulations governing the J visa. Therefore, proposals should demonstrate the applicant's capacity to meet all requirements governing the administration of the Exchange Visitor Programs as set forth in 22 CFR 62, including the oversight of Responsible Officers and Alternate Responsible Officers, screening and selection of program participants, provision of pre-arrival information and orientation to participants, monitoring of participants, proper maintenance and security of forms, record-keeping, reporting and other requirements.

Employees of the Grantee will be named Alternate Responsible Officers and will be responsible for issuing DS-2019 forms to participants in this program and performing all actions to comply with the Student and Exchange Visitor Information System (SEVIS).

A copy of the complete regulations governing the administration of Exchange Visitor (J) programs is available at <http://exchanges.state.gov> or from: United States Department of State, Office of Exchange Coordination and Designation, Office of Designation, ECA/EC/D, SA-5, Floor C2, Department of State, Washington, DC 20037.

Please refer to Solicitation Package for further information.

IV.3d.2. Diversity, Freedom and Democracy Guidelines. Pursuant to the Bureau's authorizing legislation, programs must maintain a non-political character and should be balanced and representative of the diversity of American political, social, and cultural life. "Diversity" should be interpreted in the broadest sense and encompass differences including, but not limited to ethnicity, race, gender, religion,

geographic location, socio-economic status, and disabilities. Applicants are strongly encouraged to adhere to the advancement of this principle both in program administration and in program content. Please refer to the review criteria under the "Support for Diversity" section for specific suggestions on incorporating diversity into your proposal. Public Law 104–319 provides that "in carrying out programs of educational and cultural exchange in countries whose people do not fully enjoy freedom and democracy," the Bureau "shall take appropriate steps to provide opportunities for participation in such programs to human rights and democracy leaders of such countries." Public Law 106–113 requires that the governments of the countries described above do not have inappropriate influence in the selection process. Proposals should reflect advancement of these goals in their program contents, to the full extent deemed feasible.

IV.3d.3. Program Monitoring and Evaluation. Proposals must include a plan to monitor and evaluate the project's success, both as the activities unfold and at the end of the program. The Bureau recommends that your proposal include a draft survey questionnaire or other technique plus a description of a methodology to use to link outcomes to original project objectives. The Bureau expects that the recipient organization will track participants or partners and be able to respond to key evaluation questions, including satisfaction with the program, learning as a result of the program, changes in behavior as a result of the program, and effects of the program on institutions (institutions in which participants work or partner institutions). The evaluation plan should include indicators that measure gains in mutual understanding as well as substantive knowledge.

Successful monitoring and evaluation depend heavily on setting clear goals and outcomes at the outset of a program. Your evaluation plan should include a description of your project's objectives, your anticipated project outcomes, and how and when you intend to measure these outcomes (performance indicators). The more that outcomes are "smart" (specific, measurable, attainable, results-oriented, and placed in a reasonable time frame), the easier it will be to conduct the evaluation. You should also show how your project objectives link to the goals of the program described in this RFGP.

Your monitoring and evaluation plan should clearly distinguish between program *outputs* and *outcomes*. *Outputs* are products and services delivered,

often stated as an amount. Output information is important to show the scope or size of project activities, but it cannot substitute for information about progress towards outcomes or the results achieved. Examples of outputs include the number of people trained or the number of seminars conducted. *Outcomes*, in contrast, represent specific results a project is intended to achieve and is usually measured as an extent of change. Findings on outputs and outcomes should both be reported, but the focus should be on outcomes.

We encourage you to assess the following four levels of outcomes, as they relate to the program goals set out in the RFGP (listed here in increasing order of importance):

1. Participant satisfaction with the program and exchange experience.
2. Participant learning, such as increased knowledge, aptitude, skills, and changed understanding and attitude. Learning includes both substantive (subject-specific) learning and mutual understanding.
3. Participant behavior, concrete actions to apply knowledge in work or community; greater participation and responsibility in civic organizations; interpretation and explanation of experiences and new knowledge gained; continued contacts between participants, community members, and others.
4. Institutional changes, such as increased collaboration and partnerships, policy reforms, new programming, and organizational improvements.

Please note: Consideration should be given to the appropriate timing of data collection for each level of outcome. For example, satisfaction is usually captured as a short-term outcome, whereas behavior and institutional changes are normally considered longer-term outcomes.

Overall, the quality of your monitoring and evaluation plan will be judged on how well it (1) specifies intended outcomes; (2) gives clear descriptions of how each outcome will be measured; (3) identifies when particular outcomes will be measured; and (4) provides a clear description of the data collection strategies for each outcome (*i.e.*, surveys, interviews, or focus groups). (**Please note** that evaluation plans that deal only with the first level of outcomes [satisfaction] will be deemed less competitive under the present evaluation criteria.)

Recipient organizations will be required to provide reports analyzing their evaluation findings to the Bureau in their regular program reports. All data collected, including survey responses and contact information, must

be maintained for a minimum of three years and provided to the Bureau upon request.

IV.3.d.4. Describe your plans for staffing: Please provide a staffing plan which outlines the responsibilities of each staff person and explains which staff member will be accountable for each program responsibility. Wherever possible please streamline administrative processes.

IV.3e. Please take the following information into consideration when preparing your budget:

IV.3.e.1. Applicants must submit SF–424A—"Budget Information—Non-Construction Programs" along with a comprehensive budget for the entire program. There must be a summary budget as well as breakdowns reflecting both administrative and program budgets. Applicants should provide separate sub-budgets for each program component, phase, location, or activity to provide clarification.

The summary and detailed administrative and program budgets should be accompanied by a narrative which provides a brief rationale for each line item including a methodology for estimating an appropriate average maintenance allowance levels and tuition costs for the 2012–2013 class of Humphrey Fellows and the number of participants that can be accommodated at the proposed funding level. The total administrative costs funded by the Bureau must be reasonable and appropriate.

IV.3.e.2. Allowable costs for the program and additional budget guidance are outlined in detail in the POGI document.

Please refer to the Solicitation Package for complete budget guidelines and formatting instructions.

IV.3f. Application Deadline and Methods of Submission:

Application Deadline Date: Monday, April 4, 2011.

Reference Number: ECA/A/S/U–12–01.

Methods of Submission: Applications may be submitted in one of two ways:

(1) In hard-copy, via a nationally recognized overnight delivery service (*i.e.*, Federal Express, UPS, Airborne Express, or U.S. Postal Service Express Overnight Mail, etc.), or

(2.) Electronically through <http://www.grants.gov>.

Along with the Project Title, all applicants must enter the above Reference Number in Box 11 on the SF–424 contained in the mandatory Proposal Submission Instructions (PSI) of the solicitation document.

IV.3f.1. Submitting Printed Applications. Applications must be

shipped no later than the above deadline. Delivery services used by applicants must have in-place, centralized shipping identification and tracking systems that may be accessed via the Internet and delivery people who are identifiable by commonly recognized uniforms and delivery vehicles. Proposals shipped on or before the above deadline but received at ECA more than seven days after the deadline will be ineligible for further consideration under this competition. Proposals shipped after the established deadlines are ineligible for consideration under this competition. ECA will *not* notify you upon receipt of application. It is each applicant's responsibility to ensure that each package is marked with a legible tracking number and to monitor/confirm delivery to ECA via the Internet. Delivery of proposal packages *may not* be made via local courier service or in person for this competition. Faxed documents will not be accepted at any time. Only proposals submitted as stated above will be considered.

Important note: When preparing your submission please make sure to include one extra copy of the completed SF-424 form and place it in an envelope addressed to "ECA/EX/PM".

The original and seven copies of the application should be sent to: Program Management Division, ECA-IIP/EX/PM, Ref.: ECA/A/S/U-12-01, SA-5, Floor 4, Department of State, 2200 C Street, NW., Washington, DC 20037.

IV.3f.2—Submitting Electronic Applications. Applicants have the option of submitting proposals electronically through Grants.gov (<http://www.grants.gov>). Complete solicitation packages are available at Grants.gov in the "Find" portion of the system.

Please Note: ECA bears no responsibility for applicant timeliness of submission or data errors resulting from transmission or conversion processes for proposals submitted via Grants.gov.

Please follow the instructions available in the "Get Started" portion of the site (<http://www.grants.gov/GetStarted>).

Several of the steps in the Grants.gov registration process could take several weeks. Therefore, applicants should check with appropriate staff within their organizations immediately after reviewing this RFGP to confirm or determine their registration status with Grants.gov.

Once registered, the amount of time it can take to upload an application will vary depending on a variety of factors including the size of the application and

the speed of your internet connection. In addition, validation of an electronic submission via Grants.gov can take up to two business days.

Therefore, we strongly recommend that you not wait until the application deadline to begin the submission process through Grants.gov.

The Grants.gov Web site includes extensive information on all phases/aspects of the Grants.gov process, including an extensive section on frequently asked questions, located under the "For Applicants" section of the Web site. ECA strongly recommends that all potential applicants review thoroughly the Grants.gov Web site, well in advance of submitting a proposal through the Grants.gov system. ECA bears no responsibility for data errors resulting from transmission or conversion processes.

Direct all questions regarding Grants.gov registration and submission to: Grants.gov Customer Support, Contact Center Phone: 800-518-4726, Business Hours: Monday-Friday, 7 am-9 pm Eastern Time, E-mail: support@grants.gov.

Applicants have until midnight Washington, DC time of the closing date to ensure that their entire application has been uploaded to the Grants.gov site. *There are no exceptions to the above deadline. Applications uploaded to the site after midnight of the application deadline date will be automatically rejected by the grants.gov system, and will be technically ineligible.*

Please refer to the Grants.gov Web site, for definitions of various "application statuses" and the difference between a submission receipt and a submission validation. Applicants will receive a validation e-mail from grants.gov upon the successful submission of an application. Again, validation of an electronic submission via Grants.gov can take up to two business days. *Therefore, we strongly recommend that you not wait until the application deadline to begin the submission process through Grants.gov.* ECA will *not* notify you upon receipt of electronic applications.

It is the responsibility of all applicants submitting proposals via the Grants.gov Web portal to ensure that proposals have been received by Grants.gov in their entirety, and ECA bears no responsibility for data errors resulting from transmission or conversion processes.

IV.3g. Intergovernmental Review of Applications: Executive Order 12372 does not apply to this program.

V. Application Review Information

V.1. Review Process

The Bureau will review all proposals for technical eligibility. Proposals will be deemed ineligible if they do not fully adhere to the guidelines stated herein and in the Solicitation Package. All eligible proposals will be reviewed by the program office. Eligible proposals will be subject to compliance with Federal and Bureau regulations and guidelines and forwarded to Bureau grant panels for advisory review. Proposals may also be reviewed by the Office of the Legal Adviser or by other Department elements. Final funding decisions are at the discretion of the Department of State's Assistant Secretary for Educational and Cultural Affairs. Final technical authority for cooperative agreements resides with the Bureau's Grants Officer.

Review Criteria

Technically eligible applications will be competitively reviewed according to the criteria stated below. These criteria are not rank ordered and all carry equal weight in the proposal evaluation:

1. *Quality of the program idea:* Proposals should exhibit originality, substance, precision, and relevance to the Bureau's mission as well as to the objectives of the Humphrey Fellowship Program.
2. *Program planning:* Detailed agenda and relevant work plan should demonstrate substantive undertakings and logistical capacity. Agenda and plan should adhere to the program overview and guidelines described above. Objectives should be reasonable, feasible, and flexible.
3. *Multiplier effect/impact:* The proposed program should maximize the Humphrey Program's potential to promote mutual understanding at the individual, community, and professional levels and to encourage long-term individual and institutional linkages.
4. *Support of diversity:* Proposals should demonstrate substantive support of the Bureau's policy on diversity. Achievable and relevant features should be cited in both program administration (selection of participants, program venue and program evaluation) and program content (orientation and wrap-up sessions, program meetings, resource materials and follow-up activities).
5. *Institutional capacity and record:* Proposed personnel and institutional resources should be adequate and appropriate to achieve program goals. Proposals should demonstrate an institutional record of successful exchange programs, including

responsible fiscal management and full compliance with all reporting requirements for past Bureau awards (grants or cooperative agreements) as determined by Bureau Grants Staff. The Bureau will consider the past performance of prior recipients and the demonstrated potential of new applicants.

6. *Follow-on and alumni activities:* Proposals should provide a plan for continued follow-on activity (both with and without Bureau support) ensuring that the Humphrey Fellowship year is not an isolated event. Activities should include tracking and maintaining updated lists of all alumni and facilitating follow-up activities for alumni.

7. *Project evaluation:* Proposals should include a plan to evaluate the activity's success, both as the activities unfold and at the end of the program. A draft survey questionnaire or other technique plus description of a methodology to use to link outcomes to original project objectives is recommended. Successful applicants will be expected to submit intermediate reports after major project components are concluded.

8. *Cost-effectiveness and cost-sharing:* The overhead and administrative components of the proposal, including salaries and honoraria, should be kept as low as possible. All other items should be necessary and appropriate. Proposals should maximize cost-sharing through other private sector support as well as institutional direct funding contributions.

(VI.) Award Administration Information:

VI.1 *Award Notices:*

Final awards cannot be made until funds have been appropriated by Congress, allocated and committed through internal Bureau procedures. Successful applicants will receive a Federal Assistance Award (FAA) from the Bureau's Grants Office. The FAA and the original proposal with subsequent modifications (if applicable) shall be the only binding authorizing document between the recipient and the U.S. Government. The FAA will be signed by an authorized Grants Officer, and mailed to the recipient's responsible officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review from the ECA program office coordinating this competition.

VI.2. *Administrative and National Policy Requirements:*

Terms and Conditions for the Administration of ECA agreements include the following:

Office of Management and Budget Circular A-122, "Cost Principles for Nonprofit Organizations"

Office of Management and Budget Circular A-21, "Cost Principles for Educational Institutions"

OMB Circular A-87, "Cost Principles for State, Local and Indian Governments"

OMB Circular No. A-110 (Revised), Uniform Administrative

Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and other Nonprofit Organizations

OMB Circular No. A-102, Uniform Administrative Requirements for Grants-in-Aid to State and Local Governments

OMB Circular No. A-133, Audits of States, Local Government, and Non-profit Organizations

Please reference the following Web sites for additional information:

<http://www.whitehouse.gov/omb/grants>
<http://fa.statebuy.state.gov>

VI.3. *Reporting Requirements:* You must provide ECA with a hard copy original plus one copy of the following reports:

(1) A final comprehensive program and financial report no more than 90 days after the expiration of the award;

(2) A concise, one-page final program report summarizing program outcomes no more than 90 days after the expiration of the award. This one-page report will be transmitted to OMB, and be made available to the public via OMB's USAspending.gov Web site—as part of ECA's Federal Funding Accountability and Transparency Act (FFATA) reporting requirements.

(3) A SF-PPR, "Performance Progress Report" Cover Sheet with all program reports.

(4) Annual program reports and quarterly financial reports.

Award recipients will be required to provide reports analyzing their evaluation findings to the Bureau in their regular program reports. (Please refer to IV. Application and Submission Instructions (IV.3.d.3) above for Program Monitoring and Evaluation information.)

All data collected, including survey responses and contact information, must be maintained for a minimum of three years and provided to the Bureau upon request.

All reports must be sent to the ECA Grants Officer and ECA Program Officer listed in the final assistance award document.

VII. Agency Contacts

For questions about this announcement, contact: Paul Schelp, U.S. Department of State, Office of Global Educational Programs, SA-5, 4th Floor, ECA/A/S/U, 2200 C Street, NW., Washington, DC 20037, *telephone:* 202-632-6331, fax 202-632-9479, *pschelp@state.gov*.

All correspondence with the Bureau concerning this RFGP should reference the above title and reference number ECA/A/S/U-12-01.

Please read the complete announcement before sending inquiries or submitting proposals. Once the RFGP deadline has passed, Bureau staff may not discuss this competition with applicants until the proposal review process has been completed.

VIII. Other Information

Notice

The terms and conditions published in this RFGP are binding and may not be modified by any Bureau representative. Explanatory information provided by the Bureau that contradicts published language will not be binding. Issuance of the RFGP does not constitute an award commitment on the part of the Government. The Bureau reserves the right to reduce, revise, or increase proposal budgets in accordance with the needs of the program and the availability of funds. Awards made will be subject to periodic reporting and evaluation requirements per section VI.3 above.

Dated: January 4, 2011.

Ann Stock,

Assistant Secretary for Educational and Cultural Affairs, U.S. Department of State.

[FR Doc. 2011-499 Filed 1-12-11; 8:45 am]

BILLING CODE 4710-05-P

DEPARTMENT OF STATE

[Public Notice 7297]

Culturally Significant Objects Imported for Exhibition Determinations: "Kings, Queens, and Courtiers: Art in Early Renaissance France"

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236-3 of August 28, 2000, I hereby determine that the objects to be

included in the exhibition "Kings, Queens, and Courtiers: Art in Early Renaissance France" imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The Art Institute of Chicago, Chicago, IL, from on or about February 27, 2011, until on or about May 30, 2011, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the exhibit objects, contact Julie Simpson, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202-632-6467). The mailing address is U.S. Department of State, SA-5, L/DP, Fifth Floor (Suite 5H03), Washington, DC 20522-0505.

Dated: January 11, 2011.

Ann Stock,

Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2011-806 Filed 1-12-11; 8:45 am]

BILLING CODE 4710-05-P

DEPARTMENT OF STATE

[Public Notice: 7299]

Culturally Significant Objects Imported for Exhibition Determinations: "Rembrandt and His School: Masterworks From The Frick and Lugt Collections"

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236-3 of August 28, 2000, I hereby determine that the objects to be included in the exhibition "Rembrandt and His School: Masterworks from The Frick and Lugt Collections," imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to a loan agreement with a foreign owner or custodian. I also determine that the exhibition or display of the exhibit objects at The Frick Collection, New York, NY, from on or about February 15, 2011, until on or

about May 22, 2011, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the exhibit objects, contact Julie Simpson, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202-632-6467). The mailing address is U.S. Department of State, SA-5, L/DP, Fifth Floor (Suite 5H03), Washington, DC 20522-0505.

Dated: January 11, 2011.

Ann Stock,

Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2011-808 Filed 1-12-11; 8:45 am]

BILLING CODE 4710-05-P

DEPARTMENT OF STATE

[Public Notice: 7298]

Culturally Significant Objects Imported for Exhibition Determinations: "Cézanne's Card Players"

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236-3 of August 28, 2000, I hereby determine that the objects to be included in the exhibition "Cézanne's Card Players" imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The Metropolitan Museum of Art, New York, NY, from on or about February 7, 2011, until on or about May 8, 2011, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the exhibit objects, contact Julie Simpson, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202-632-6467). The mailing address is U.S. Department of State, SA-5, L/DP, Fifth Floor (Suite 5H03), Washington, DC 20522-0505.

Dated: January 11, 2011.

Ann Stock,

Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2011-807 Filed 1-12-11; 8:45 am]

BILLING CODE 4710-05-P

DEPARTMENT OF STATE

[Public Notice 7292]

Request for Comments and Suggestions for the Agenda of the Environmental Affairs Council (Eac) of the Dominican Republic-Central America-United States Free Trade Agreement (Cafta-Dr)

ACTION: Notice of CAFTA-DR EAC meeting and request for comments on the meeting agenda.

SUMMARY: The Department of State and the Office of the United States Trade Representative (USTR) are providing notice that, as set forth in chapter 17 of the Dominican Republic-Central America-United States Free Trade Agreement (CAFTA-DR), the CAFTA-DR governments intend to hold the fifth meeting of the Environmental Affairs Council (EAC) in Washington, DC on January 27, 2011, at the Organization of American States, 200 17th Street NW., Washington, DC 20006. The EAC will hold a public session in the afternoon, with a reception immediately following.

During the meeting, the EAC members will present on their respective countries' progress in implementing chapter 17 and on the impacts of environmental cooperation in their countries. The EAC will also receive a presentation from the CAFTA-DR Secretariat for Environmental Matters (SEM) and discuss the Organization of American States' Second Evaluation Report: Monitoring Progress of the Environmental Cooperation Agenda in the CAFTA-DR Countries. For the public session of the meeting, the EAC will present the results of the above discussion elements with a particular focus on the chapter 17 obligations and environmental cooperation successes. The public will have the opportunity to ask questions and discuss implementation of chapter 17 and environmental cooperation with EAC members. In addition, the SEM will present on the citizen submissions mechanism established under chapter 17. More information on the EAC is detailed below under Supplementary Information.

The Department of State and USTR invite written comments or suggestions regarding the EAC meeting agenda and the Environmental Cooperation Expo. In

preparing comments, we encourage submitters to refer to chapter 17 of the CAFTA–DR, the Final Environment Review of the CAFTA–DR and the Agreement among the CAFTA–DR parties on Environmental Cooperation (ECA) (available at <http://www.state.gov/g/oes/env/trade/caftadr/index.htm>).

DATES: To be assured of timely consideration, all comments or suggestions are requested no later than January 20, 2011.

ADDRESSES: Written comments or suggestions should be submitted to both: (1) Rebecca Slocum, U.S. Department of State, Bureau of Oceans and International Environmental and Scientific Affairs, Office of Environmental Policy by e-mail to SlocumRB@state.gov with the subject line “CAFTA–DR EAC Meeting” or by fax to (202) 647–5947; and (2) Kelly Milton, Director for International Environmental & Conservation Policy, Office of the United States Trade Representative by e-mail to KMilton@ustr.eop.gov with the subject line “CAFTA–DR EAC Meeting” or by fax to (202) 395–9517.

Persons with access to the Internet will be able to review and comment on the notice by going to the [Regulations.gov](http://www.regulations.gov) Web site at: <http://www.regulations.gov/search/Regs/home.html#home>, and searching on docket ID DOS–2011–0015.

FOR FURTHER INFORMATION CONTACT: Rebecca Slocum, 202–647–4828 or Kelly Milton, 202–395–9590.

SUPPLEMENTARY INFORMATION: Article 17.5 of the CAFTA–DR establishes an Environmental Affairs Council (EAC). Article 17.5 requires the EAC to meet to review the implementation of, and progress under, chapter 17. Article 17.5 further requires, unless the governments otherwise agree, that each meeting of the EAC include a session in which members of the EAC have an opportunity to meet with the public to discuss matters relating to the implementation of chapter 17.

In Article 17.9 of the CAFTA–DR, the governments recognize the importance of strengthening capacity to protect the environment and to promote sustainable development in concert with strengthening trade and investment relations and state their commitment to expanding their cooperative relationship on environmental matters. Article 17.9 also references the ECA, which sets out certain priority areas of cooperation on environmental activities that are also reflected in Annex 17.9 of the CAFTA–DR. These priority areas include, among other things: reinforcing

institutional and legal frameworks and the capacity to develop, implement, administer, and enforce environmental laws, regulations, standards, and policies; conserving and managing shared, migratory and endangered species in international trade and management of protected areas; promoting best practices leading to sustainable management of the environment; and facilitating technology development and transfer and training to promote clean production technologies.

The public is advised to refer to the State Department website at <http://www.state.gov/g/oes/env/> and the USTR Web site at <http://www.ustr.gov> for further information.

Dated: January 10, 2011.

Willem H. Brakel, PhD,

Director, Office of Environmental Policy, Department of State.

[FR Doc. 2011–618 Filed 1–12–11; 8:45 am]

BILLING CODE 4710–09–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection(s): Flight Engineers and Flight Navigators.

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on September 22, 2010, vol. 75, no. 183, page 57828–57829. Information collected is used to determine certification eligibility of Flight Engineers and Flight Navigators.

DATES: Written comments should be submitted by February 14, 2011.

FOR FURTHER INFORMATION CONTACT: Carla Scott on (202) 267–9895, or by e-mail at: Carla.Scott@faa.gov.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0007.

Title: Flight Engineers and Flight Navigators.

Form Numbers: FAA Form 8400–3.

Type of Review: Renewal of an information collection.

Background: FAA Form 8400–3, Application for an Airman Certificate and/or Rating (for flight engineer and flight navigator) and applications for approval of related training courses are submitted to FAA for evaluation. The information is reviewed to determine applicant eligibility and compliance with prescribed provisions of FAR Part 63, Certification: Flight Crewmembers Other Than Pilots.

Respondents: Approximately 1,036 flight engineers and flight navigators.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 15 minutes.

Estimated Total Annual Burden: 498 hours.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/FAA, and sent via electronic mail to oir_submission@omb.eop.gov, or faxed to (202)395–6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street, NW., Washington, DC 20503.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA’s performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB’s clearance of this information collection.

Issued in Washington, DC, on January 6, 2011.

Carla Scott,

FAA Information Collection Clearance Officer, IT Enterprises Business Services Division, AES–200.

[FR Doc. 2011–594 Filed 1–12–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA-2011-0001-N-1]

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and its implementing regulations, the Federal Railroad Administration (FRA) hereby announces that it is seeking renewal of the following currently approved information collection activities. Before submitting these information collection requirements for clearance by the Office of Management and Budget (OMB), FRA is soliciting public comment on specific aspects of the activities identified below.

DATES: Comments must be received no later than March 14, 2011.

ADDRESSES: Submit written comments on any or all of the following proposed activities by mail to either: Mr. Robert Brogan, Office of Safety, Planning and Evaluation Division, RRS-21, Federal Railroad Administration, 1200 New Jersey Avenue, SE., Mail Stop 25, Washington, DC 20590, or Ms. Kimberly Toone, Office of Information Technology, RAD-20, Federal Railroad Administration, 1200 New Jersey Avenue, SE., Mail Stop 35, Washington, DC 20590. Commenters requesting FRA to acknowledge receipt of their respective comments must include a self-addressed stamped postcard stating, "Comments on OMB control number 2130-0566." Alternatively, comments may be transmitted via facsimile to (202) 493-6216 or (202) 493-6479, or via e-mail to Mr. Brogan at Robert.Brogan@dot.gov, or to Ms. Toone at Kimberly.Toone@dot.gov. Please refer to the assigned OMB control number in

any correspondence submitted. FRA will summarize comments received in response to this notice in a subsequent notice and include them in its information collection submission to OMB for approval.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Brogan, Office of Planning and Evaluation Division, RRS-21, Federal Railroad Administration, 1200 New Jersey Avenue, SE., Mail Stop 25, Washington, DC 20590 (telephone: (202) 493-6292) or Ms. Kimberly Toone, Office of Information Technology, RAD-20, Federal Railroad Administration, 1200 New Jersey Avenue, SE., Mail Stop 35, Washington, DC 20590 (telephone: (202) 493-6139). (These telephone numbers are not toll-free.)

SUPPLEMENTARY INFORMATION: The Paperwork Reduction Act of 1995 (PRA), Public Law 104-13, § 2, 109 Stat. 163 (1995) (codified as revised at 44 U.S.C. 3501-3520), and its implementing regulations, 5 CFR Part 1320, require Federal agencies to provide 60 days notice to the public for comment on information collection activities before seeking approval for reinstatement or renewal by OMB. 44 U.S.C. 3506(c)(2)(A); 5 CFR 1320.8(d)(1), 1320.10(e)(1), 1320.12(a). Specifically, FRA invites interested respondents to comment on the following summary of proposed information collection activities regarding (i) whether the information collection activities are necessary for FRA to properly execute its functions, including whether the activities will have practical utility; (ii) the accuracy of FRA's estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (iii) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (iv) ways for FRA to minimize the burden of information collection activities on the public by automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (e.g., permitting electronic

submission of responses). See 44 U.S.C. 3506(c)(2)(A)(i)-(iv); 5 CFR 1320.8(d)(1)(I)-(iv). FRA believes that soliciting public comment will promote its efforts to reduce the administrative and paperwork burdens associated with the collection of information mandated by Federal regulations. In summary, FRA reasons that comments received will advance three objectives: (i) Reduce reporting burdens; (ii) ensure that it organizes information collection requirements in a "user friendly" format to improve the use of such information; and (iii) accurately assess the resources expended to retrieve and produce information requested. See 44 U.S.C. 3501.

Below are brief summaries of eight currently approved information collection activities that FRA will submit for clearance by OMB as required under the PRA:

Title: Reflectorization of Freight Rolling Stock.

OMB Control Number: 2130-0566.

Abstract: The Federal Railroad Administration (FRA) issued this regulation to mandate the reflectorization of freight rolling stock (freight cars and locomotives) to enhance the visibility of trains in order to reduce the number and severity of accidents at highway-rail grade crossings in which train visibility acted as a contributing factor. The information collected is used by FRA to ensure that railroads/car owners follow the schedule established by the regulation for placing retro-reflective material on the sides of freight rolling stock (freight cars and locomotives) in order to improve the visibility of trains. The information is also used by FRA to confirm that railroads/car owners meet the prescribed standards for the application, inspection, and maintenance of the required retro-reflective material.

Type of Request: Extension of a currently approved collection.

Affected Public: Businesses.

Respondent Universe: 685 Railroads.

Form Number(s): FRA F 6180.113.

REPORTING BURDEN

CFR section	Respondent universe	Total annual responses	Average time per response	Total annual burden hours
224.7—Waivers	685 Railroads/car owners	10 petitions	1 hour	20 hours.
224.15—Special approval procedures—Petitions.	3 Manufacturers	60 petitions	40 hours	2,400 hours.
—Public comment	3 Manufacturers/railroads	5 comments	1 hour	5 hours.
224.107—Implementation Schedule: Freight cars.	685 Railroads/car owners	400 reports/forms ..	15 minutes	100 hours.
—Existing freight cars w/o retroreflective sheeting.	685 Railroads/car owners	400 reports/forms ...	20 minutes	8,000 hours.

REPORTING BURDEN—Continued

CFR section	Respondent universe	Total annual responses	Average time per response	Total annual burden hours
—Updated reflectorization implementation plans.	685 Railroads/car owners	5 Failure Reports ...	2 hours	10 hours.
—Failure reports	685 Railroads/car owners	172 reports/forms ..	20 hours	3,440 hours.
II. Existing Cars with retroreflective sheeting (b). Locomotives.	685 Railroads/car owners	35 reports/forms	15 minutes	9 hours.
—Existing locomotives w/o retroreflective sheeting.	685 Railroads/car owners	35 reports/forms	3 hours	105 hours.
—Updated reflectorization implementation plans.	685 Railroads/car owners	1 Failure Report	2 hours	2 hours.
—Failure reports	685 Railroads/car owners	617 reports/forms ...	4 hours	2,468 hours.
II. Existing locomotives with retroreflective sheeting				
224.109—Inspection, repair, replacement—fr. cars.	AAR + 300 car shops	240,000 Notificat ...	10 minutes	40,000 hours.
—Locomotives: records of restriction.	22,800 Locomotives	4,560 records	3 minutes	228 hours.

Total Responses: 246,300.
Estimated Total Annual Burden: 56,787 hours.
Status: Regular Review.
 Pursuant to 44 U.S.C. 3507(a) and 5 CFR 1320.5(b), 1320.8(b)(3)(vi), FRA informs all interested parties that it may not conduct or sponsor, and a respondent is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Authority: 44 U.S.C. 3501–3520.
 Issued in Washington, DC, on January 7, 2011.

Kimberly Coronel,
 Director, Office of Financial Management,
 Federal Railroad Administration.
 [FR Doc. 2011–570 Filed 1–12–11; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[U.S. DOT Docket No. NHTSA–2010–0179]

Reports, Forms, and Record Keeping Requirements

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.
ACTION: Request for public comment on proposed collection of information.

SUMMARY: Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and

reinstatements of previously approved collections.

This document describes the collection of information for which NHTSA intends to seek OMB approval.
DATES: Comments must be received on or before March 14, 2011.

ADDRESSES: You may submit comments identified by DOT Docket ID Number NHTSA–2010–0179 using any of the following methods:

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

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

Hand Delivery: West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Fax: 1–202–493–2251.

Instructions: Each submission must include the Agency name and the Docket number for this Notice. Note that all comments received will be posted without change to <http://www.regulations.gov> including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Alan Block, Contracting Officer's Technical Representative, Office of Behavioral Safety Research (NTI–131), National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE., W46–499, Washington, DC 20590. Mr. Block's phone number is 202–366–6401 and his email address is alan.block@dot.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for

approval, it must publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulations (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following:

(i) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) How to enhance the quality, utility, and clarity of the information to be collected; and

(iv) How to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

In compliance with these requirements, NHTSA asks public comment on the following proposed collection of information:

Demonstration Tests of Different High Visibility Enforcement Models

Type of Request—New information collection requirement.

OMB Clearance Number—None.

Form Number—NHTSA Forms 1121, 1122, 1123.

Requested Expiration Date of Approval—3 years from date of approval.

Summary of the Collection of Information—The National Highway Traffic Safety Administration (NHTSA) proposes to collect information from the public to evaluate three programs of sustained enforcement of the drinking and driving laws. The programs will extend over a period of 2 years. A baseline wave of telephone interviews with residents in 3 program sites and 2 comparison sites not carrying out a demonstration program will be conducted prior to the start of the enforcement program. Additional telephone survey waves will be conducted at each of the 5 sites at approximately 6 month intervals following the baseline survey wave until a final telephone survey wave is conducted after the conclusion of the program, for a total of 5 telephone survey waves including the baseline. Sample size for the program sites will be 1,200 while sample size for the comparisons sites will be 500, totaling 23,000 interviews. During the 3rd and 5th survey waves, 50 individuals interviewed during the baseline wave at each of the sites will be re-interviewed. This will add 500 interviews, for a grand total of 23,500 telephone interviews over a period of approximately 26 months. The survey will ask questions about drinking behavior, awareness of the enforcement program, impressions of the program's effectiveness and utility, and perceived risk of alcohol-impaired drivers being stopped by law enforcement officers. Interview length will average 10 minutes.

Augmenting the telephone surveys at each of the 3 program sites will be data collected from individuals at locations where there is an increased likelihood of persons at high risk of driving while alcohol-impaired, i.e., at bars. Data will be collected from 100 bar patrons concurrent with each of the 5 telephone survey waves for a total of 1,500 face-to-face interviews. Interview length will average 5 minutes and ask about awareness of the program and perceived risk of alcohol-impaired drivers being stopped by law enforcement officers.

Data will also be collected from drivers at the program and comparison sites through a roadside survey before, midway, and after the 2-year intervention period. Breath samples will be obtained to identify any changes in the distribution of roadside BACs (Blood Alcohol Concentration) across data collection periods, and the drivers will also be administered a 5-minute face-to-face interview. Sample size will be 100 drivers per site per data collection wave, for a total of 1,500 drivers. The interviews will collect

information on program awareness and perceived risk of an alcohol-impaired driver being stopped by law enforcement officers.

In conducting the proposed telephone interviews, the interviewers would use computer-assisted telephone interviewing to reduce interview length and minimize recording errors. The proposed data collection at bars and the roadside survey would be anonymous; they would not collect any personal information that would allow anyone to identify respondents. The telephone interviews during wave 1 will include some collection of personally identifying information in order to conduct a small number of re-interviews during waves 3 and 5. However, that information will be held exclusively by the survey contractor, protected from disclosure to any other parties, and destroyed once no longer needed for re-contacting prospective respondents. Moreover, the personally identifiable information will be separated from the survey responses. No personally identifiable information will be collected during telephone survey waves 2 through 5.

Description of the Need for the Information and Proposed Use of the Information—NHTSA was established to reduce the number of deaths, injuries, and economic losses resulting from motor vehicle crashes on the Nation's highways. As part of this statutory mandate, NHTSA is authorized to conduct research as a foundation for the development of motor vehicle standards and traffic safety programs.

The heavy toll that alcohol-impaired driving exacts on the nation in fatalities, injuries, and economic costs is well documented. High visibility enforcement has historically had the strongest support in the research literature for effectiveness in reducing alcohol-impaired driving. Studies have demonstrated that prolonged commitment to highly visible and well-publicized enforcement of the drinking and driving laws, with enforcement and communication activities conducted on a regular basis, can result in substantial reduction in alcohol-related and alcohol-impaired driving crashes. In practice, however, law enforcement agencies have consolidated their high visibility alcohol enforcement efforts into a small number of enforcement waves that occur each year. The high visibility enforcement becomes an enhanced form of enforcement rather than something that the officers normally do. Thus attempting to sustain the high visibility enforcement over time entails determining how law enforcement agencies can integrate high

visibility enforcement of the drinking and driving laws so that it is not producing an extra burden for officers but is rather a normal and regular part of their work.

NHTSA plans to demonstrate three community programs of high visibility enforcement of the drinking and driving laws. Two of those programs will be designed as fully integrated high visibility enforcement programs. Since many law enforcement agencies would be unable to move directly to a fully integrated program, a third program will be demonstrated that is operating at an intermediate level between current common practice and full integration. NHTSA will collect information to assess the extent to which the programs penetrate public awareness, how effective the programs are perceived by residents in the intervention communities, and whether changes occur over the course of the programs in the perceived risk of an alcohol-impaired driver being stopped by law enforcement officers. Because the alcohol crash fatality problem is concentrated among certain groups, particular attention will be paid to assessing this information for drivers most likely to drive at BACs above the legal limit. In addition to self-report information, NHTSA will collect roadside BAC data to obtain a measure of the distribution of BACs among drivers on the road.

NHTSA will use the findings from this proposed collection of information to assist States, localities, and law enforcement agencies to design and implement sustained programs of high visibility enforcement of the drinking and driving laws.

Description of the Likely Respondents (Including Estimated Number, and Proposed Frequency of Response to the Collection of Information)—Under this proposed effort, the Contractor would conduct 23,500 telephone interviews, 1,500 face-to-face interviews with bar patrons, and 1,500 face-to-face interviews with drivers who participate during roadside surveys. The telephone interviews will be conducted with drivers age 18 and older in the five selected communities, with over-sampling of drivers 18 through 34. Interview length will average 10 minutes. Interviews would be conducted with drivers at residential phone numbers selected through random digit dialing. Businesses are ineligible for the sample and would not be interviewed. A total of 250 respondents who complete the interview during the initial baseline survey wave will be administered the survey two additional times separated

by 1-year intervals, for a total of three administrations of the survey over slightly more than a 2 year period. All other members of the sample will be administered the survey one time only.

The interviews with bar patrons will be conducted with individuals 21 years of age and older. Interview length will average approximately 5 minutes, and each member of the sample would complete one interview. Businesses are ineligible for the sample and would not be interviewed.

The roadside survey interviews will be conducted with drivers 18 and older. Interviews would average 5 minutes, and each member of the sample would complete one interview. Businesses are ineligible for the sample and would not be interviewed.

Estimate of the Total Annual Reporting and Record Keeping Burden Resulting from the Collection of Information—NHTSA estimates that respondents would require an average of 10 minutes to complete the telephone interviews or a total of 3,917 hours for the 23,500 respondents. The interviews with bar patrons will average 5 minutes or a total of 125 hours for the 1,500 respondents. The roadside survey interviews will also average 5 minutes or a total of 125 hours for the 1,500 respondents. The total number of estimated reporting burden hours on the general public would be 4,167. The annual reporting burden would be 1,923 hours based on a 26 month data collection period. The respondents would not incur any reporting cost from the information collection. The respondents also would not incur any record keeping burden or record keeping cost from the information collection.

Authority: 44 U.S.C. 3506(c)(2)(A).

Jeffrey Michael,

Associate Administrator, Research and Program Development.

[FR Doc. 2011-645 Filed 1-12-11; 8:45 am]

BILLING CODE 4910-59-P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Petition for Exemption From the Vehicle Theft Prevention Standard; Ford Motor Company

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Grant of petition for exemption.

SUMMARY: This document grants in full the Ford Motor Company's (Ford)

petition for an exemption of the Fusion vehicle line in accordance with 49 CFR Part 543, *Exemption from the Theft Prevention Standard*. This petition is granted because the agency has determined that the antitheft device to be placed on the line as standard equipment is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the 49 CFR Part 541, *Federal Motor Vehicle Theft Prevention Standard*.

DATES: The exemption granted by this notice is effective beginning with the 2012 model year.

FOR FURTHER INFORMATION CONTACT: Ms. Carlita Ballard, Office of International Policy, Fuel Economy and Consumer Programs, NHTSA, 1200 New Jersey Avenue, SE., Washington, DC 20590. Ms. Ballard's telephone number is (202) 366-0846. Her fax number is (202) 493-2990.

SUPPLEMENTARY INFORMATION: In a petition dated September 21, 2010, Ford requested an exemption from the parts-marking requirements of the Theft Prevention Standard (49 CFR Part 541) for the MY 2012 Ford Fusion vehicle line. The petition requested an exemption from parts-marking pursuant to 49 CFR Part 543, *Exemption from Vehicle Theft Prevention Standard*, based on the installation of an antitheft device as standard equipment for an entire vehicle line.

Under § 543.5(a), a manufacturer may petition NHTSA to grant exemptions for one vehicle line per model year. Ford has petitioned the agency to grant an exemption for its Fusion vehicle line beginning with MY 2012. In its petition, Ford provided a detailed description and diagram of the identity, design, and location of the components of the antitheft device for the Fusion vehicle line. Ford will install its "SecuriLock" passive transponder-based electronic immobilizer antitheft device as standard equipment on the vehicle line. Features of the antitheft device will include an electronic key, ignition lock, and a passive immobilizer. Ford stated that since it's MY 2006 introduction, the Fusion has been equipped with the "SecuriLock" device as standard equipment. The device does not incorporate an audible or visual alarm as standard equipment however, Ford stated that the Fusion vehicles will come equipped with a separate perimeter alarm system that utilizes both a visible and audible alarm if unauthorized access is attempted. Ford's submission is considered a complete petition as required by 49 CFR 543.7, in that it meets the general

requirements contained in § 543.5 and the specific content requirements of § 543.6.

Ford stated that the devices integration of the transponder into the normal operation of the ignition key assures activation of the system. When the ignition key is turned to the "start" position, the transceiver module reads the ignition key code and transmits an encrypted message to the cluster. Validation of the key is determined and start of the engine is authorized once a separate encrypted message is sent to the powertrain control module/transmission control module (PCM/TCM). The powertrain will function only if the key code matches the unique identification key code previously programmed into the PCM. If the codes do not match, the engine starter, ignition and fuel systems will be disabled. Ford stated that the device functions automatically each time an engine start sequence occurs. Therefore, no owner/operator actions are required to deactivate the device.

In addressing the specific content requirements of 543.6, Ford provided information on the reliability and durability of its proposed device. To ensure reliability and durability of the device, Ford conducted tests based on its own specified standards. Ford provided a detailed list of the tests conducted and believes that the device is reliable and durable since the device complied with its specified requirements for each test.

Ford stated that incorporation of several features in both devices further support reliability and durability of the device. Specifically, some of those features include: encrypted communication between the transponder, control function and the power train control module; no moving parts; inability to mechanically override the device to start the vehicle; and the body control module/remote function actuator and the power train control module share security data that form matched modules during vehicle assembly that if separated from each other will not function in other vehicles. Ford stated that the Fusion will be equipped with several other standard antitheft features (*i.e.*, a hood release, counterfeit resistant VIN plates, secondary VINs inscribed on the body, and an exterior key lock that will be located only on the driver door to limit cabin access). Ford also stated that the device's encrypted transponder technology will make key duplication virtually impossible.

Additionally, Ford noted that with the prevalence of electronic engine immobilizer systems on nearly all new

retail vehicles, the overall theft rates have been decreasing and the theft rate for the Fusion vehicles have remained very close to the overall theft rate trend. Specifically, the agency's data show that theft rates for the Fusion for MYs 2006–2008 are 1.7314, 1.8161 and 1.8797 respectively. Using an average of 3 MYs data (2006–2008), the theft rate for the Fusion vehicle line is well below the median at 1.8090.

Ford compared the effectiveness of its antitheft device with devices which NHTSA has previously determined to be as effective in reducing and deterring motor vehicle theft as would compliance with the parts-marking requirements of Part 541. Specifically, Ford provided information on the reduction in the theft rate for other vehicle lines equipped with the "SecuriLock" device. Ford's "SecuriLock" device was first introduced as standard equipment on its MY 1996 Mustang GT and Cobra vehicle lines. The "SecuriLock" system was installed on the entire Mustang vehicle line as standard equipment in MY 1997. Ford also stated that the "SecuriLock" device has been installed as standard equipment on all North American Ford, Lincoln and Mercury vehicles except for the F-Super Duty, Econoline and Crown Victoria Police Interceptor vehicles. Ford stated that according to National Insurance Crime Bureau (NICB) theft statistics, the 1997 model year Mustang with "SecuriLock" showed a 70% reduction in theft compared to its MY 1995 Mustang vehicles. Comparatively, Ford stated that there were 149 thefts reported in 1997 and 500 thefts reported in 1995. Ford also stated that the proposed device is very similar in design and implementation to the device offered on the Ford Escape vehicle line. The agency granted Ford's petition for exemption for the Escape vehicle line on April 18, 2008. Ford stated that it believes that the standard installation of the "SecuriLock" device on the Fusion vehicle line would be an effective deterrent against vehicle theft and that the low theft rate experienced by the line in CY 2008 is likely to continue or improve in future years.

The agency agrees that the device is substantially similar to devices in other vehicle lines for which the agency has already granted exemptions. Based on the evidence submitted by Ford, the agency believes that the antitheft device for the Fusion vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard (49 CFR part 541).

Pursuant to 49 U.S.C. 33106 and 49 CFR 543.7 (b), the agency grants a petition for exemption from the parts-marking requirements of Part 541 either in whole or in part, if it determines that, based upon substantial evidence, the standard equipment antitheft device is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of Part 541. The agency finds that Ford has provided adequate reasons for its belief that the antitheft device for the Ford Fusion vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard (49 CFR part 541). This conclusion is based on the information Ford provided about its device.

The agency concludes that the device will provide four of the five types of performance listed in § 543.6(a)(3): Promoting activation; preventing defeat or circumvention of the device by unauthorized persons; preventing operation of the vehicle by unauthorized entrants; and ensuring the reliability and durability of the device.

For the foregoing reasons, the agency hereby grants in full Ford's petition for exemption for the Fusion vehicle line from the parts-marking requirements of 49 CFR part 541. The agency notes that 49 CFR part 541, Appendix A–1, identifies those lines that are exempted from the Theft Prevention Standard for a given model year. 49 CFR 543.7(f) contains publication requirements incident to the disposition of all Part 543 petitions. Advanced listing, including the release of future product nameplates, the beginning model year for which the petition is granted and a general description of the antitheft device is necessary in order to notify law enforcement agencies of new vehicle lines exempted from the parts-marking requirements of the Theft Prevention Standard.

If Ford decides not to use the exemption for this line, it must formally notify the agency. If such a decision is made, the line must be fully marked according to the requirements under 49 CFR Parts 541.5 and 541.6 (marking of major component parts and replacement parts).

NHTSA notes that if Ford wishes in the future to modify the device on which this exemption is based, the company may have to submit a petition to modify the exemption. Part 543.7(d) states that a Part 543 exemption applies only to vehicles that belong to a line exempted under this part and equipped with the antitheft device on which the line's exemption is based. Further, Part

543.9(c)(2) provides for the submission of petitions "to modify an exemption to permit the use of an antitheft device similar to but differing from the one specified in that exemption."

The agency wishes to minimize the administrative burden that Part 543.9(c)(2) could place on exempted vehicle manufacturers and itself. The agency did not intend in drafting Part 543 to require the submission of a modification petition for every change to the components or design of an antitheft device. The significance of many such changes could be *de minimis*. Therefore, NHTSA suggests that if the manufacturer contemplates making any changes, the effects of which might be characterized as *de minimis*, it should consult the agency before preparing and submitting a petition to modify.

Authority: 49 U.S.C. 33106; delegation of authority at 49 CFR 1.50.

Issued on: January 7, 2011.

Joseph S. Carra,
Acting, Associate Administrator for
Rulemaking.

[FR Doc. 2011–567 Filed 1–12–11; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. AB 6 (Sub-No. 473X)]

BNSF Railway Company— Abandonment Exemption—in Rolette and Towner Counties, ND

BNSF Railway Company (BNSF), filed a verified notice of exemption under 49 C.F.R. pt. 1152 subpart F—*Exempt Abandonments* to abandon 17.75 miles of rail line between milepost 30.00, north of Bisbee and milepost 47.75 at Rolla, in Rolette and Towner Counties, N.D.¹ The line traverses United States Postal Service Zip Codes 58317, 58363, and 58367.

BNSF has certified that: (1) No local traffic has moved over the line for at least 2 years;² (2) there is no overhead traffic on the line; (3) no formal complaint filed by a user of rail service on the line (or by a state or local

¹ On December 23, 2010, the Rollo Job Development Authority (RJDA) filed a letter in opposition. While the Board will not delay service and publication of this notice based on that letter alone, RJDA has a number of post-publication/service options available to it, as set forth in this notice, should it choose to pursue the matter further.

² BNSF states that the line was embargoed on March 29, 2007 due to soft track conditions and sub-grade issues and the subsequent destruction by fire of two bridges.

government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7 (environmental report), 49 CFR 1105.8 (historic report), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho*, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on February 11, 2011, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,³ formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),⁴ and trail use/rail banking requests under 49 CFR 1152.29 must be filed by January 24, 2011. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by February 1, 2011, with the Surface Transportation Board, 395 E Street, SW., Washington, DC 20423-0001.

A copy of any petition filed with the Board should be sent to BNSF's representative: Karl Morell, 1455 F St., NW., Suite 225, Washington, DC 20005.

If the verified notice contains false or misleading information, the exemption is void *ab initio*.

BNSF has filed a combined environmental and historic report which addresses the effects, if any, of the abandonment on the environment and historic resources. OEA will issue an environmental assessment (EA) by January 14, 2011. Interested persons

may obtain a copy of the EA by writing to OEA (Room 1100, Surface Transportation Board, Washington, DC 20423-0001) or by calling OEA, at (202) 245-0305. Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1 800-877-8339. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), BNSF shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the line. If consummation has not been effected by BNSF's filing of a notice of consummation by January 12, 2012, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available on our Web site at "WWW.STB.DOT.GOV."

Decided: January 10, 2011.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Andrea Pope-Matheson,
Clearance Clerk.

[FR Doc. 2011-632 Filed 1-12-11; 8:45 am]

BILLING CODE 4915-01-P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35446]

City of Temple, Tex.—Acquisition Exemption—Georgetown Railroad Company

AGENCY: Surface Transportation Board.

ACTION: Notice instituting proceeding; request for comments.

SUMMARY: On December 15, 2010, the City of Temple, Tex. (Temple), a noncarrier, filed a petition under 49 U.S.C. 10502 for exemption from the provisions of 49 U.S.C. 10901 to acquire from the Georgetown Railroad Company (Georgetown) an approximately 6.277-mile line of railroad, between milepost 0.0, near Belton, and milepost 6.277, at Smith, in Bell County, Tex. (the line), and the trackage rights granted to Georgetown to operate over the line.¹ In

a related transaction, Temple & Central Texas Railway, Inc. (TCTR), a Class III carrier, filed a verified notice of exemption under 49 CFR 1150.41 to operate over the line. That notice was served and published in the **Federal Register** on December 10, 2010 (75 FR 77,044). *Temple & Central Tex. Ry.—Operation Exemption—City of Temple, Tex.*, FD 35447 (STB served Dec. 10, 2010). The Board seeks comments from interested persons on Temple's request to acquire the line.

DATES: Written comments must be filed with the Board by February 2, 2011. Replies must be filed by February 9, 2011.

ADDRESSES: Comments may be submitted either via the Board's e-filing format or in the traditional paper format. Any person using e-filing should attach a document and otherwise comply with the instructions at the E-FILING link on the Board's Web site, at <http://www.stb.dot.gov>. Any person submitting a filing in the traditional paper format should send an original and 10 copies to: Surface Transportation Board, Attn: Docket No. FD 35446, 395 E Street, SW., Washington, DC 20423-0001.

In addition, send one copy of any comments to Louis E. Gitomer, Law Offices of Louis E. Gitomer, 600 Baltimore Avenue, Suite 301, Towson, MD 21204.

FOR FURTHER INFORMATION CONTACT: Julia Farr at 202-245-0359. Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1-800-877-8339.

SUPPLEMENTARY INFORMATION: On December 15, 2010, Temple filed a petition under 49 U.S.C. 10502 for exemption from the provisions of 49 U.S.C. 10901 to acquire the line. Previously Temple had filed a notice of exemption to acquire and operate over the line.² Temple stated in that notice that the purpose of the acquisition was to construct a pipeline underneath the right-of-way and subsequently convert the line into a trail under the National Trails System Act, 16 U.S.C. 1247(d). The Director of the Office of Proceedings stated in the April 23 notice that the Board has found that acquiring a line for the purpose of abandoning rather than operating over it constitutes a misuse of Board procedures. Accordingly, Temple's notice was rejected without prejudice. Subsequently, Temple entered into an agreement with TCTR, which operates

³ The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Office of Environmental Analysis (OEA) in its independent investigation) cannot be made before the exemption's effective date. See *Exemption of Out-of-Serv. Rail Lines*, 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

⁴ Each OFA must be accompanied by the filing fee, which is currently set at \$1,500. See 49 CFR 1002.2(f)(25).

¹ Temple has also concurrently filed a motion for protective order pursuant to 49 CFR 1104.14(b) to allow Temple to file the unredacted Purchase and Sale Agreement under seal. That motion will be addressed in a separate decision.

² *City of Temple, Tex.—Acquisition and Operation Exemption—Georgetown R.R. Co.*, FD 35369 (STB served Apr. 23, 2010) (April 23 notice).

other railroad lines owned by Temple, to operate over the line. Temple states that its agreement with TCTR requires that TCTR solicit business over the line and to provide common carrier service for remunerative business. Temple states that in the event TCTR is unable to provide service over the line, Temple will assume the residual common carrier obligation to provide service. Temple requests expedited action on its petition.

By issuance of this notice, the Board is instituting an exemption proceeding pursuant to 49 U.S.C. 10502(b).

Decided: January 10, 2011.

By the Board, Rachel D. Campbell,
Director, Office of Proceedings.

Andrea Pope-Matheson,

Clearance Clerk.

[FR Doc. 2011-639 Filed 1-12-11; 8:45 am]

BILLING CODE 4915-01-P

DEPARTMENT OF VETERANS AFFAIRS

Gulf War and Health, Volume 6, Physiologic, Psychologic, and Psychosocial Effects of Deployment-Related Stress

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: As required by law, the Department of Veterans Affairs (VA) hereby gives notice that the Secretary of Veterans Affairs, under the authority granted by the Persian Gulf War Veterans Act of 1998, Public Law 105-277, title XVI, 112 Stat. 2681-742 through 2681-749 (codified at 38 U.S.C. 1118), has determined that there is no basis to establish any new presumptions of service connection at this time for any of the diseases, illnesses, or health effects discussed in the November 15, 2007, National Academy of Sciences (NAS) report titled, "Gulf War and Health, Volume 6, Physiologic, Psychologic, and Psychosocial Effects of Deployment-Related Stress." This determination does not in any way preclude VA from granting service connection on a direct basis for any disease, including those specifically discussed in this notice, nor does it change any existing rights or procedures.

FOR FURTHER INFORMATION CONTACT: Gerald Johnson, Regulations Staff (211D), Compensation and Pension Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, telephone (202)

461-9727. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION:

I. Statutory Requirements

The Persian Gulf War Veterans Act of 1998, Public Law 105-277, title XVI, 112 Stat. 2681-742 through 2681-749 (codified at 38 U.S.C. 1118), and the Veterans Programs Enhancement Act of 1998, Public Law 105-368, 112 Stat. 3315, directed the Secretary to enter into an agreement with NAS to review and evaluate the available scientific evidence regarding associations between illnesses and exposure to toxic agents, environmental or wartime hazards, or preventive medicines or vaccines to which service members may have been exposed during service in the Southwest Asia theater of operations during the Persian Gulf War. Congress prescribed the inquiry it expected NAS to carry out in the event such an agreement was reached. Congress directed NAS to identify agents, hazards, medicines, and vaccines to which service members may have been exposed during the Persian Gulf War. Congress mandated that NAS determine, to the extent possible: (1) Whether there is a statistical association between exposure to the agent, hazard, medicine, or vaccine and the illness, taking into account the strength of the scientific evidence and the appropriateness of the scientific methodology used to detect the association; (2) the increased risk of illness among individuals exposed to the agent, hazard, medicine or vaccine; and (3) whether a plausible biological mechanism or other evidence of a causal relationship exists between exposure to the agent, hazard, medicine, or vaccine and the illness. Public Law 105-277, 112 Stat. 2681-747.

II. NAS Reports and VA Action

In 1998, NAS began a program to examine the scientific and medical literature on the potential health effects of specific agents and hazards to which Gulf War veterans might have been exposed during their deployment. Five reports have examined health outcomes related to: Depleted uranium, pyridostigmine bromide, sarin, and vaccines (Volume 1); insecticides and solvents (Volume 2); fuels, combustion products, and propellants (Volume 3); health effects of serving in the Gulf War irrespective of exposure information (Volume 4); and infectious diseases (Volume 5). Among the 700,000 U.S. military personnel deployed to the theater, many veterans have reported chronic symptoms and illnesses that

they have attributed to their service in the Gulf.

Upon receipt of each NAS report, VA must determine whether a presumption of service connection is warranted for any disease or illness discussed in the report. The statute provides that a presumption of service connection is warranted if VA determines that there is a positive association (*i.e.*, the credible evidence for an association is equal to or outweighs the credible evidence against an association) between exposure of humans or animals to a biological, chemical, or other toxic agent, environmental or wartime hazard, or preventive medicine or vaccine known or presumed to be associated with service in the Southwest Asia theater of operations during the Persian Gulf War and the occurrence of a diagnosed or undiagnosed illness in humans or animals. 38 U.S.C. 1118(b). If the Secretary determines that a presumption of service connection is not warranted, he is to publish a notice of that determination, including an explanation of the scientific basis for that determination. 38 U.S.C. 1118(c)(3)(A).

III. NAS Report: "Gulf War and Health, Volume 6, Physiologic, Psychologic, and Psychosocial Effects of Deployment-Related Stress"

In "Gulf War & Health, Volume 6, Physiologic, Psychologic, and Psychosocial Effects of Deployment-Related Stress," available at http://www.nap.edu/catalog.php?record_id=11922 (accessed September 2, 2010), NAS evaluated the association between deployment-related stress and long-term adverse health effects for veterans deployed to the Persian Gulf and the Middle East to include not only veterans of the 1990-1991 Gulf War, but also veterans returning from Operation Enduring Freedom (OEF) and Operation Iraqi Freedom (OIF). This study was conducted at the request of VA to determine the possibility of an association between exposure to deployment-related stressors in the Gulf War and long-term adverse health effects.

The NAS committee reviewed published and peer-reviewed scientific and medical literature to characterize and weigh the strengths and limitations of the available evidence regarding the association between deployment to a war zone and specific adverse health effects. The committee considered studies of veterans of World War II, the Korean War, the Vietnam War, and the 1991 Gulf War.

The NAS committee's charge was to comprehensively review, evaluate, and summarize the peer-reviewed scientific and medical literature regarding the association between deployment-related stress and long-term adverse health effects in Gulf War veterans.

Specifically, the committee was to study the physiologic, psychological and psychosocial effects of stress, and VA requested that the study's findings not be limited to veterans of the Gulf War but be applicable to OEF and OIF.

The NAS committee considered all studies that identified health effects found in military personnel deployed to a war zone in order to evaluate the associations between deployment-related stress and adverse health effects. The potential health effects considered included not only physiologic effects and psychiatric effects, but also depression and posttraumatic stress disorder (PTSD), and psychosocial effects, such as marital conflict and incarceration. In addition, the NAS committee also considered studies of deployed veterans with combat-related PTSD and associated health effects, because PTSD can result only after exposure to a traumatic stressor and potentially traumatic events are common in a war zone. The NAS committee relied entirely on epidemiologic studies to draw its conclusion about the strength of the evidence for an association between deployment to a war zone (stressor) and health effects. The challenge of epidemiologic studies is to isolate the risk factors that contribute to health effects in populations that are inherently uncontrollable in the experimental sense; therefore, statistical techniques are used to take in to account factors such as bias and confounding.

Detailed information on the committee's findings may be found at: http://www.nap.edu/catalog.php?record_id=11922 (accessed September 2, 2010). The report findings are organized by category and can be found under Table of Contents.

In its report, NAS organized its conclusions into five categories, representing different degrees of association between illness and exposure to deployment-related stressors. The categories NAS used are "Sufficient Evidence of a Causal Relationship," "Sufficient Evidence of an Association," "Limited but Suggestive Evidence of an Association," "Inadequate/Insufficient Evidence to Determine Whether an Association Exists," and "Limited/Suggestive Evidence of No Association." These are the same categories of association that

have been used by previous NAS committees in their reports.

IV. VA's Determination

This notice conveys the Secretary's determination that a presumption of service connection is not warranted at the present time for any disease, illness, or health effect discussed in the NAS report, based on association with any substance known or suspected to be associated with service in the Gulf War.

The Secretary has determined that no new presumptions of service connection are warranted under 38 U.S.C. 1118 because the report does not demonstrate that the standard set forth in section 1118 for the creation of a presumption of service connection has been met. In particular, the report does not purport to link any health effects to exposure to "a biological, chemical, or other toxic agent, environmental or wartime hazard, or preventive medicine or vaccine known or presumed to be associated with service in the Armed Forces in the Southwest Asia theater of operations during the Persian Gulf War." 38 U.S.C. 1118(a)(2)(A). As explained in more detail below, the report investigated the effects of stressors associated with deployment to any war zone, not just the Gulf War zone. Furthermore, the report does not identify health effects associated with a "biological, chemical, or other toxic agent, environmental or wartime hazard, or preventive medicine or vaccine." *Id.* As discussed below, the statutory reference to agents, hazards, medicines, or vaccines is most reasonably construed to refer to exposure to specific substances capable of causing illness and not to the general effects of service in a war zone as an "exposure" in itself. *Id.*

Under 38 U.S.C. 501, the Secretary has discretion to issue any regulations necessary or appropriate to the administration of Veterans benefits. VA evaluated the findings in the NAS report to determine whether any presumptions or other regulatory changes are warranted under that discretionary authority. As explained below, VA has decided not to propose to issue any regulatory changes under that general authority based on the findings in the NAS report. This decision is based on one or more of the following with respect to the health effects evaluated in the report: (1) The report did not find an association between the health effects studied and service in a war zone, (2) the health effects studied were not a disease, injury, or illness for which service connection can be granted (e.g. suicide or marital conflict), or (3) existing VA regulations are sufficient to ensure that benefits will be

provided to veterans who incur the health effect as a result of service.

A. New Presumptions Under 38 U.S.C. 1118 Are Not Warranted

Public Law 105-277 requires the Secretary to determine whether a presumption of service connection is warranted by reason of a disease "having a positive association with exposure to a biological, chemical, or other toxic agent, environmental or wartime hazard, or preventive medicine or vaccine known or presumed to be associated with service in the Armed Forces in the Southwest Asia theater of operations during the Persian Gulf War." Public Law 105-277 § 1602 (codified in pertinent part at 38 U.S.C. 1118(a)(2)(A) and (b)(1)(B)). The statute does not explain the meaning of the phrase "known or presumed to be associated with service in the Armed Forces in the Southwest Asia theater of operations during the Persian Gulf War," and there is no legislative history explaining the meaning of that phrase.

Consistent with VA's past interpretation of section 1118, see 72 FR 48734, 48739-41 (Aug. 24, 2007), we conclude that the statutory phrase "associated with service in the Armed Forces in the Southwest Asia theater of operations during the Persian Gulf War" is most reasonably construed to refer to a relationship between the substance or hazard and the specific circumstance of service in the Southwest Asia theater of operations during the Persian Gulf War, as distinguished from features of military or civilian life in general that are not unique to service in the Gulf War. The phrase "associated with" clearly connotes a direct relationship, and the requirement that the substance or hazard be associated with service at a particular time and place indicates an intent to distinguish between substances and hazards associated with general military or civilian life and those unique to service at the specified time and place. If military populations of all eras of wartime experience the same or similar deployment-related stressors related to deployment to a war zone, we believe it would be unreasonable to conclude that such stressors are "associated with" service in the Persian Gulf during the Gulf War. As the report explains, "The US military has participated in numerous wars on both US and foreign soil and, regardless of the conflict, many of the deployment-related stressors to which military personnel can be exposed are the same: possible death or injury to oneself, killing or injuring others, poor living conditions, and harsh physical environment." Similarly, the report

noted the universality of symptom-based illnesses among war zone veterans from essentially all eras: "Male and female veterans who have been deployed to a war zone, regardless of the war in which they served, report more symptoms and poorer health than do their nondeployed counterparts. Symptoms range from severe, such as chest pain and numbing in the extremities, to minor, such as loss of appetite." Gulf War and Health, Volume 6, Physiologic, Psychologic, and Psychosocial Effects of Deployment-Related Stress, at p. 31. The report specifically notes that this was not a unique issue for Gulf War veterans: "Some researchers have attempted to cluster the symptoms into new diseases but in general the symptoms are too broad and nonspecific to suggest the presence of a new illness specific to the Gulf War." We do not believe that Congress intended VA to establish presumptions for the known health effects of military deployments common to all military populations. Rather, the requirement that the agent, hazard, medicine, or vaccine be "associated with" Gulf War service makes clear that VA's task is to focus on the unique exposure environment in the Persian Gulf during the Persian Gulf War. *Id.* at 257

This reading of the statutory language comports with the clear purpose of both Public Law 105-277 and Public Law 105-368. *Id.* Both statutes reflect the Government's commitment to addressing the unique health issues presented by Gulf War veterans, by establishing a process for identifying diseases and illnesses that may be associated with Gulf War service. It is by now well known that many Gulf War veterans have reported a variety of similar symptoms that cannot presently be identified with a known diagnosis or cause and that were not considered "diseases" for the purposes of the statutes generally authorizing VA to pay compensation for service-connected disability or death due to disease or injury. Congress responded initially to that situation by authorizing VA to pay compensation for "undiagnosed illness" in such veterans. The process established by Public Law 105-277 and Public Law 105-368 reflects a further effort to bridge the existing gaps in medical and scientific knowledge and to ensure that Gulf War veterans may obtain compensation for diagnosed or undiagnosed illnesses that may have been caused by the unique exposures or hazards of service during the Gulf War. Establishing presumptions of service connection for illnesses associated with

exposures or hazards specifically related to Gulf War service obviously would further that objective. In contrast, establishing presumptions of service connection for the exclusive benefit of Gulf War veterans based solely on the well-known health effects of exposures shared in common with all veterans of other wartime deployments would not significantly further the purposes of those statutes. Moreover, establishing such presumptions would create significant inequities in the veterans' benefits system that Congress could not have intended.

Public Law 105-277 requires VA to establish presumptions of service connection, when the statutory requirements are met, exclusively for veterans who served in the Southwest Asia theater of operations during the Persian Gulf War. If the statute were construed to require presumptions based on exposure in the Persian Gulf War to stressors to which other veterans serving at other times and places are commonly exposed at similar levels, it would raise significant concerns of fairness and reasonableness. For example, veterans exposed or presumably exposed to stressors such as separation from family or fear of injury during the Gulf War might be entitled to presumptive service connection for certain psychiatric illnesses associated with such experiences, while veterans who served in other conflicts like Vietnam and had equal or greater exposure to deployment-related traumatic experiences would not be entitled to presumptive service connection. The fact that most service members deployed to a war zone incur some degree of exposure to the stressors NAS considered further underscores the arbitrariness that would attach to establishing presumptions for a limited class of veterans based on such common exposures. As discussed below in subsection B of this notice, current VA regulations and policies address the effects of such combat-related exposures and are not limited to veterans of Gulf War service. Providing by statute and regulation for the disparate treatment of similarly situated veterans would substantially undermine confidence in the objectivity and fairness of the veterans benefits system. Additionally, establishing different adjudicative rules for the claims of similarly situated veterans without any reasoned basis for the distinction would undoubtedly cause confusion to the VA personnel responsible for deciding claims, as well as to veterans and their representatives in presenting and supporting their claims.

We do not believe that Congress intended VA to establish presumptions unique to Gulf War veterans based on the well-known health effects of exposures common to deployments outside the Gulf War theater. As explained above, the language and purpose of Public Law 105-277 and Public Law 105-368 indicate that Congress did not intend such a result, and we believe it is reasonable to presume that Congress did not intend arbitrary or unfair distinctions. We note that statutes generally must be construed to avoid serious constitutional concerns. *See Edward J. DeBartolo Corp. v. Florida Gulf Coast Building & Construction Trades Council*, 485 U.S. 568, 575 (1988). We cannot say it is beyond Congress' power to establish presumptions exclusively for Gulf War veterans based on exposures not known to differ significantly from service outside the Gulf War. However, the apparent unfairness, in our view, of that result supports the conclusion that Congress did not intend such a result.

We recognize that some diseases and illnesses may be unique to the Gulf War theater. For example, nine diseases are currently entitled to a presumption of service connection based upon service in the Gulf War. 75 FR 59968 (September 29, 2010). As explained above, however, there is presently insufficient evidence to indicate that the stressors and health effects considered by NAS related to the Gulf War differed significantly from stressors present in other war zones and their attendant health effects.

Although the Secretary has determined that presumptions of service connection are not warranted for the health effects of deployment stressors as discussed in the NAS report, we want to make clear that this determination will not preclude the granting of service connection for those health effects that are diseases, injuries, or illnesses (as discussed in greater detail below, some of the health effects (*e.g.* suicide and marital conflict) are not themselves diseases, injuries, or illnesses and therefore VA has no authority to grant service connection on the basis of those health effects alone). The health effects that NAS found to be supported by limited/suggestive evidence are generally well-known health effects of exposure to war zone-related stressors. The established associations between war zone stressors and certain health effects like PTSD provide a sufficient basis for examining physicians and VA adjudicators to determine whether a veteran's disease is associated with exposure to stressors experienced in

service. We note further that our conclusion that the war zone-related stressors cannot be determined to be "associated with" Gulf War service is not intended to suggest that they are irrelevant to further investigations of Gulf War veterans' health.

Finally, establishment of any new presumptions based on the report is also unwarranted because the report does not identify health effects associated with a "biological, chemical, or other toxic agent, environmental or wartime hazard, or preventive medicine or vaccine." Rather, the report examined health effects associated with deployment-related "stressors." The statutory reference to agents, hazards, medicines, or vaccines is most reasonably construed to refer to exposure to specific substances capable of causing illness and not to the general effects of service in a war zone as an "exposure" in itself. This interpretation is consistent with the list of agents, hazards, medicines, and vaccines Congress provided in § 1603(d) of Public Law 105-277.

B. New Presumptions Under the Secretary's General Rulemaking Authority (38 U.S.C. 501) Are Not Warranted

Under 38 U.S.C. 501, the Secretary has discretion to issue any regulations necessary or appropriate to the administration of Veterans benefits. VA evaluated the findings in the NAS report to determine whether any presumptions or other regulatory changes are warranted under that discretionary authority. As explained below, VA has decided not to propose to issue any regulatory changes under that general authority based on the findings in the NAS report. This decision is based on one or more of the following with respect to the health effects evaluated in the report: (1) The report did not find an association between the health effects studied and service in a war zone, (2) the health effects studied were not a disease, injury, or illness for which service connection can be granted (e.g. suicide or marital conflict), or (3) existing VA regulations are sufficient to ensure that benefits will be provided to veterans who incur the health effect as a result of service. The sections below explain in more detail the bases for this decision.

i. Inadequate/Insufficient Evidence to Determine Whether an Association Exists

For some health effects, the report found that evidence from available studies is of insufficient quantity, quality, or consistency to permit a

conclusion regarding the existence of an association between deployment to a war zone and a specific health effect in humans. Therefore, the evidence for these conditions does not provide sufficient evidence of association between the health effect and service to warrant any regulatory changes. The health effects under this category of association include:

Cancer
Diabetes mellitus
Thyroid disease
Neurocognitive and neurobehavioral effects
Sleep disorders or objective measures of sleep disturbance
Hypertension
Coronary heart disease
Chronic respiratory health effects
Structural gastrointestinal diseases
Reproductive effects
Homelessness
Adverse employment outcomes

ii. Sufficient Evidence of Association or Limited But Suggestive Evidence of an Association

For some health effects, the report found that evidence from available studies is sufficient to conclude that there is a positive association, i.e. a consistent positive association has been observed between deployment to a war zone and a specific health effect in human studies in which chance and bias, including confounding, could be ruled out with reasonable confidence. The health effects under this category of association include:

Psychiatric disorders, including PTSD, other anxiety disorders, and depressive disorders
Alcohol abuse
Accidental death in the early years after deployment
Suicide in the early years after deployment
Marital and family conflict

For some health effects, the report found that evidence from available studies is suggestive of an association between deployment to a war zone, but the body of evidence is limited by inability to rule out chance of bias, including confounding, with confidence. The health effects under this category of association include:

Drug abuse
Chronic fatigue syndrome
Gastrointestinal symptoms consistent with functional gastrointestinal disorders, such as irritable bowel syndrome or functional dyspepsia
Skin disorders
Fibromyalgia and chronic widespread pain
Increased symptom reporting, unexplained illness, and chronic pain
Incarceration

VA has decided not to propose new presumptions of service connection for any of these health effects for the

reasons discussed in the sections that follow.

iii. Health Effects that Are Not Injuries, Diseases, or Illnesses

Some health effects evaluated by the report are not injuries, diseases, or illnesses and therefore cannot form the basis of a grant of service connection. See 38 CFR 3.1(m); 38 U.S.C. 105. Unless these phenomena, such as accidental death, can be linked to a disease or injury incurred or aggravated in service, VA would have no authority to compensate veterans or their survivors, through new presumptions or otherwise, absent new legislative authority. These health effects include: Accidental death in the early years after deployment
Marital and family conflict
Incarceration
Suicide in the early years after deployment

With respect to suicide, although suicide itself is not a disease or injury for which service connection can be granted, VA regulations at 38 CFR 3.302 provide that, if a veteran had a service connected disability involving mental unsoundness, VA will presume that the suicide resulted from that condition. Accordingly, no change in the current regulation is needed with respect to suicide for this reason as well.

iv. Health Effects Statutorily Barred From Service Connection

Alcohol abuse and drug abuse are health effects evaluated by the report which are statutorily barred from service connection under 38 U.S.C. 1110. See also 38 CFR 3.301(d). A veteran may only establish service connection for alcohol abuse or drug abuse on a secondary basis if the alcohol abuse or drug abuse is proximately due to another service-connected condition. See *Allen v. Principi*, 237 F.3d 1368 (Fed. Cir. 2001); 38 CFR 3.310(a). Therefore, establishment of a presumption of service connection for alcohol abuse or drug abuse is prohibited.

v. Psychiatric Disorders

The report evaluated a number of psychological health effects from the deployment-related stressors. A presumption of service connection is not warranted for any of these psychiatric health effects, which include the following:

PTSD
Anxiety
Depression

The NAS report notes that these psychiatric conditions may be triggered by the experience of wartime

deployment. However, it is also well established that these conditions, particularly anxiety and depression, are widespread and may be triggered by multiple life events, including those occurring before and after service. When a veteran seeks service-connected benefits for a psychiatric disease, VA routinely provides a psychiatric examination to assist in establishing that the condition is related to the veteran's service. This process works efficiently to ensure that veterans are properly compensated for psychiatric disabilities that are associated with service. Accordingly, VA has determined that a broad presumption of service connection for such psychiatric conditions is not needed.

With respect to PTSD, we also believe that existing VA regulations provide an effective means of ensuring that service-connected benefits are properly provided for PTSD related to deployment to a combat zone and that a presumption of service connection is thus unnecessary. The diagnosis of PTSD and a determination that PTSD is related to service both require the identification of a specific stressor sufficient to cause PTSD. Because the identification of a stressor is essential to a proper diagnosis of PTSD, a presumption of service connection for a veteran's diagnosed PTSD would not eliminate that requirement. Further, existing VA regulations provide liberal evidentiary standards for establishing the existence of stressors associated with combat or deployment to a combat zone. Under 38 CFR 3.304(f)(2), if a veteran engaged in combat with the enemy, the veteran's lay statements regarding the occurrence of an in-service stressor are sufficient to establish that fact, absent clear and convincing evidence to the contrary and provided the veteran's statements are consistent with the circumstances, conditions, or hardships of the veteran's service.

Further, recent amendments to 38 CFR 3.304(f) have liberalized the evidentiary standard for establishing the required in-service stressor in certain circumstances. 75 FR 39843 (July 13, 2010). This amendment eliminates the requirement for corroborating that the claimed in-service stressor occurred if a stressor claimed by a veteran is related

to the veteran's fear of hostile military or terrorist activity and a VA psychiatrist or psychologist, or a psychiatrist or psychologist with whom VA has contracted, confirms that the claimed stressor is adequate to support a diagnosis of PTSD and that the veteran's symptoms are related to the claimed stressor, provided that the claimed stressor is consistent with the places, types, and circumstances of the veteran's service. This rule provides a low evidentiary standard for establishing the existence of stressors associated with certain aspects of deployment to a combat zone such as fear of hostile military or terrorist activity related to such deployments.

vi. Skin Disorders

With respect to skin disorders, as mentioned above the report placed skin disorders under the association category Limited but Suggestive Evidence of an Association. This association category indicates that the report found that evidence from available studies is suggestive of an association between deployment to a war zone and skin disorders, but the body of evidence is limited by inability to rule out chance of bias, including confounding, with confidence. Specifically, the report found a number of studies showing increased prevalence of skin disorders in deployed veterans, but that the studies varied widely as to which specific types of skin disorders were more prevalent, and NAS noted that some of the observed increases could be attributable to chance or to undetermined environmental exposures, while others may be secondary to PTSD or other stress disorders. In view of the varied nature of the findings, the evidence does not indicate a basis for presuming specific skin diagnoses to be associated with Gulf War service or other wartime deployments. To the extent the evidence shows increased reporting of signs or symptoms relating to the skin, 38 U.S.C. 1117 and 38 CFR 3.317 already provide for presumptive service connection of undiagnosed or unexplained illnesses involving such signs or symptoms.

vii. Health Effects Already Covered by Existing Regulatory or Statutory Presumptions

The remainder of the health effects evaluated by the report are already considered in the presumptions of service connection for undiagnosed illnesses and medically unexplained chronic multisymptom illnesses under 38 U.S.C. 1117 and 38 CFR 3.317. Chronic fatigue syndrome and fibromyalgia are presumptively service-connected as medically unexplained chronic multisymptom illnesses. 38 CFR 3.317(a)(2)(B). VA has also recently proposed to clarify that functional gastrointestinal disorders are medically unexplained chronic multisymptom illnesses. 75 FR 70162 (November 17, 2010). Additionally, chronic pain and increased symptom reporting can be considered as signs and symptoms that may be manifestations of undiagnosed illness or medically unexplained chronic multisymptom illness under § 3.317(a)(2)(i). Therefore, establishment of a presumption for these health effects is not necessary.

V. Conclusion

For the reasons stated above, the Secretary has determined that a presumption of service connection is not warranted at this time for any of the diseases, illnesses, or health effects discussed in the NAS report issued on November 15, 2007, titled, "Gulf War and Health, Volume 6: Physiologic, Psychologic, and Psychosocial Effects of Deployment-Related Stress."

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. John R. Gingrich, Chief of Staff, Department of Veterans Affairs, approved this document on January 6, 2011, for publication.

Dated: January 7, 2011.

Robert C. McFetridge,

Director, Regulations Policy and Management, Department of Veterans Affairs.

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Part II

Department of
Health and Human
Services

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 480
Medicare Programs; Hospital Inpatient Value-Based Purchasing Program;
Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 480

[CMS–3239–P]

RIN 0938–AQ55

Medicare Program; Hospital Inpatient Value-Based Purchasing Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: In this proposed rule, we are proposing to implement a Hospital Value-Based Purchasing program (“Hospital VBP program” or “the program”) under section 1886(o) of the Social Security Act (“Act”), under which value-based incentive payments will be made in a fiscal year to hospitals that meet performance standards with respect to a performance period for the fiscal year involved. The program will apply to payments for discharges occurring on or after October 1, 2012, in accordance with section 1886(o) of the Social Security Act (as added by section 3001(a) of the Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010 (collectively known as the Affordable Care Act)). The measures we are proposing to initially adopt for the program are a subset of the measures that we have already adopted for the existing Medicare Hospital Inpatient Quality Reporting Program (Hospital IQR program), formerly known as the Reporting Hospital Quality Data for the Annual Payment Update Program (RHQDAPU), and we are proposing, based on whether a hospital meets or exceeds the performance standards that we are proposing to establish with respect to the measures, to reward the hospital based on its actual performance, rather than simply its reporting of data for those measures.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on March 8, 2011.

ADDRESSES: In commenting, please refer to file code CMS–3239–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address only:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3239–P, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3239–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–8691 in advance to schedule your arrival with one of our staff members.

Comments 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: Allison Lee, (410) 786–8691.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the

comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, 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 1–800–743–3951.

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Acronyms

Because of the many terms to which we refer by acronym in this proposed rule, we are listing the acronyms used and their corresponding meanings in alphabetical order below:

AHRQ Agency for Healthcare Research and Quality

AMI Acute Myocardial Infarction
 CCN CMS Certification number
 CMS Centers for Medicare & Medicaid Services
 DRG Diagnosis-Related Group
 FISMA Federal Information Security and Management Act
 HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems
 HF Heart Failure
 HIPAA Health Insurance Portability and Accountability Act
 HOP QDRP Hospital Outpatient Quality Data Reporting Program
 IPPS Inpatient prospective payment systems
 IQR Inpatient Quality Reporting
 NQF National Quality Forum
 PN Pneumonia
 PQRI Physician Quality Reporting Initiative
 PRRB Provider Reimbursement Review Board
 PSI Patient Safety Indicator
 QIO Quality Improvement Organization
 QRS Quality Review Study
 RFA Regulatory Flexibility Act
 RHQDAPU Reporting Hospital Quality Data for the Annual Payment Update Program
 RIA Regulatory Impact Analysis
 SCIP Surgical Care Improvement
 VBP Value-Based Purchasing

I. Background

A. Overview

The Centers for Medicare & Medicaid Services (CMS) promotes higher quality and more efficient health care for Medicare beneficiaries. In recent years, we have undertaken a number of initiatives to lay the foundation for rewarding health care providers and suppliers for the quality of care they provide by tying a portion of their Medicare payments to their performance on quality measures. These initiatives, which include demonstration projects and quality reporting programs, have been applied to various health care settings, including physicians' offices, ambulatory care facilities, hospitals, nursing homes, home health agencies, and dialysis facilities. The overarching goal of these initiatives is to transform Medicare from a passive payer of claims to an active purchaser of quality health care for its beneficiaries.

This effort is supported by our adoption of an increasing number of widely-agreed upon quality measures for purposes of our existing quality reporting programs. We have worked with stakeholders to define measures of quality in almost every setting. These measures assess structural aspects of care, clinical processes, patient experiences with care, and, increasingly, outcomes.

We have implemented quality measure reporting programs that apply to various settings of care. With regard to hospital inpatient services, we

implemented the Hospital IQR program. In addition, we have implemented quality reporting programs for hospital outpatient services through the Hospital Outpatient Quality Data Reporting Program (HOP QDRP), and for physicians and other eligible professionals through the Physician Quality Reporting Initiative (PQRI). We have also implemented quality reporting programs for home health agencies and skilled nursing facilities based on conditions of participation, and an end-stage renal disease quality reporting program based on conditions for coverage.

This new program will necessarily be a fluid model, subject to change as knowledge, measures and tools evolve. We view the Hospital VBP program under section 1886(o) of the Social Security Act (the Act) as the next step in promoting higher quality care for Medicare beneficiaries and transforming Medicare into an active purchaser of quality health care for its beneficiaries.

In developing this rule as well as other value-based payment initiatives, CMS applied the following principles for the development and use of measures and scoring methodologies.

Purpose:

CMS views value-based purchasing as an important step to revamping how care and services are paid for, moving increasingly toward rewarding better value, outcomes, and innovations instead of merely volume.

Use of Measures:

- Public reporting and value-based payment systems should rely on a mix of standards, process, outcomes, and patient experience measures, including measures of care transitions and changes in patient functional status. Across all programs, CMS seeks to move as quickly as possible to the use of primarily outcome and patient experience measures. To the extent practicable and appropriate, outcomes and patient experience measures should be adjusted for risk or other appropriate patient population or provider characteristics.

- To the extent possible and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across Medicare's and Medicaid's public reporting and payment systems. CMS seeks to evolve to a focused core-set of measures appropriate to the specific provider category that reflects the level of care and the most important areas of service and measures for that provider.

- The collection of information should minimize the burden on providers to the extent possible. As part of that effort, CMS will continuously

seek to align its measures with the adoption of meaningful use standards for health information technology (HIT), so the collection of performance information is part of care delivery.

- To the extent practicable, measures used by CMS should be nationally endorsed by a multi-stakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures.

Scoring Methodology:

- Providers should be scored on their overall achievement relative to national or other appropriate benchmarks. In addition, scoring methodologies should consider improvement as an independent goal.

- Measures or measurement domains need not be given equal weight, but over time, scoring methodologies should be more weighted towards outcome, patient experience and functional status measures.

- Scoring methodologies should be reliable, as straightforward as possible, and stable over time and enable consumers, providers, and payers to make meaningful distinctions among providers' performance.

CMS welcomes comments on these principles.

B. Hospital Inpatient Quality Data Reporting Under Section 501(b) of Public Law 108–173

Section 501(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Public Law 108–173, added section 1886(b)(3)(B)(vii) to the Act. This section established the original authority for the Hospital IQR program and revised the mechanism used to update the standardized payment amount for inpatient hospital operating costs. Specifically, section 1886(b)(3)(B)(vii)(I) of the Act provided for a reduction of 0.4 percentage points to the annual percentage increase (sometimes referred to at that time as the market basket update) for FY 2005 through FY 2007 for a subsection (d) hospital if the hospital did not submit data on a set of 10 quality indicators established by the Secretary as of November 1, 2003. It also provided that any reduction applied only to the fiscal year involved, and would not be taken into account in computing the applicable percentage increase for a subsequent fiscal year. The statute thereby established an incentive for many subsection (d) hospitals to submit data on the quality measures established by the Secretary.

We implemented section 1886(b)(3)(B)(vii) of the Act in the FY

2005 IPPS final rule (69 FR 49078) and codified the applicable percentage change in § 412.64(d) of our regulations. We adopted additional requirements under the Hospital IQR program in the FY 2006 IPPS final rule (70 FR 47420).

C. Hospital Inpatient Quality Reporting Under Section 5001(a) of Public Law 109-171

1. Change in the Reduction to the Annual Percentage Increase

Section 5001(a) of the Deficit Reduction Act of 2005 (DRA), Public Law 109-171, further amended section 1886(b)(3)(B) of the Act to, among other things, revise the mechanism used to update the standardized payment amount for hospital inpatient operating costs by adding new section 1886(b)(3)(B)(viii) to the Act. Specifically, sections 1886(b)(3)(B)(viii)(I) and (II) of the Act as added by the DRA originally provided that the annual percentage increase for FY 2007 and each subsequent fiscal year shall be reduced by 2.0 percentage points for a subsection (d) hospital that does not submit quality data in a form and manner, and at a time, specified by the Secretary. Section 1886(b)(3)(B)(viii)(I) of the Act also provided that any reduction in a hospital's annual percentage increase will apply only with respect to the fiscal year involved, and will not be taken into account for computing the applicable percentage increase for a subsequent fiscal year.

In the FY 2007 IPPS final rule (71 FR 48045), we amended our regulations at § 412.64(d)(2) to reflect the 2.0 percentage point reduction required under the DRA.

2. Selection of Quality Measures

Section 1886(b)(3)(B)(viii)(V) of the Act, before it was amended by section 3001(a)(2)(B) of the Affordable Care Act, required that, effective for payments beginning with FY 2008, the Secretary add other measures that reflect consensus among affected parties, and to the extent feasible and practicable, have been set forth by one or more national consensus building entities. The National Quality Forum (NQF) is a voluntary consensus standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other health care stakeholder organizations. The NQF was established to standardize health care quality measurement and reporting through its consensus development process. We have generally adopted NQF-endorsed measures for purposes of the Hospital

IQR program. However, we believe that consensus among affected parties also can be reflected by other means, including consensus achieved during the measure development process, consensus shown through broad acceptance and use of measures, and consensus achieved through public comment.

Section 1886(b)(3)(B)(viii)(VI) of the Act authorizes the Secretary to replace any quality measures or indicators in appropriate cases, such as when all hospitals are effectively in compliance with a measure, or the measures or indicators have been subsequently shown to not represent the best clinical practice. We interpreted this provision to give us broad discretion to replace measures that are no longer appropriate for the Hospital IQR program.

We have adopted 45 measures under the Hospital IQR program for the FY 2011 payment determination. Of these measures, 27 are chart-abstracted process of care measures, which assess the quality of care furnished by hospitals in connection with four topics: Acute Myocardial Infarction (AMI); Heart Failure (HF); Pneumonia (PN); and Surgical Care Improvement (SCIP) (75 FR 50182). Fifteen of the measures are claims-based measures, which assess the quality of care furnished by hospitals on the following topics: 30-day mortality and 30-day readmission rates for Medicare patients diagnosed with either AMI, HF, or PN; Patient Safety Indicators/Inpatient Quality Indicators/Composite Measures; and Patient Safety Indicators/Nursing Sensitive Care. Three of the measures are structural measures that assess hospital participation in cardiac surgery, stroke care, and nursing sensitive care systemic databases. Finally, the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) patient experience of care survey is included as a measure for the FY 2011 payment determination.

The technical specifications for the Hospital IQR program measures, or links to Web sites hosting technical specifications, are contained in the CMS/The Joint Commission Specifications Manual for National Hospital Inpatient Quality Measures (Specifications Manual). This Specifications Manual is posted on the CMS QualityNet Web site at <https://www.QualityNet.org/>. We maintain the technical specifications by updating this Specifications Manual semiannually, or more frequently in unusual cases, and include detailed instructions and calculation algorithms for hospitals to use when collecting and submitting data on required measures. These

semiannual updates are accompanied by notifications to users, providing sufficient time between the change and the effective date in order to allow users to incorporate changes and updates to the specifications into data collection systems.

3. Public Display of Quality Measures

Section 1886(b)(3)(B)(viii)(VII) of the Act, before it was amended by section 3001(a)(2)(C) of the Affordable Care Act, required that the Secretary establish procedures for making data submitted under the Hospital IQR program available to the public after ensuring that a hospital has the opportunity to review the data before it is made public. To meet this requirement, we have displayed most Hospital IQR program data on the *Hospital Compare* website, <http://www.hospitalcompare.hhs.gov>, after a 30-day preview period. An interactive Web tool, this Web site assists beneficiaries by providing information on hospital quality of care to those who need to select a hospital. It further serves to encourage beneficiaries to work with their doctors and hospitals to discuss the quality of care hospitals provide to patients, thereby providing an additional incentive to hospitals to improve the quality of care that they furnish. The *Hospital Compare* website currently makes public data on clinical process of care measures, risk adjusted outcome measures, the HCAHPS patient experience of care survey, and structural measures. However, data that we believe is not suitable for inclusion on *Hospital Compare* because it is not salient or will not be fully understood by beneficiaries, as well as data for which there are unresolved display or design issues may be made available on other CMS Web sites that are not intended to be used as an interactive Web tool, such as <http://www.cms.hhs.gov/HospitalQualityInits/>. In such circumstances, affected parties are notified via CMS listservs, CMS e-mail blasts, national provider calls, and QualityNet announcements regarding the release of preview reports followed by the posting of data on a Web site other than *Hospital Compare*.

D. 2007 Report to Congress: Plan To Implement a Medicare Hospital Value-Based Purchasing Program

Section 5001(b) of the DRA required the Secretary to develop a plan to implement a value-based purchasing program for payments made under the Medicare program for subsection (d) hospitals. In developing the plan, we were required to consider the on-going development, selection, and modification process for measures of

quality and efficiency in hospital inpatient settings; the reporting, collection, and validation of quality data; the structure, size, and sources of funding of value-based payment adjustments; and the disclosure of information on hospital performance.

In 2007, we submitted to Congress a report that discusses options for a plan to implement a Medicare hospital VBP program that builds on the Hospital IQR program. We recommended replacing the Hospital IQR program with a new program that would include both a public reporting requirement and financial incentives for better performance. We also recommended that a hospital VBP program be implemented in a manner that would not increase Medicare spending.

To calculate a hospital's total performance score under the plan, we analyzed a potential performance scoring model that incorporated measures from different quality "domains," including clinical process of care and patient experience of care. We examined ways to translate that score into an incentive payment by making a portion of the base diagnosis-related group (DRG) payment contingent on performance. We analyzed criteria for selecting performance measures and considered a potential phased approach to transition from Hospital IQR to value-based purchasing. In addition, we examined redesigning the current data transmission process and validation infrastructure, including making enhancements to the *Hospital Compare* Web site, as well as an approach to monitor the impact of value-based purchasing.

E. Provisions of the Affordable Care Act

Section 3001(a) of the Patient Protection and Affordable Care Act (Pub. L. 111-148), enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), enacted on March 30, 2010 (collectively known as the Affordable Care Act), added a new section 1886(o) to the Social Security Act (the Act) which requires the Secretary to establish a hospital value-based purchasing program under which value-based incentive payments are made in a fiscal year to hospitals meeting performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary. Section 1886(o)(1)(B) of the Act directs the Secretary to begin making value-based incentive payments under the Hospital VBP program to hospitals for discharges occurring on or

after October 1, 2012. These incentive payments will be funded for FY 2013 through a reduction to FY 2013 base operating DRG payments for each discharge of 1%, as required by section 1886(o)(7). Section 1886(o)(1)(C) provides that the Hospital VBP program applies to subsection (d) hospitals (as defined in section 1886(d)(1)(B)), but excludes from the definition of the term "hospital," with respect to a fiscal year: 1) a hospital that is subject to the payment reduction under section 1886(b)(3)(B)(viii)(I) for such fiscal year; 2) a hospital for which, during the performance period for the fiscal year, the Secretary cited deficiencies that pose immediate jeopardy to the health and safety of patients; and 3) a hospital for which there is not a minimum number (as determined by the Secretary) of applicable measures for the performance period for the fiscal year involved, or for which there is not a minimum number (as determined by the Secretary) of cases for the applicable measures for the performance period for such fiscal year.

II. Provisions of the Proposed Regulations

A. Overview of the Proposed Hospital VBP Program

This proposed rule proposes to implement a Hospital Value-Based Purchasing program ("Hospital VBP program" or "the program") under section 1886(o) of the Social Security Act ("Act"), under which value-based incentive payments will be made in a fiscal year (beginning FY 2013) to hospitals that meet performance standards established with respect to a performance period ending prior to the beginning of such fiscal year. This proposed rule was developed based on extensive research we conducted on hospital value-based purchasing, including research that formed the basis of a 2007 report we submitted to Congress, entitled "Report to Congress: Plan to Implement a Medicare Hospital Value-Based Purchasing Program" (November 21, 2007), a copy of which is available on the CMS Web site, and takes into account input from both stakeholders and other interested parties. As described more fully below, we are proposing to initially adopt for the FY 2013 Hospital VBP program 18 measures that we have already adopted for the Hospital IQR Program, categorized into two domains, as follows: 17 of the proposed measures will be clinical process of care measures, which we will group into a clinical process of care domain, and 1 measure will be the HCAHPS survey,

which will fall under a patient experience of care domain. With respect to the clinical process of care and HCAHPS measures, we are proposing to use a three-quarter performance period from July 1, 2011 through March 31, 2012 for the FY 2013 payment determination and to determine whether hospitals meet the proposed performance standards for these measures by comparing their performance during the proposed performance period to their performance during a proposed three-quarter baseline period from July 1, 2009 through March 31, 2010. We are also proposing to initially adopt for the FY 2014 Hospital VBP program three outcome measures. With respect to the proposed outcome measures, we are proposing to use an 18-month performance period from July 1, 2011 to December 31, 2012. Furthermore, for the proposed outcome measures, we are proposing to establish performance standards and to determine whether hospitals meet those standards by comparing their performance during the proposed performance period to their performance during a proposed baseline period of July 1, 2008 to December 31, 2009.

In general, we are proposing to implement a methodology for assessing the total performance of each hospital based on performance standards, under which we will score each hospital based on achievement and improvement ranges for each applicable measure. Additionally, we are proposing to calculate a total performance score for each hospital by combining the greater of the hospital's achievement or improvement points for each measure to determine a score for each domain, multiplying each domain score by a proposed weight (clinical process of care: 70 percent, patient experience of care: 30 percent), and adding together the weighted domain scores. We are proposing to convert each hospital's total performance score into a value-based incentive payment utilizing a linear exchange function. All of these proposals are addressed in greater detail below.

B. Proposed Performance Period

Section 1886(o)(4) of the Act requires the Secretary to establish a performance period for a fiscal year that begins and ends prior to the beginning of such fiscal year. In considering various performance periods that could apply for purposes of the fiscal year 2013 payment adjustments, we recognized that hospitals submit data on the chart-abstracted measures adopted for the Hospital IQR Program on a quarterly

basis, and for that reason, we would propose that the performance period commence at the beginning of a quarter. We also recognize that we must balance the length of the period for collecting measure data with the need to undertake the rulemaking process in order to establish the performance period and provide the public with an opportunity to meaningfully comment on that proposal. With these considerations in mind, we concluded that July 1, 2011 is the earliest date that the performance period could begin.

We then considered how long the performance period should be. Our preference would have been to propose to use a full year as the performance period for the clinical process of care and HCAHPS measures we are proposing to initially adopt for the FY 2013 Hospital VBP program, consistent with our analysis that using a full year performance period provides high levels of data accuracy and reliability for scoring hospitals on these measures. We concluded, however, that this would not give us sufficient time to calculate the total performance scores, calculate the value-based incentive payments, notify hospitals regarding their payment adjustments, and implement the payment adjustments. We subsequently analyzed how a shorter performance period might affect a hospital's performance score. Using the most recent clinical process of care and HCAHPS measure data available, we examined the feasibility of proposing to adopt a one quarter, two quarter, or three quarter performance period by comparing each of these periods to a four quarter baseline period. We did this to determine how closely a hospital's total performance score calculated using one, two, or three quarters of data would approximate what the hospital's total performance score would be if we proposed to use four quarters of data. Under our analysis, the total performance scores approximated using three quarters of data closely correlated with total performance scores approximated using four quarters of data. Specifically, our analysis showed that the three quarter performance period would have a correlation coefficient of 0.96815 (p-value .0001), while a two quarter performance period would have a correlation coefficient of 0.90358 (p-value .0001).

We also recognize that under the Hospital IQR program, hospitals have 135 days to submit chart abstracted data following the close of each quarter. Because we are proposing to implement a Hospital VBP program that builds on the Hospital IQR program, we would like, to the extent possible, to maintain

our existing Hospital IQR program requirements. We believe that the 135 day time lag supports the adoption of a three quarter performance period based on the analysis discussed above, and that a one or two quarter performance period would provide lower data accuracy for scoring hospitals and adjusting their payments.

Therefore, we propose to use the fourth quarter of FY 2011 (July 1, 2011–September 30, 2011) and the first and second quarters of FY 2012 (October 1, 2011–March 31, 2012) as the performance period for proposed clinical process of care and HCAHPS measures we are proposing to initially adopt for the FY 2013 Hospital VBP program. Hospitals will be scored based on how well they perform on the proposed clinical process of care and HCAHPS measures during this proposed performance period. We note that we anticipate proposing to use a full year as the performance period for the clinical process of care and HCAHPS measures in the future. For the three mortality outcome measures currently specified for the Hospital IQR program for the FY 2011 payment determination (MORT–30–AMI, MORT–30–HF, MORT–30–PN) that we propose below to adopt for the FY 2014 Hospital VBP program payment determination, we are proposing to establish a performance period of July 1, 2011 to December 31, 2012. An eighteen-month performance period for mortality measures is intended to ensure the measures' reliability by capturing more cases than could be observed over one year of measurement. We plan to add additional measures to the Hospital VBP program, including but not limited to AHRQ and HAC measures that have been specified for the Hospital IQR program and propose that the performance period for those measures will begin one year after these measures have been displayed on the *Hospital Compare* Web site for the reasons discussed below.

C. Proposed Measures

Section 1886(o)(2)(A) of the Act requires the Secretary to select for the Hospital VBP program measures, other than readmission measures, from the measures specified for the Hospital IQR program. Section 1886(o)(2)(B)(i) requires the Secretary to ensure that the selected measures include measures on six specified conditions or topics: Acute Myocardial Infarction (AMI); Heart Failure (HF); Pneumonia (PN); Surgeries, as measured by the Surgical Care Improvement Project (SCIP); Healthcare-Associated Infections (HAI); and, the Hospital Consumer Assessment of Healthcare Providers and Systems

survey (HCAHPS). Section 1886(o)(2)(C)(i) provides that the Secretary may not select a measure with respect to a performance period for a fiscal year unless the measure has been specified under section 1886(b)(3)(B)(viii) of the Act and included on the *Hospital Compare* website for at least one year prior to the beginning of the performance period. Section 1886(o)(2)(C)(ii) provides that a measure selected under section 1886(o)(2)(A) shall not apply to a hospital if the hospital does not furnish services appropriate to the measure.

Our measure development and selection activities for the Hospital IQR Program take into account national priorities, such as those established by the National Priorities Partnership,¹ and the Department of Health and Human Services,² as well as other widely accepted criteria established in medical literature.³ Because we must select measures for the Hospital VBP program from the pool of measures that have been adopted for the Hospital IQR program, the measures to be selected for inclusion in Hospital VBP would also reflect these priorities.

In the FY 2011 IPPS/RV 2011 LTCH PPS final rule, we stated that in future expansions and updates to the Hospital IQR program measure set, we would be taking into consideration several important goals. These goals include: (a) Expanding the types of measures beyond process of care measures to include an increased number of outcome measures, efficiency measures, and patients' experience of care measures; (b) expanding the scope of hospital services to which the measures apply; (c) considering the burden on hospitals in collecting chart-abstracted data; (d) harmonizing the measures used in the Hospital IQR program with other CMS quality programs to align incentives and promote coordinated efforts to improve quality; (e) seeking to use measures based on alternative sources of data that do not require chart abstraction or that utilize data already being reported by many hospitals, such as data that hospitals report to clinical data registries, or all payer claims databases; and (f) weighing the relevance and utility of the measures compared to the burden on hospitals in submitting data under the Hospital IQR program. In addition, we believe that we

¹ <http://www.nationalprioritiespartnership.org/>.

² <http://www.hhs.gov/secretary/about/priorities/priorities.html>.

³ Chassin, M.R.; Loeb, J.M.; Schmaltz, S.P. and Wachter, R.M. (2010) "Accountability Measures—Using Measurement to Promote Quality Improvement." *New England Journal of Medicine*. Vol 363: 683–688.

must act with all speed and deliberateness to expand the pool of measures used in the Hospital VBP program. This goal is supported by at least two Federal reports documenting that tens of thousands of patients do not receive safe care in the nation's hospitals.⁴ For this reason, we believe that we need to adopt measures for the Hospital VBP program relevant to improving care, particularly as these measures are directed toward improving patient safety, as quickly as possible. We believe that speed of implementation is a critical factor in the success and effectiveness of this program.

The Hospital VBP program that we are proposing to implement has been developed with the focused intention to motivate all subsection (d) hospitals to which the program applies to take immediate action to improve the quality of care they furnish to their patients. Because we view as urgent the necessity to improve the quality of care furnished by these hospitals, and because we believe that hospitalized patients in the United States currently face patient safety risks on a daily basis, we are proposing in this proposed rule to adopt an initial measure set for the Hospital VBP program. However, we are also proposing to add additional measures to the Hospital VBP program in the future in such a way that their performance period will begin immediately after they are displayed on *Hospital Compare* for a period of time of at least one year, but without the necessity of notice and comment rulemaking. We propose this because of the urgency to improve the quality of hospital care, and in order to minimize any delay to take substantive action in favor of patient safety. The details of this proposal are discussed below.

We have stated that for the Hospital IQR Program, we give priority to quality

measures that assess performance on: (a) Conditions that result in the greatest mortality and morbidity in the Medicare population; (b) conditions that are high volume and high cost for the Medicare program; and (c) conditions for which wide cost and treatment variations have been reported, despite established clinical guidelines. In addition, we stated that we seek to select measures that address the six quality aims of effective, safe, timely, efficient, patient-centered, and equitable healthcare. Current and long term priority topics include: Prevention and population health; safety; chronic conditions; high cost and high volume conditions; elimination of health disparities; healthcare-associated infections and other adverse healthcare outcomes; improved care coordination; improved efficiency; improved patient and family experience of care; effective management of acute and chronic episodes of care; reduced unwarranted geographic variation in quality and efficiency; and adoption and use of interoperable health information technology.

We have also stated that these criteria, priorities, and goals are consistent with section 1886(b)(3)(B)(viii)(X) of the Act, as added by section 3001(a)(2)(D) of the Affordable Care Act, which requires the Secretary, to the extent practicable and with input from consensus organizations and other stakeholders, to take steps to ensure that the Hospital IQR program measures are coordinated and aligned with quality measures applicable to physicians and other providers of services and suppliers under Medicare.

Currently, there are 45 measures specified under the Hospital IQR program for the FY 2011 payment determination. We view all of these measures (with the exception of the measures of readmission) as "candidate

measures" for the Hospital VBP program. We recognize that we cannot add any measure to the program unless it meets the requirements of section 1886(o). In determining what measures to initially propose for the FY 2013 Hospital VBP program we considered several factors. First, a measure must be included on the *Hospital Compare* Web site for at least one year prior to the beginning of the performance period and specified under the Hospital IQR program. The SCIP-Inf-9 and 10 measures do not meet this requirement nor do any of the nine (previously ten given the Nursing Sensitive Care—Failure to Rescue measure was harmonized with the Death Among Surgical Patients with Serious, treatable Complications) Agency for Healthcare Research and Quality (AHRQ) measures. Therefore, these measures were not considered candidate measures. It is our intention to add measures to the Hospital VBP program as soon as this requirement is met in order to help improve patient care as quickly as possible.

As noted above, we recognize that we cannot include in the measure set any readmission measures in accordance with section 1886(o)(2)(A) of the Act. We also are not proposing at this time to adopt the current Hospital IQR structural measures because we believe that these measures require further development if they are to be used for the Hospital VBP program. We seek public comment at this time on the possible utility of adopting structural measures for the Hospital VBP program measure set and how these measures might contribute to the improvement of patient safety and quality of care. Table 1 contains a list of the remaining initial eligible measures.

TABLE 1—INITIAL ELIGIBLE MEASURES FOR THE FY 2013 HOSPITAL VBP PROGRAM

Measure ID	Measure description
Process Measures	
AMI-1	Aspirin at Arrival.
AMI-2	Aspirin Prescribed at Discharge.
AMI-3	ACE/ARB Inhibitor.
AMI-4	Adult Smoking Cessation Advice/Counseling.
AMI-5	Beta Blocker Prescribed at Discharge.
AMI-7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival.
AMI-8a	Primary PCI Received Within 90 Minutes of Hospital Arrival.
HF-1	Discharge Instructions.
HF-2	Evaluation of LVS Function.
HF-3	ACEI or ARB for LVSD.
HF-4	Adult Smoking Cessation Advice/Counseling.

⁴ See OEI-06-09-00090 "Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries." Department of Health and Human

Services, Office of Inspector General, November 2010. See also, 2009 National Healthcare Quality

Report, pp. 107–122. "Patient Safety," Agency for Healthcare Research and Quality.

TABLE 1—INITIAL ELIGIBLE MEASURES FOR THE FY 2013 HOSPITAL VBP PROGRAM—Continued

Measure ID	Measure description
PN-2	Pneumococcal Vaccination.
PN-3b	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital.
PN-4	Adult Smoking Cessation Advice/Counseling.
PN-5c	Timing of Receipt of Initial Antibiotic Following Hospital Arrival.
PN-6	Initial Antibiotic Selection for CAP in Immunocompetent Patient.
PN-7	Influenza Vaccination.
SCIP-Inf-1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision.
SCIP-Inf-2	Prophylactic Antibiotic Selection for Surgical Patients.
SCIP-Inf-3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time.
SCIP-Inf-4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose.
SCIP-Inf-6	Surgery Patients with Appropriate Hair Removal.
SCIP-Card-2	Surgery Patients on a Beta Blocker Prior to Arrival That Received a Beta Blocker During the Perioperative Period.
SCIP-VTE-1	Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered.
SCIP-VTE-2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery.
Outcome Measures	
MORT-30-AMI	Acute Myocardial Infarction (AMI) 30-Day Mortality Rate.
MORT-30-HF	Heart Failure (HF) 30-Day Mortality Rate.
MORT-30-PN	Pneumonia (PN) 30-Day Mortality Rate.
Survey Measures	
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey.

To determine which measures we would propose to initially adopt for the FY 2013 Hospital VBP program, we then examined whether any of the eligible Hospital IQR measures (table above) should be excluded from the Hospital VBP program measure set because hospital performance on them is “topped out,” meaning that all but a few hospitals have achieved a similarly high level of performance on them. We believe that measuring hospital performance on topped-out measures will have no meaningful effect on a hospital’s total performance score. Scoring a topped-out measure for purposes of the Hospital VBP program would also present a number of challenges. First, as we discuss below, we are proposing that the benchmark performance standard for all measures will be the performance at the mean of the top decile (defined in section II. E. of this proposed rule). Applied to a topped-out measure, the benchmark would be statistically indistinguishable from the highest attainable score for the measure and, in our view, could lead to unintended consequences as hospitals strive to meet the benchmark. Examples of unintended consequences could include, but are not limited to, inappropriate delivery of a service to some patients (such as delivery of antibiotics to patients without a confirmed diagnosis of pneumonia), unduly conservative decisions on whether to exclude some patients from the measure denominator, and a focus

on meeting the benchmark at the expense of actual improvements in quality or patient outcomes. Second, we have found that for topped-out measures, it is significantly more difficult to differentiate among hospitals performing above the median. Third, because a measure cannot be applied to a hospital unless the hospital furnishes services appropriate to the measure, data reporting under the Hospital VBP program will not be the same for all hospitals. To the extent that a hospital can report a higher proportion of topped-out measures, for which its scores would likely be high, we believe that such a hospital would be unfairly advantaged in the determination of its total performance score.

To determine whether an eligible Hospital IQR measure is topped out, we initially focused on the top distribution of hospital performance on each measure and noted if their 75th and 90th percentiles were statistically indistinguishable. Based on our analysis, we identified 7 topped-out measures: AMI-1 Aspirin at Arrival; AMI-5 Beta Blocker at Discharge; AMI-3 ACEI or ARB at Discharge; AMI-4 Smoking Cessation; HF-4 Smoking Cessation; PN-4 Smoking Cessation; and SCIP-Inf-6 Surgery Patients with Appropriate Hair Removal. We then observed that two of these measures identified as topped out (AMI-3 ACEI or ARB at Discharge and HF-4 Smoking Cessation) had significantly lower mean scores than the others, which led us to

question whether our analysis was too focused on the top ends of distributions and whether additional criteria that could account for the entire distribution might be more appropriate. To address this, we analyzed the truncated coefficient of variation for each of the measures. The coefficient of variation (CV) is a common statistic that expresses the standard deviation as a percentage of the sample mean in a way that is independent of the units of observation. Applied to this analysis, a large CV would indicate a broad distribution of individual hospital scores, with large and presumably meaningful differences between hospitals in relative performance. A small CV would indicate that the distribution of individual hospital scores is clustered tightly around the mean value, suggesting that it is not useful to draw distinctions between individual hospital performance scores. We used a modified version of the CV, namely a truncated CV, for each measure, in which the five percent of hospitals with the lowest scores, and the five percent of hospitals with highest scores were first truncated (set aside) before calculating the CV. This was done to avoid undue effects of the highest and lowest outlier hospitals, which if included, would tend to greatly widen the dispersion of the distribution and make the measure appear to be more reliable or discerning. For example, a measure for which most hospital scores are tightly clustered

around the mean value (a small CV) might actually reflect a more robust dispersion if there were also a number of hospitals with extreme outlier values, which would greatly increase the perceived variance in the measure. Accordingly, the truncated CV was added as an additional criterion requiring that a topped-out measure also exhibit a truncated CV < 0.10. Using both the truncated CV and data showing whether hospital performance at the 75th and 90th percentiles was statistically indistinguishable, we reexamined the available measures and determined that the same seven measures continue to meet our proposed definition for being topped-out.

Our priorities for the Hospital VBP program are to transform how Medicare pays for care and to encourage hospitals to continually improve the quality of care they furnish. Our analysis of the impact of including the topped-out measures discussed above shows that their use would mask true performance differences among hospitals and, as a result, would fail to advance these priorities. Therefore, we are proposing to not include these 7 topped-out measures (AMI-1 Aspirin at Arrival; AMI-5 Beta Blocker at Discharge; AMI-3 ACEI or ARB at Discharge; AMI-4 Smoking Cessation; HF-4 Smoking Cessation; PN-4 Smoking Cessation; and SCIP-Inf-6 Surgery Patients with Appropriate Hair Removal) in the list of measures we are proposing to initially adopt for the FY 2013 Hospital VBP program.

We examined whether the following outcome measures adopted for the Hospital IQR program are appropriate for inclusion in the FY 2013 Hospital VBP program. These measures are as follows: (1) AHRQ patient safety indicators (PSIs), inpatient quality indicators (IQIs) and composite measures; (2) AHRQ PSI and nursing sensitive care measure; and (3) AMI, HF, and PN mortality measures (Medicare patients). We believe that these outcome measures provide important information relating to treatment outcomes and patient safety. We also believe that adding these outcome measures would significantly improve the correlation between patient outcomes and Hospital VBP performance. However, because under section 1886(o)(2)(C)(i) of the Act, we may only select measures if they have been included on the *Hospital Compare* Internet website for a least one year prior to the beginning of the performance period, we believe that the AHRQ Patient Safety Indicators (PSI) and Inpatient Quality Indicators (IQI) and composite measures, and the AHRQ Nursing Sensitive Care measure are not

yet eligible for inclusion in the FY 2013 Hospital VBP program. These measures are currently specified for the Hospital IQR program but have not yet been included on *Hospital Compare*. Because of the urgency to act quickly to improve patient safety, we plan to adopt them for use in the Hospital VBP Program as rapidly as possible and will continue working to develop additional robust outcome measures for the Hospital VBP program. We invite comments on the addition of the AHRQ PSI, IQI, and Nursing Sensitive Care measures for Hospital VBP program inclusion in FY 2014 and future years.

We considered whether the current publicly-reported 30-day mortality claims-based measures (Mort-30-AMI, Mort-30-HF, Mort-30-PN) should be included in the FY 2013 Hospital VBP program. The mortality measures assess hospital-specific, risk-standardized, all-cause 30-day mortality rates for patients hospitalized with a principal diagnosis of heart attack, heart failure, and pneumonia. All-cause mortality is defined for purposes of these measures as death from any cause within 30 days after the index admission date, regardless of whether the patient died while still in the hospital or after discharge. On July 1, 2009, the specifications for these measures were changed from a one-year reporting period to a three-year rolling average. This was done to address concerns regarding the reliability of the measures, and the three-year rolling average allows us to include a larger number of cases in the measure calculations, although our analysis shows that eighteen months of these data is also reliable. We do not believe that the three-quarter performance period we are proposing to use for the initial clinical process of care and HCAHPS measures for the FY 2013 Hospital VBP program would be appropriate to use for these mortality outcome measures because we do not believe that the data collected for these mortality measures during those three quarters will provide us with sufficiently accurate information about a hospital's outcomes on which to score hospitals on these measures and base payment. The detailed methodology for the 30-day risk standardized mortality measures is available on <http://www.qualitynet.org>.

However, we propose to adopt these currently reported 30-day mortality claims-based measures (MORT-30-AMI, MORT-30-HF, and MORT-30-PN) as measures for the FY 2014 Hospital VBP program and, as proposed above, to establish a performance period with respect to these measures of July 1, 2011 to December 31, 2012.

The eligible clinical process of care measures that have not been excluded for reasons previously discussed cover acute myocardial infarction, heart failure, pneumonia, and surgeries (as measured by the Surgical Care Improvement Project (SCIP)). Therefore, we believe that they meet the requirements in section 1886(o)(2)(B)(i)(I)(aa)-(dd) of the Act. Section 1886(o)(2)(B)(i)(ee) of the Act requires the Secretary to also select for purposes of the FY 2013 Hospital VBP program measures that cover healthcare-associated infections (HAI) "as measured by the prevention metrics and targets established in the HHS Action Plan to Prevent Healthcare-Associated Infections (or any successor plan) of the Department of Health and Human Services." The SCIP measures that we discuss above were developed to support practices that have demonstrated an ability to significantly reduce surgical complications such as HAIs. Compliance with these SCIP infection measures is also included as a targeted metric in the HHS *Action Plan to Prevent Healthcare-Associated Infections* issued in 2009, available on the HHS website. As a result, we believe that the SCIP-Inf-1; SCIP-Inf-2; SCIP-Inf-3; and SCIP-Inf-4 measures we have adopted for the Hospital IQR program meet the requirement in section 1886(o)(2)(B)(i)(I)(ee) and we propose to categorize them under a HAI condition topic instead of under the SCIP condition topic.

Under section 1886(o)(2)(B)(i)(II), the Secretary must select measures for the FY 2013 Hospital VBP program related to the Hospital Consumer Assessment of Healthcare Providers and Systems survey (HCAHPS). CMS partnered with the Agency for Healthcare Research and Quality (AHRQ) to develop HCAHPS. The HCAHPS survey is the first national, standardized, publicly reported survey of patients' experiences of hospital care, and we propose to adopt it for the FY 2013 Hospital VBP program. HCAHPS, also known as the CAHPS® Hospital Survey, is a survey instrument and data collection methodology for measuring patients' perceptions of their hospital experience.

The HCAHPS survey asks discharged patients 27 questions about their recent hospital stay that are used to measure the experience of patients across 10 dimensions in the Hospital IQR program. The survey contains 18 core questions about critical aspects of patients' hospital experiences (communication with nurses and doctors, the responsiveness of hospital staff, the cleanliness and quietness of the hospital environment, pain

management, communication about medicines, discharge information, overall rating of the hospital, and whether they would recommend the hospital). The survey also includes four items to direct patients to relevant questions if a patient did not have a particular experience covered by the survey, such as taking new medications or needing medicine for pain. Three items in the survey are used to adjust for the mix of patients across hospitals, and two items related to race and ethnicity support congressionally-mandated reports on disparities in health care.

The HCAHPS survey is administered to a random sample of adult patients across medical conditions between 48 hours and six weeks after discharge; the survey is not restricted to Medicare beneficiaries. Hospitals must survey patients throughout each month of the year. The survey is available in official English, Spanish, Chinese, Russian and Vietnamese versions. The survey and its protocols for sampling, data collection and coding, and file submission can be found in the HCAHPS *Quality Assurance Guidelines, Version 5.0*,

which is available on the official HCAHPS website, <http://www.hcahpsonline.org>.

AHRQ carried out a rigorous, scientific process to develop and test the HCAHPS instrument. This process entailed multiple steps, including: A public call for measures; literature review; cognitive interviews; consumer focus groups; stakeholder input; a three-state pilot test; small-scale field tests; and soliciting public comments via several **Federal Register** notices. In May 2005, the HCAHPS survey was endorsed by the National Quality Forum (NQF). CMS adopted the entire HCAHPS survey as a measure in the Hospital IQR program in October 2006, and the first public reporting of HCAHPS results occurred in March 2008. The survey, its methodology and the results it produces are available on the HCAHPS website at <http://www.hcahpsonline.org/home.aspx>. With respect to our display of the HCAHPS measure on *Hospital Compare* for purposes of the Hospital IQR program, we publicly report the measure as 10 separate items. The “cleanliness of hospital environment,”

“quietness of hospital environment,” “overall rating of the hospital,” and “recommend the hospital” survey items are displayed as stand-alone items. The remaining 6 items (communication with nurses, communication with doctors, responsiveness of hospital staff, pain management, communication about medicines, discharge information) are composites of the remaining survey items.

Finally, we propose to not include the PN-5c measure in the Hospital VBP program. We do not believe that this measure is appropriate for inclusion because it could lead to inappropriate antibiotic use. We intend to propose to retire this measure, as well as several other measures that we are not proposing to adopt for the Hospital VBP program, from the Hospital IQR program in the near future.

Accordingly, we propose to initially select the following 17 clinical process of care measures, and the HCAHPS measure, for inclusion in the FY 2013 Hospital VBP program. The proposed list of initial measures is provided in Table 2.

TABLE 2—PROPOSED INITIAL MEASURES FOR FY 2013 HOSPITAL VBP PROGRAM

Measure ID	Measure description
Clinical Process of Care Measures	
Acute myocardial infarction:	
AMI-2	Aspirin Prescribed at Discharge.
AMI-7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival.
AMI-8a	Primary PCI Received Within 90 Minutes of Hospital Arrival.
Heart Failure:	
HF-1	Discharge Instructions.
HF-2	Evaluation of LVS Function.
HF-3	ACEI or ARB for LVSD.
Pneumonia:	
PN-2	Pneumococcal Vaccination.
PN-3b	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital.
PN-6	Initial Antibiotic Selection for CAP in Immunocompetent Patient.
PN-7	Influenza Vaccination.
Healthcare-associated infections:	
SCIP-Inf-1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision.
SCIP-Inf-2	Prophylactic Antibiotic Selection for Surgical Patients.
SCIP-Inf-3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time.
SCIP-Inf-4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose.
Surgeries:	
SCIP-Card-2	Surgery Patients on a Beta Blocker Prior to Arrival That Received a Beta Blocker During the Perioperative Period.
SCIP-VTE-1	Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered.
SCIP-VTE-2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery.
Survey Measures	
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey. ⁵

⁵ Proposed dimensions of the HCAHPS survey for use in the FY 2013 Hospital VBP program include:

Communication with Nurses, Communication with Doctors, Responsiveness of Hospital Staff, Pain

Management, Communication about Medicines, Cleanliness and Quietness of Hospital Environment, Discharge

Information and Overall Rating of Hospital.

We solicit public comments on these proposed measures and also on our intention to add additional measures to the Hospital VBP Program as rapidly as possible going forward. To that end, we are proposing to implement a subregulatory process to expedite the timeline for adding measures to the Hospital VBP program beginning with the FY 2013 program. Under this process we could add any measure to the Hospital VBP program if that measure is adopted under the Hospital IQR program and has been included on the *Hospital Compare* Web site for at least one year. We are proposing that the performance period for all of these measures would start exactly one year after the date these measures are publicly posted on *Hospital Compare*, consistent with section 1886(o)(2)(C)(i). Under this proposed subregulatory process, we would solicit comments from the public on the appropriateness of adopting one or more Hospital IQR measures for the Hospital VBP program. We would also assess the Hospital IQR measure rates using the criteria we used to select the proposed measures for the initial FY 2013 Hospital VBP measure set and notify the public regarding our findings. We would propose performance period end dates for any measure we selected for Hospital VBP program in rulemaking. We are also proposing to implement a subregulatory process to retire Hospital VBP measures. Under this process, we would post our intention to retire measures on the CMS Web site at least 60 days prior to the date that we will retire the measure. We would also, as we do with respect to Hospital IQR measures that we believe pose immediate patient safety concerns if reporting on them is continued, notify hospitals and the public of the retirement of the measure and the reasons for its retirement through the usual hospital and QIO communication channels used for the Hospital IQR program, which include e-mail blasts to hospitals and the dissemination of Standard Data Processing System (SDPS) memoranda to QIOs, as well as posting the information on the QualityNet Web site. We would then confirm the retirement of the measure from the Hospital VBP program measure set in a rulemaking vehicle. We make this proposal because it will allow us to ensure that the Hospital VBP program measure set focuses on the most current quality improvement and patient safety priorities. We are seeking public comment on our proposals and other methods that allow for the addition of

measures to the Hospital VBP program as rapidly as possible in order to improve quality and safety for patients.

For value-based incentive payments made with respect to discharges occurring during FY 2014 or a subsequent fiscal year, CMS is required by statute to ensure that the measures selected for the Hospital VBP program include efficiency measures, including measures of "Medicare Spending per beneficiary." CMS solicits public comment as to what services should be included and what should be excluded in a "Medicare spending per beneficiary" calculation. For example, the calculation could include outlier payments and/or Part B payments for services furnished during an inpatient hospital stay, or could include Part A and Part B payments for services received by a beneficiary during some window of time prior to the admission and/or after the discharge. We also solicit public comment on what, if any, type(s) of hospital segmentation or adjustment should be considered.

In addition, we are considering different approaches for measuring internal hospital efficiency. Internal hospital efficiency measures could assess hospital spending per admission, as determined using cost reports or other sources. CMS seeks comment on this and other approaches for measuring internal hospital efficiency.

D. Proposed Performance Standards

Section 1886(o)(3)(A) requires the Secretary to establish performance standards with respect to the measures selected under the Hospital VBP program for a performance period for a fiscal year. The performance standards must include levels of achievement and improvement (section 1886(o)(3)(B)), and must be established and announced not later than 60 days prior to the beginning of the performance period for the fiscal year involved (section 1886(o)(3)(C)). Achievement and improvement levels are discussed more fully in section II. E. of this proposed rule. In addition, as part of the process for establishing the performance standards, the Secretary must take into account appropriate factors, such as: (1) Practical experience with the measures, including whether a significant proportion of hospitals failed to meet the performance standard during previous performance periods; (2) historical performance standards; (3) improvement rates; and (4) the opportunity for continued improvement (section 1886(o)(3)(D)).

To determine what the proposed performance standard for each proposed clinical process of care measure and the

proposed HCAHPS measure should be for purposes of the FY 2013 Hospital VBP program, we analyzed the most reliable and current hospital data that we have on each of these measures by virtue of the Hospital IQR program. Because we are proposing to adopt a performance period that is less than a full year for FY 2013, we were also sensitive to the fact that hospital performance on the proposed measures may be affected by seasonal variations in patient mix, case severity, and other factors.

To address this potential variation and ensure that the hospital scores reflect their actual performance on the measures, we believe that the performance standard for each clinical process of care measure and HCAHPS should be based on how well hospitals performed on the measure during the same three quarters in a baseline period. In determining what three-quarter baseline period would be the most appropriate to propose to use for the FY 2013 Hospital VBP program, we wanted to ensure that the baseline would be as close in time to the proposed performance period as possible. We believe that selecting a three-quarter baseline period from July 1, 2009 to March 31, 2010 will enable us to achieve this goal. Although the proposed baseline period has ended, we are still in the process of validating this data and expect the validation process to be complete by the end of January 2011.

We also believe that an essential goal of the Hospital VBP program is to provide incentives to all hospitals to improve the quality of care that they furnish to their patients. In determining what level of hospital performance would be appropriate to select as the performance standards for each measure, we focused on selecting levels that would challenge hospitals to continuously improve or maintain high levels of performance. As required by Section 1886(o)(3)(D), we specifically considered hospitals' practical experience with the measures, particularly through the Hospital IQR program, examining how different achievement and improvement thresholds would have historically impacted hospitals, how hospital performance may have changed over time, and how hospitals could continue to improve. For these reasons, we propose to set the achievement performance standard (achievement threshold) for each proposed measure at the median of hospital performance (50th percentile) during the baseline period of July 1, 2009 through March 31, 2010. As proposed in section II. E. of

this proposed rule, hospitals would receive achievement points only if they exceed the achievement performance standard and could increase their achievement score based on higher levels of performance. We believe these achievement performance standards represent achievable standards of excellence. We also propose to set the improvement performance standard

(improvement threshold) for each proposed measure at each specific hospital's performance on the measure during the proposed baseline period of July 1, 2009 through March 31, 2010. We believe that these improvement performance standards ensure that hospitals will be adequately incentivized to improve.

Because our process for validating the proposed baseline period of data is not

yet complete, we are unable to provide the precise achievement threshold values for what these performance standards will be at this time. These values will be specified in the final rule. We specify example achievement performance standards, using July 1, 2008 through March 31, 2009 data, in Table 3 below.

TABLE 3—EXAMPLE ACHIEVEMENT PERFORMANCE STANDARDS FOR FY 2013 HOSPITAL VBP PROPOSED MEASURES

Measure ID	Measure description	Example performance standard
Process Measures		
AMI-2	Aspirin Prescribed at Discharge	0.987
AMI-7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival	0.673
AMI-8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	0.856
HF-1	Discharge Instructions	0.872
HF-2	Evaluation of LVS Function	0.983
HF-3	ACEI or ARB for LVSD	0.944
PN-2	Pneumococcal Vaccination	0.929
PN-3b	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital.	0.951
PN-6	Initial Antibiotic Selection for CAP in Immunocompetent Patient	0.909
PN-7	Influenza Vaccination	0.909
SCIP-Inf-1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision	0.955
SCIP-Inf-2	Prophylactic Antibiotic Selection for Surgical Patients	0.978
SCIP-Inf-3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time	0.927
SCIP-Inf-4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose	0.912
SCIP-VTE-1	Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered.	0.938
SCIP-VTE-2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery.	0.913
Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey <ul style="list-style-type: none"> • Communication with Nurses • Communication with Doctors • Responsiveness of Hospital Staff • Pain Management • Communication About Medicines • Cleanliness and Quietness of Hospital Environment • Discharge Information • Overall Rating of Hospital 	.500

We also propose to use an 18-month performance period of July 1, 2011 to December 31, 2012, with a baseline period of July 1, 2008 to December 31, 2009, for the mortality measures (MORT-30-AMI, MORT-30-HF, MORT-30-PN) we are proposing to initially include in the FY 2014 Hospital VBP program. Like the proposed clinical process of care and HCAHPS measures, we propose to set the achievement performance standard (achievement threshold) for each proposed outcome measure at the median of hospital performance (50th percentile) during the proposed baseline period. Similarly, we propose to set the improvement performance standard (improvement threshold) for each proposed outcome

measure at each specific hospital's performance on each measure during the proposed baseline period of July 1, 2008 to December 31, 2009. We provide the following sample achievement thresholds, (displayed as survival rates) derived from July 2006–July 2009 as examples of the achievement performance standards for that period:

- MORT-30-AMI: 83.7%
- MORT-30-HF: 88.8%
- MORT-30-PN: 88.5%.

We solicit public comments on the proposed performance standards as described above.

E. Proposed Methodology for Calculating the Total Performance Score

1. Statutory Provisions—Proposed Methodology for Calculating the Total Performance Score

Section 1886(o)(5)(A) of the Act requires the Secretary to develop a methodology for assessing each hospital's total performance based on performance standards with respect to the measures selected for a performance period. Using such methodology, the Secretary must provide for an assessment for each hospital for each performance period. Section 1886(o)(5)(B) of the Act sets forth four additional requirements related to the scoring methodology developed by the

Secretary under section 1886(o)(5)(A). Specifically, section 1886(o)(5)(B)(i) requires the Secretary to ensure that the application of the scoring methodology results in an appropriate distribution of value-based incentive payments among hospitals receiving different levels of hospital performance scores, with hospitals achieving the highest hospital performance scores receiving the largest value-based incentive payments. Section 1886(o)(5)(B)(ii) provides that under the methodology, the hospital performance score must be determined using the higher of its achievement or improvement score for each measure. Section 1886(o)(5)(B)(iii) requires that the hospital scoring methodology provide for the assignment of weights for categories of measures as the Secretary deems appropriate. Section 1886(o)(5)(B)(iv) prohibits the Secretary from setting a minimum performance standard in determining the hospital performance score for any hospital. Finally, section 1886(o)(5)(B)(v) requires that the hospital performance score for a hospital reflect the measures that apply to the hospital.

2. Additional Factors for Consideration—Proposed Methodology for Calculating the Total Performance Score

In addition to statutory requirements, we also considered several additional factors when developing the proposed performance scoring methodology for the Hospital Value-Based Purchasing program. First, we believe it is important that the performance scoring methodology is straight forward and transparent to hospitals, patients, and other stakeholders. Hospitals must be able to clearly understand performance scoring methods and performance expectations to maximize quality improvement efforts. The public must understand performance score methods to utilize publicly reported information when choosing hospitals. Second, we believe the scoring methodologies for all Medicare Value-Based Purchasing programs, including (but not limited to) the End Stage Renal Disease Quality Incentive Program (42 CFR Part 413) should be aligned as appropriate given their specific statutory requirements. This alignment will facilitate the public's understanding of quality information disseminated in these programs and foster more informed consumer decision making about health care. Third, we believe differences in performance scores must reflect true differences in performance. In order to ensure this in the proposed Hospital Value-Based Purchasing Program, we assessed the quantitative characteristics

of the measures we are proposing to use to calculate a performance score, including the current state of measure development, distribution of current hospital performance in the proposed measure set, number of measures, and the number and grouping of measure domains. Fourth, we must appropriately measure both quality achievement and improvement in our Hospital Value-Based Purchasing program. Section 1886(o)(5)(B)(ii) of the Act specifies that performance scores under the Hospital Value-Based Purchasing program be calculated utilizing the higher of achievement and improvement scores for each measure, and that explicit direction has implications for the design of the performance scoring methodology. We must also consider the impact of performance scores utilizing achievement and improvement on hospital behavior due to payment implications. Fifth, we wish to eliminate unintended consequences for rewarding inappropriate hospital behavior and outcomes to patients in our performance scoring methodology. Sixth, we wish to utilize the most currently available data to assess hospital improvement in a performance score methodology. We believe that more current data would result in a more accurate performance score, but recognize that hospitals require time to abstract and collect quality information. We also require time to process this information accurately.

This proposed rule's method for calculating the improvement score relies on a comparison of the current payment year's performance period with a "baseline" period of July 1, 2008 through December 31, 2009 for the three 30-day mortality measures, rather than a comparison of the current year with the previous year (as outlined in the 2007 report to Congress). We propose this baseline period because these data are the most currently available data at this time for public comment. We plan to propose future annual updates to the baseline period through future rulemaking. We recognize that comparing a payment year's performance period with the previous year's performance period may be a better estimate of incremental improvement. As noted above, we solicit comment on the merits and impact of all of the factors related to our performance score methodology alternatives, including the choice of how to define the baseline year.

We solicit comment on the merits and impact of all of these factors related to our performance score methodology alternatives described in the next section of this proposed rule.

Specifically, we welcome suggestions on improving the simplicity of the Hospital Value-Based Purchasing program performance score methodology and its alignment with other CMS Value-Based Purchasing programs. We recognize that statutorily mandated differences may require differences in performance score methodologies among the CMS Value-Based Purchasing programs.

3. Background—Proposed FY 2013 Hospital VBP Program Scoring Methodology

In November 2007, CMS published a report entitled, "Report to Congress: Plan to Implement a Medicare Hospital Value-Based Purchasing Program" (referred to in this proposed rule as the "2007 Report to Congress").⁶ In addition to laying the groundwork for hospital value-based purchasing, the 2007 Report to Congress analyzed and presented a potential performance scoring methodology (called the Performance Assessment Model) for the Hospital VBP program. The Performance Assessment Model combines scores on individual measures across different quality categories or "domains" (for example, clinical process of care, patient experience of care) to calculate a hospital's total performance score. The Performance Assessment Model provides a methodology for evaluating a hospital's performance on each quality measure based on the higher of an attainment score in the measurement period or an improvement score, which is determined by comparing the hospital's current measure score with a baseline period of performance. The use of an improvement score is intended to provide an incentive for a broad range of hospitals that participate in a hospital VBP program by awarding points for showing improvement on quality measures, not solely for outperforming other hospitals.

Under the Performance Assessment Model, measures are grouped into domains, for example, clinical process of care (which could include AMI, HF, PN, and SCIP) and patient experience of care (for example, HCAHPS). A score is calculated for each domain by combining the measure scores within that domain, weighting each measure equally. The domain score reflects the percentage of points earned out of the total possible points for which a hospital is eligible. A hospital's total performance score is determined by aggregating the scores across all

⁶The report may be found at <http://www.cms.gov/AcuteInpatientPPS/downloads/HospitalVBPPlanRTCFINALSUBMITTED2007.pdf>.

domains. In aggregating the scores across domains, the domains could be weighted equally or unequally, depending on the policy goals. The total performance score is then translated into the percentage of Hospital VBP incentive payment earned using an exchange function, which aligns payments with desired policy goals.

4. Proposed FY 2013 Hospital VBP Program Scoring Methodology

We believe that the Performance Assessment Model presented and analyzed in the 2007 Report to Congress provides a useful foundation for developing a FY 2013 Hospital VBP program performance scoring methodology that comports with the requirements in section 1886(o) of the Act. The Performance Assessment Model outlines an approach that we believe is well-understood by patient advocates, hospitals and other stakeholders, was developed during a year-long process that involved extensive stakeholder input, and was presented by us to Congress. Since issuing the report, we have conducted further, extensive research on a number of important methodology issues for the Hospital VBP program, including the impact of topped-out measures on scoring, appropriate case minimum thresholds for measures, appropriate measure minimum thresholds per domain, and other issues required to ensure a high level of confidence in the scoring methodology (all of which we discuss in this proposed rule).

After carefully reviewing and evaluating a number of potential performance scoring methodologies for the Hospital VBP program, we propose to use a Three-Domain Performance Scoring Model, although only two domains will receive weight in FY 2013. This methodology is very similar to the Performance Assessment Model; however it incorporates an outcome measures domain in addition to the clinical process of care and patient experience of care domains. While we do not propose to adopt any outcome measures for the FY 2013 Hospital VBP program, we propose to adopt these measures as part of an outcome measures domain for FY 2014. Therefore, we refer to the proposed methodology as the Three-Domain Performance Scoring Model and describe how the outcomes measures would apply when the domain is eventually given weight.

We present below the proposed Three-Domain Performance Scoring Model, which includes setting benchmarks and thresholds, scoring hospitals on achievement and improvement for three domains (clinical

process of care, patient experience of care, and outcomes), weighting the domains, and calculating the hospital total performance score. In the discussion, we highlight any differences between the Three-Domain Performance Scoring Model and the Performance Assessment Model, along with our reasons for the departure.

a. Clinical Process of Care and Outcome Measures Scoring Under the Three-Domain Performance Scoring Model: Setting Performance Benchmarks and Thresholds

As stated above, section 1886(o)(5)(B)(ii) of the Act requires that under the Hospital VBP performance scoring methodology, hospital performance scores be determined using the higher of achievement or improvement scores for each measure. With respect to scoring hospital performance on the proposed clinical process of care and outcome measures, we propose to use a methodology based on the scoring methodology set forth in the 2007 Report to Congress Performance Assessment Model. Under this methodology, a hospital's performance on each quality measure is evaluated based on the higher of an attainment score (herein, "achievement score") in the performance period or an improvement score, which is determined by comparing the hospital's score in the performance period with its score during a baseline period of performance. In determining the achievement score, we propose that hospitals would receive points along an achievement range, which is a scale between the achievement threshold (the minimum level of hospital performance required to receive achievement points) and the benchmark (the mean of the top decile of hospital performance during the baseline period). In determining the improvement score, we propose that hospitals would receive points along an improvement range, which is a scale between the hospital's prior score on the measure during the baseline period and the benchmark.

Under this methodology, we propose to establish the benchmarks and achievement thresholds using national data from a three-quarter baseline period of July 1, 2009 through March 31, 2010. We discuss our rationale for proposing to use this baseline period in section D. of this proposed rule.

To define a high level of hospital performance on a given measure, we propose to set the benchmark at the mean of the top decile of hospital scores on the measure during the baseline period. We believe this will ensure that the benchmark represents demonstrably high but achievable standards of

excellence; in other words, the benchmark will reflect observed scores for the group of highest-performing hospitals on a given measure.

We considered several options for setting the achievement threshold, including the 25th, 50% (median), and 75th percentile scores. The higher and lower options were rejected for being too stringent and too lenient, respectively. Setting the achievement threshold at the 50th percentile, however, balances the agency's goal to reward only those hospitals that can demonstrate a certain level of quality with the desire to set the bar at an attainable level. We decided that the median score (that is, the point at which the performance of the hospital is better than the performance of half of all hospitals during the baseline period) would be an appropriate threshold for earning some merit, that is, to earn one or more points for achievement. The higher the hospital's achievement falls over the achievement performance standard, the higher the score, until the hospital reaches what we believe to be an empirical standard of excellence (that is, the benchmark). Therefore, we propose to set the achievement threshold at the 50th percentile of hospital performance on the measure during the baseline period. Hospitals will have to score at or above this threshold to earn achievement points.

We believe that these proposed definitions are in keeping with the statutory requirements and reflect the evidence-based approach for determining thresholds and benchmarks set forth in the 2007 Report to Congress.

b. Clinical Process of Care and Outcome Measures Scoring Under the Three-Domain Performance Scoring Model: Scoring Hospital Performance Based on Achievement

Like the Performance Assessment Model set forth in the 2007 Report to Congress, for each of the proposed clinical process and outcome measures that apply to the hospital, we propose that a hospital would earn 0–10 points for achievement based on where its performance for the measure fell relative to the achievement threshold (which we propose above to define as performance during the baseline period at the 50th percentile) and the benchmark (which we propose above to define as performance during the baseline period at the mean of the top decile), according to the following formula:

$$[9 * ((\text{Hospital's performance period score} - \text{achievement threshold}) / (\text{benchmark} - \text{achievement threshold}))] + .5, \text{ where the hospital}$$

performance period score falls in the range from the achievement threshold to the benchmark. All achievement points would be rounded to the nearest whole number (for example, an achievement score of 4.5 would be rounded to 5). If a hospital's score was:

- Equal to or greater than the benchmark, the hospital would receive 10 points for achievement
- Equal to or greater than the achievement threshold (but below the benchmark), the hospital would receive a score of 1–9 based on a linear scale established for the achievement range (which distributes all points proportionately between the achievement threshold and the benchmark so that the interval in performance between the score needed to receive a given number of achievement points and one additional achievement point is the same throughout the range of performance from the achievement threshold to the benchmark).
- Less than the achievement threshold (that is, the lower bound of the achievement range), the hospital would receive 0 points for achievement.

c. Clinical Process of Care and Outcome Measures Scoring Under the Three-Domain Performance Scoring Model: Scoring Hospital Performance Based on Improvement

In keeping with the approach analyzed for the 2007 Report to Congress, for the proposed clinical process of care and outcome measures,

we propose that a hospital would earn 0–9 points based on how much its performance on the measure during the performance period improved from its performance on the measure during the baseline period. A unique improvement range for each measure would be established for each hospital that defines the distance between the hospital's baseline period score and the national benchmark for the measure (the mean of the top decile), according to the following formula:

$$[10 * ((\text{Hospital performance period score} - \text{Hospital baseline period score}) / (\text{Benchmark} - \text{Hospital baseline period score}))] - .5$$

where the hospital performance score falls in the range from the hospital's baseline period score to the benchmark

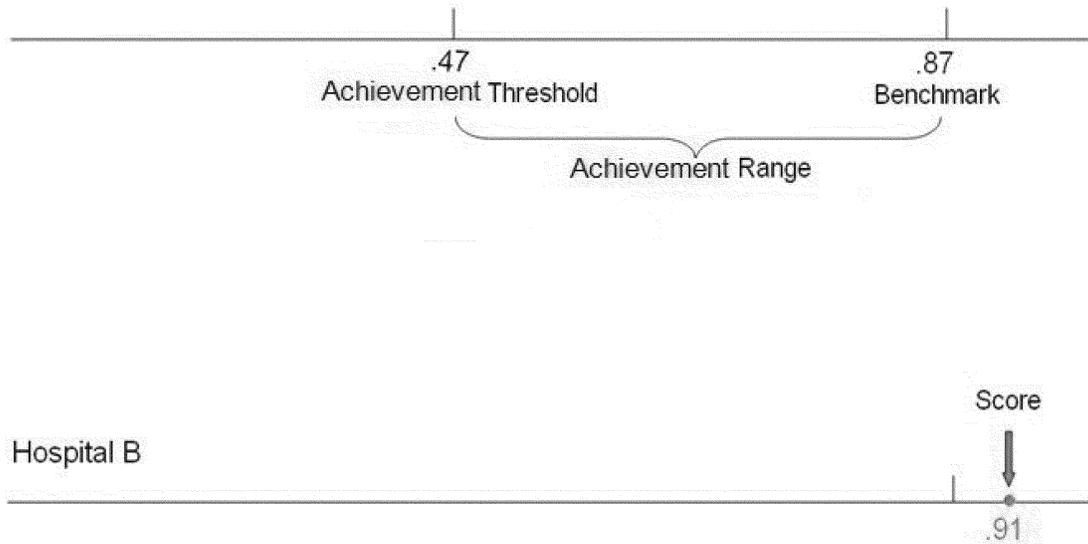
All improvement points would be rounded to the nearest whole number. If a hospital's score on the measure during the performance period was:

- Greater than its baseline period score but below the benchmark (within the improvement range), the hospital would receive a score of 0–9 based on the linear scale that defines the improvement range
- Equal to or lower than its baseline period score on the measure, the hospital would receive 0 points for improvement.

d. Examples To Illustrate Clinical Process of Care and Outcome Measures Scoring Under the Three-Domain Performance Scoring Model

Three examples are presented to illustrate how the proposed Three-Domain Performance Scoring Model would be applied in the context of the proposed clinical process of care and outcome measures. The hospitals were selected from an empirical database created from 2004–2005 data to support the development of the Performance Assessment Model, and all performance scores are calculated for the pneumonia measure, “patients assessed and given pneumococcal vaccine.” Figure 1 shows the scoring for Hospital B. The benchmark calculated for the pneumonia measure in this case was 0.87 (the mean value of the top decile in 2004), and the achievement threshold was 0.47 (the performance of the median or the 50th percentile hospital in 2004). Hospital B's 2005 performance rate of 0.91 during the performance period for this measure exceeds the benchmark, so Hospital B would earn 10 (the maximum) points for achievement. The hospital's performance rate on a measure is expressed as a decimal. In the illustration, Hospital B's performance rate of 0.91 means that 91 percent of applicable patients admitted for pneumonia were assessed and given the pneumococcal vaccine. (Because Hospital B has earned the maximum number of points possible for this measure, its improvement score would be irrelevant.)

Measure: PN Pneumococcal Vaccination



Hospital B Earns: 10 points for achievement performance exceeding the benchmark
 Hospital B Score: = 10 points on this measure

Figure 2 shows the scoring for another hospital, Hospital I. As can be seen below, the hospital's performance on this measure went from 0.21 (below the achievement threshold) in the baseline period to 0.70 (above the achievement threshold) in the performance period. Applying the achievement scale, Hospital I would earn 6 points for this measure, calculated as follows:

$$[9 * ((0.70 - 0.47)/(0.87 - 0.47))] + 0.5 = 5.175 + 0.5 = 5.675, \text{ rounded to } 6 \text{ points.}$$

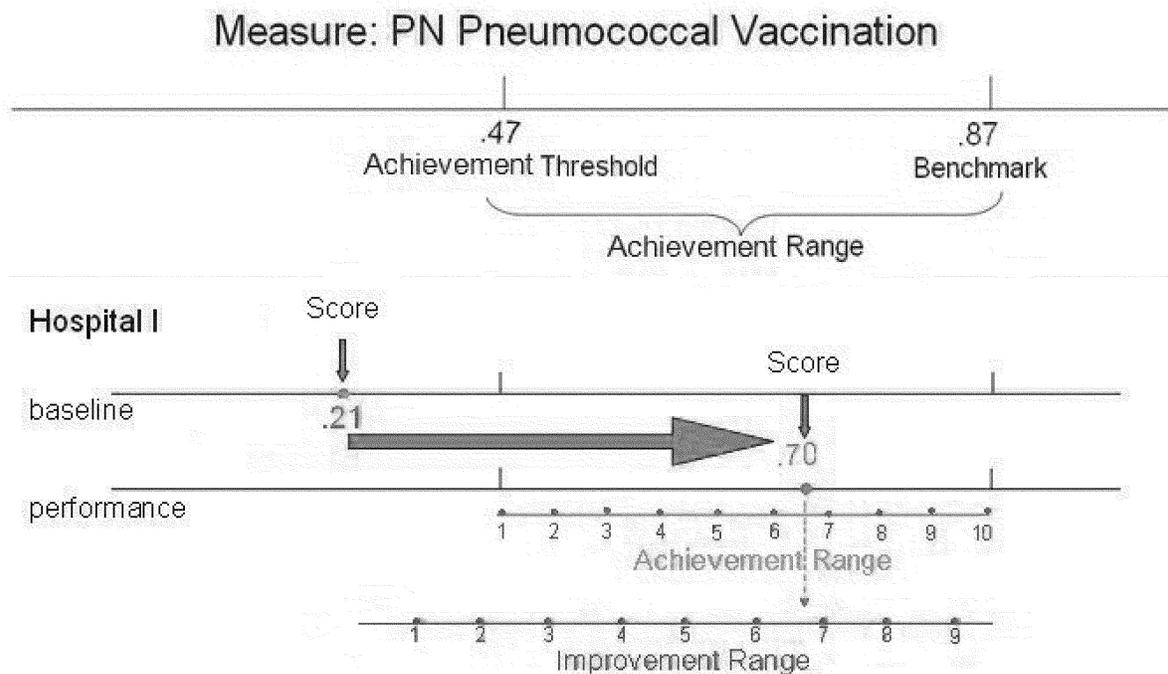
However, because Hospital I's performance during the performance period is also greater than its performance during the baseline period, it would be scored based on improvement as well. According to the improvement scale, based on Hospital

I's period-to-period improvement, from 0.21 to 0.70, Hospital I would earn 7 points, calculated as follows:

$$[10 * ((0.70 - 0.21)/(0.87 - 0.21))] - 0.5 = 6.92, \text{ rounded to } 7 \text{ points.}$$

Because the higher of the two scores is used for determining the measure score, Hospital I would receive 7 points for this measure (rounded to the nearest whole number).

Figure 2. Example of Hospital Earning Points by Achievement or Improvement, Clinical Process of Care and Outcome Measure Scoring Under Three-Domain Performance Scoring Model



Hospital I Earns: 6 points for achievement

7 points for improvement

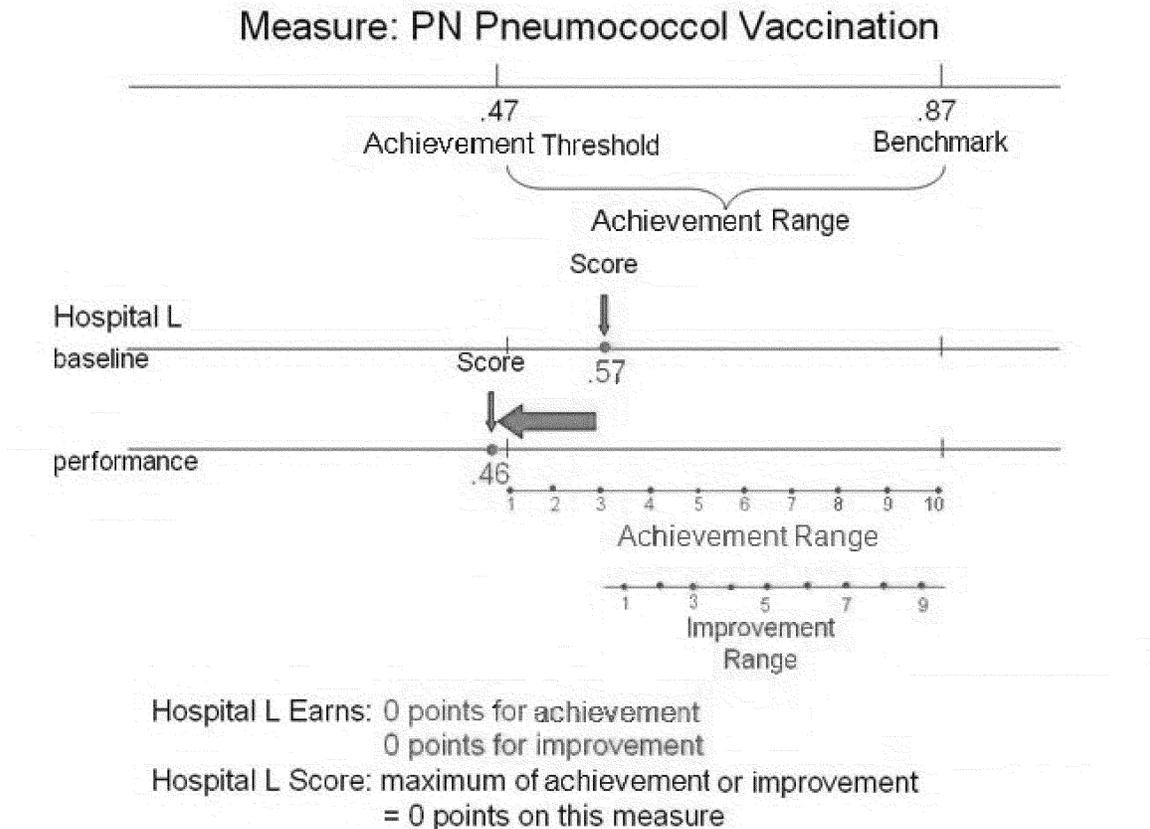
**Hospital I Score: maximum of achievement improvement
= 7 points on this measure**

In Figure 3 shown below, Hospital L's performance on the pneumonia measure drops from 0.57 to 0.46 (a decline of 0.11 points). Because this hospital's performance during the performance

period is lower than the achievement threshold of 0.47, it receives 0 points based on achievement. It would also receive 0 points for improvement, because its performance during the

performance period is lower than its performance during the baseline period. In this example, Hospital L would receive 0 points for the measure.

Figure 3. Example of Hospital Earning No Points, Clinical Process of Care and Outcome Measure Scoring Under Three-Domain Performance Scoring Model



e. Calculation of the Overall Clinical Process of Care and Outcome Measure Domain Scores Under the Three-Domain Performance Scoring Model

We propose that both a hospital's overall clinical performance score and outcome performance score would be based on all measures that apply to the hospital. We propose that a measure applies to a hospital if, during the performance period, the hospital treats a minimum number of cases (which we propose to define as 10 cases in section F of this proposed rule) that meet the technical specifications for reporting the measure. We also propose that at least 4 measures within a domain must apply to the hospital in order for the hospital to receive a performance score on that domain (this proposal is also discussed more fully in section F of this proposed rule). Thus, the number and type of measures that apply to each hospital will vary, depending on the services the hospital provides (for example, some hospitals may not perform percutaneous coronary intervention; therefore, this measure would not apply to them). As proposed above, for each applicable measure, a hospital would receive a

score based on the higher of its achievement and improvement scores. Because the clinical process of care and outcome measure performance scores will be based only on the measures that apply to the hospital, we propose to normalize the domain scores across hospitals by converting the points earned for each domain to a percentage of total points.

With respect to the clinical process of care and outcome domains, we propose that the points earned for each measure that applies to the hospital would be summed (weighted equally) to determine the *total earned points* for the domain:

Total earned points for domain = Sum of points earned for all applicable domain measures

Under the proposed approach, each hospital would also have a corresponding universe of *total possible points* for each of the clinical process and outcome domains calculated as follows:

Total possible points for domain = Total number of domain measures that apply to the hospital multiplied by 10 points

We also propose that the hospital's clinical process of care and outcome domain scores would each be a percentage, calculated as follows:

Domain score = Total earned points divided by Total possible points multiplied by 100%

As an example, four clinical process of care measures apply to Hospital E, and Hospital E reports data on at least 10 cases for each of these measures. Under the proposed scoring methodology discussed above, Hospital E is awarded 9, 5, 3, and 10 points, respectively, for these measures. Hospital E's total earned points for the clinical process of care measure domain would be calculated by adding together all the points Hospital E was awarded, resulting in a total of 27 points. Hospital E's total possible points would be the total number of measures that apply to the hospital (four measures) and for which the hospital had the minimum number of cases multiplied by 10 points, for a total of 40 points. Hospital E's clinical process of care domain score would be the total earned points (that is, 27 points) divided by the total possible

points (that is, 40 points) multiplied by 100, which yields a result of 67.5.

5. Scoring Patient Experience of Care Measures (HCAHPS) Under the Three-Domain Performance Scoring Model

Since the 2007 Report to Congress was published, we have performed additional analyses on methods of scoring HCAHPS measures for purposes of the Hospital VBP program using data collected from a greater number of hospitals and over a longer period of time. We have found that the model laid out in the 2007 Report to Congress has good measurement properties and functions as intended with respect to achievement, consistency, and improvement. We believe that the scoring approach proposed here, which is based on the HCAHPS model set forth in the 2007 Report to Congress, reflects both the interrelated nature of HCAHPS dimensions and the importance of providing incentives to hospitals to improve on each of eight dimensions of patient experience.

The scoring approach we propose for HCAHPS performance for the FY 2013 Hospital VBP program captures eight HCAHPS dimensions (seven composites and one global rating of care) and would seek to incentivize hospitals to improve on each of the eight dimensions of patient experience (See Table 4). We propose that the 8 dimensions will be structured similar to the 10 HCAHPS items that we currently report on *Hospital Compare*, except that we are proposing to combine the cleanliness of hospital environment and quietness of hospital environment items into a single dimension and to not include the recommend the hospital item. We are proposing these changes because we did not want to give more weight to the two items capturing environmental issues by treating them as separate dimensions and the "Recommend the hospital" item is very similar to the included "Overall rating" item.

We are proposing to score each of the eight HCAHPS dimensions using an approach that parallels the one we are proposing to use to score the clinical process measures, using an achievement point range from 0–10 and an improvement point range from 0–9, with the total score on each HCAHPS dimension being the higher of the achievement or improvement score. In order to ensure statistical reliability, we are also proposing that, for inclusion in the Hospital VBP program for FY 2013, hospitals report a minimum of 100 HCAHPS surveys during the performance period (we discuss this proposal further in section F of this proposed rule).

In order to be consistent with what we do under the Hospital IQR program, we are also proposing to give hospitals that have 5 or fewer HCAHPS-eligible discharges in a month the option to not submit HCAHPS surveys for that month as part of their quarterly data submission. However, in contrast to the proposed clinical process of care measure scoring methodology, under which different numbers of measures might apply to different hospitals, all hospitals that report HCAHPS data would be expected to report the complete survey.

As we are proposing to do with respect to scoring the proposed clinical process of care measures, we are proposing that achievement thresholds and benchmarks would be used to score hospital performance during the performance period, and these achievement thresholds and benchmarks would be established using data from the proposed baseline period. Thus, a hospital's achievement score would be based on a fixed standard rather than on its current standing relative to its peers. The achievement threshold for each HCAHPS dimension would correspond to median performance in the baseline period (50th percentile performance). Therefore, hospitals would earn points for achievement if they performed at least as well in the performance period as the mid-performing hospital performed during the baseline period. The benchmark corresponds to excellent performance observed in the baseline period and we are proposing to set it such that the maximum achievement points (10 points) would be awarded if the hospital performed at least at the 95th percentile of performance during the baseline period. We are proposing to set the actual benchmarks and achievement thresholds for the FY 2013 Hospital VBP program using data from the proposed baseline period (July 1, 2009 through March 31, 2010).

Similar to the proposed clinical process measures, we are proposing that each of the eight HCAHPS dimensions would be given equal weight in calculating the overall HCAHPS score. However, unlike the proposed scoring approach for the proposed clinical process of care measures, we are proposing to construct the patient experience of care measures score for the FY 2013 Hospital VBP using three elements: Achievement points, improvement points, and consistency points.

As shown in Table 4, for each of the eight HCAHPS dimensions we propose for the FY 2013 Hospital VBP program, scores would be based on the publicly

reported adjusted proportions of best category ("top-box") responses. (Top-box responses, as publicly reported on the *Hospital Compare* website, are the most positive responses to HCAHPS survey questions.) Please note that the "Cleanliness and Quietness" dimension is the average of the publicly reported stand-alone "Cleanliness" and "Quietness" ratings.

TABLE 4—EIGHT PROPOSED HCAHPS DIMENSIONS FOR THE FY 2013 HOSPITAL VBP PROGRAM

Dimension (Composite or stand-alone item)	Constituent HCAHPS survey items
1. Nurse communication. (% "Always")	Nurse-Courtesy/Respect. Nurse-Listen. Nurse-Explain.
2. Doctor communication. (% "Always")	Doctor-Courtesy/Respect. Doctor-Listen. Doctor-Explain.
3. Cleanliness and quietness. (% "Always")	Cleanliness.
4. Responsiveness of hospital staff. (% "Always")	Quietness. Bathroom Help.
5. Pain management (% Always")	Call Button. Pain Control. Help with Pain.
6. Communication about medications. (% "Always")	New Medicine-Reason. New Medicine-Side Effects.
7. Discharge information. (% "Yes")	Discharge-Help. Discharge-Systems.
8. Overall rating	Overall Rating.

a. Patient Experience of Care Measure (HCAHPS) Scoring Under the Three-Domain Performance Scoring Model: Scoring Hospitals on Achievement

Section 1886(o)(3)(A) requires the Secretary to establish performance standards with respect to the measures selected under the Hospital VBP program for a performance period for a fiscal year. The performance standards must include levels of achievement and improvement (section 1886(o)(3)(B)). The scoring methodology we are proposing to implement for HCAHPS includes achievement, improvement and consistency points. The achievement and improvement points are very similar to what is proposed for clinical measures. The consistency points measure whether hospitals are meeting the achievement thresholds across the eight proposed HCAHPS dimensions, which we believe will encourage hospitals to meet those thresholds for all of them. Consistency points are an additional form of achievement measurement that

complements achievement points earned through hospital performance on individual HCAHPS dimensions.

The first proposed component of the patient experience of care/HCAHPS Hospital VBP program scoring algorithm is achievement points, which rewards hospital performance at or above the proposed baseline median on each of the eight HCAHPS dimensions. A minimum score of 0 corresponds to all eight dimensions being below the baseline median (that is, the dimension-specific achievement threshold), while a maximum score of 80 corresponds to all eight dimensions being at or greater than the 95th percentile from the baseline period (that is, the dimension-specific benchmark). We propose to assign 0 to 10 points for each of the eight HCAHPS dimensions as follows:

- If the hospital's score on a dimension is equal to or greater than the benchmark (that is, the baseline 95th percentile performance), the hospital would receive 10 points for achievement on that dimension
- If the hospital's score on a dimension is within the achievement range (that is, equal to or greater than the achievement threshold of 50th percentile performance but below the benchmark of 95th percentile performance), the hospital would receive a score of 1–9, based on a linear scale established for the achievement range and rounding to the nearest whole point according to the following formula:

$((\text{Hospital HCAHPS performance period dimension score} - 50)/5) + 0.5$ For example, if performance on a given dimension is at the 60th percentile, the hospital would receive 3 achievement points, calculated as follows: $((60 - 50)/5) + 0.5 = 2 + 0.5 = 2.5$, which would be rounded to 3.

- If the hospital's score on a dimension is less than the achievement threshold for the dimension (that is, less than the 50th percentile of performance), the hospital would receive 0 points for achievement.

b. HCAHPS Performance Scoring Under the Three-Domain Performance Scoring Model: Scoring Hospitals on Improvement

The second proposed component of the HCAHPS Hospital VBP scoring algorithm is improvement points. For each HCAHPS dimension, a hospital could earn from 0–9 improvement points for each dimension depending on how much its performance on the dimension improved from its performance on the dimension during the baseline period. This proposed

approach would recognize and encourage improvement for each of the eight HCAHPS dimensions. A unique improvement range for each hospital on each HCAHPS dimension would be established. Improvement points would be awarded proportionately and would be rounded to the nearest whole number. The score is based on the proportion of possible improvement in the performance period from the baseline period score on a given dimension to the benchmark on the same dimension. We propose to calculate improvement points for each of the eight dimensions according to the following formula:

$[10 * ((\text{Hospital performance period score} - \text{Hospital baseline period score}) / (\text{Benchmark} - \text{Hospital baseline period score})) - 0.5]$, where the hospital performance score falls in the range from the hospital's baseline period score to the benchmark

All improvement points would be rounded to the nearest whole number. If a hospital's score on the measure during the performance period was:

- Greater than its baseline period score but below the benchmark (within the improvement range), the hospital would receive a score of 0–9 based on the linear scale that defines the improvement range
- Equal to or lower than its baseline period score on the measure, the hospital would receive 0 points for improvement.
- If there is no improvement or if the score from the baseline period was already at the benchmark, the improvement score is 0.

For example, if a hospital's baseline score on a given dimension was at the 45th percentile and the hospital's score on the dimension during the performance period was at the 70th percentile, the hospital's improvement points on that dimension would be 5, calculated as follows:

$[10 * ((70 - 45)/(95 - 45))] - 0.5 = 4.5$, which would be rounded to 5.

c. HCAHPS Performance Scoring Model: Calculation of Consistency Points

The third proposed component of the HCAHPS Hospital VBP scoring algorithm is the consistency score. The consistency score recognizes consistent achievement across dimensions. To ensure at least adequate performance across all HCAHPS dimensions, we are proposing that for the FY 2013 Hospital VBP program hospitals earn consistency points ranging from 0–20 based on how many of their dimension scores meet or exceed the achievement threshold. The

purpose of the consistency score (referred to as the “minimum performance score” in the 2007 Report to Congress), is to incentivize hospitals to continually improve on all HCAHPS dimensions to the point where their score on each dimension is at or above the achievement threshold. We believe that providing this type of incentive that applies to an entire domain is consistent with promoting wider systems changes within hospitals to improve quality.

We are proposing that a hospital would receive 0 consistency points if its performance on one or more HCAHPS dimensions during the performance period was at least as poor as the worst-performing hospital's performance on that dimension during the baseline period. A hospital would receive a maximum score of 20 consistency points if its performance on all eight HCAHPS dimensions was at or above the achievement threshold (50% of hospital performance during the baseline period).

We propose for the FY 2013 Hospital VBP program that a maximum of 20 consistency points would be awarded proportionately based on the single lowest of a hospital's 8 HCAHPS dimension scores during the performance period compared to the median baseline performance score for that specific HCAHPS dimension. If all 8 of a hospital's dimension scores during the performance period were at or above the 50th percentile achievement threshold in the baseline period, then that hospital would earn all 20 points. (That is, if the lowest of a hospital's eight HCAHPS dimension scores was at or above the 50th percentile of hospital performance on that dimension during the baseline period, then that hospital would earn the maximum of 20 consistency points). Consistency points would be awarded proportionately according to the number of percentiles the lowest dimension score is between the 0th and 50th percentile of hospital performance during the baseline period. Consistency points would be rounded to the nearest whole number (for example, 9.5 consistency points would be rounded to 10 points). We propose to define the lowest percentile as the lowest dimension score among the eight HCAHPS dimensions that would be scored under the FY 2013 Hospital VBP program. The formula for the HCAHPS consistency score is as follows:

$(2 * (\text{lowest percentile}/5)) - 0.5$, rounded to the nearest whole number, with a minimum of zero and a maximum of 20 consistency points

For example:

- If the lowest score a hospital receives on an HCAHPS dimension is at or below the 0th percentile of hospital performance on that dimension during the baseline period, then 0 consistency points would be awarded to that hospital.

- If the lowest score a hospital receives on an HCAHPS dimension is equal to the 10th percentile of hospital performance on that dimension during the baseline period, then 4 (that is, $(2 * (10/5)) - 0.5 = 3.5$, rounded to 4) consistency points would be awarded to that hospital.

- If the lowest score a hospital receives on a HCAHPS dimension is

equal to the 25th percentile of hospital performance on that dimension during the baseline period, then 10 (that is, $(2 * (25/5)) - 0.5 = 9.5$, rounded to 10) consistency points would be awarded to that hospital.

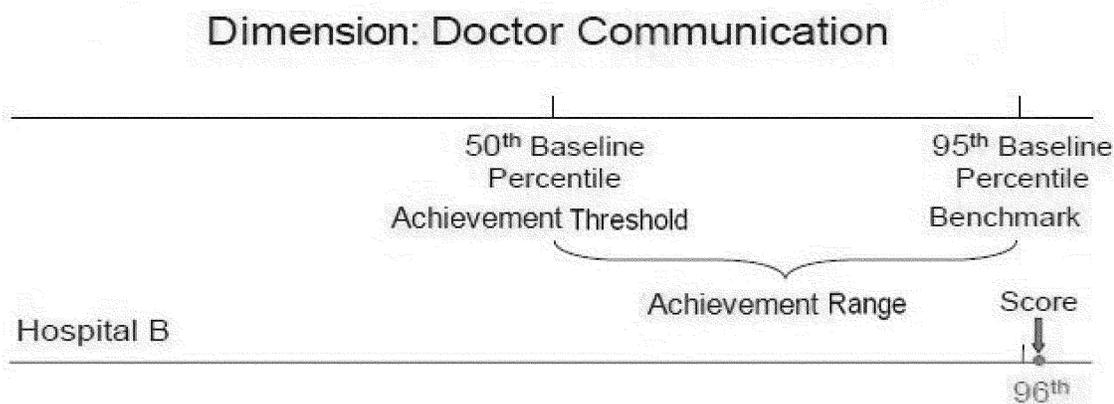
- If a hospital's score on all eight HCAHPS dimensions were at or above the achievement threshold (50th percentile of hospital performance during the baseline period), then 20 consistency points would be awarded to that hospital.

d. Examples To Illustrate HCAHPS Measure Scoring Model

Examples are presented here to illustrate how the proposed Three-

Domain Performance Scoring Model would apply in the context of scoring the proposed HCAHPS dimensions. The dimension used for this illustration is doctor communication. Figure 4 shows Hospital B's scoring on the doctor communication dimension. It was placed at the 96th percentile, which exceeded the benchmark. Thus, Hospital B would earn the maximum of 10 points for achievement. Because this is the highest number of achievement points the hospital could attain for this dimension, its improvement from its baseline period score on this measure would not be relevant.

Figure 4. Example of Hospital Earning Points by Exceeding Benchmark, HCAHPS Measure Scoring Under the Three-Domain Performance Scoring Model



Hospital B's performance in measurement period equates to the 96th percentile in the baseline period

Hospital B Earns: 10 points for achievement for performance exceeding the benchmark

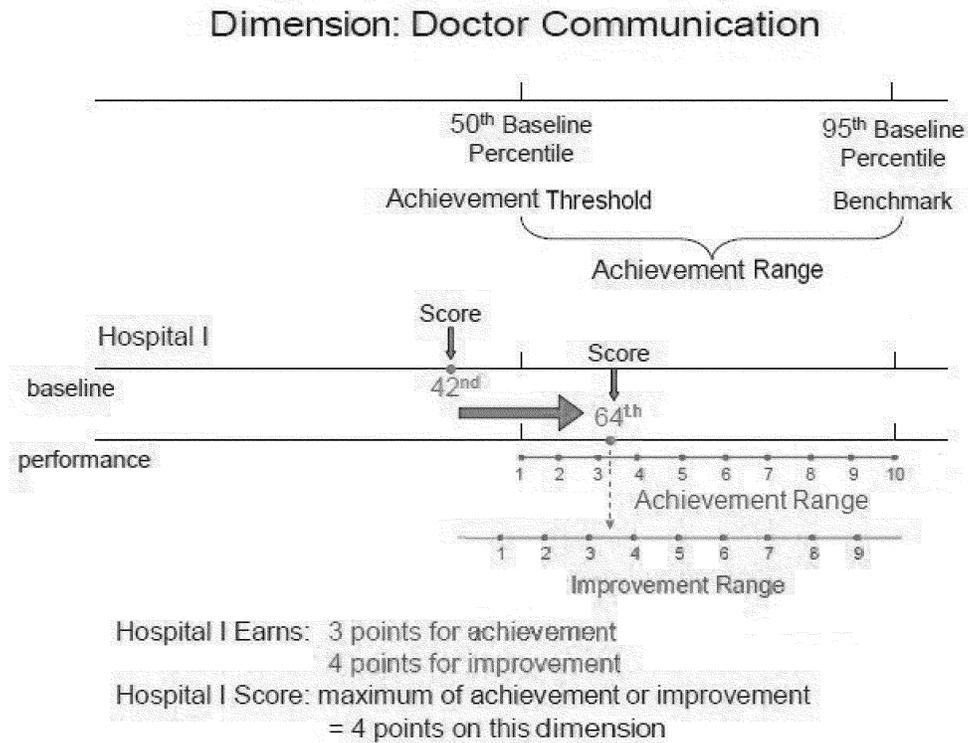
Hospital B Score: = 10 points on this dimension

Figure 5 shows that Hospital I's performance on the doctor communication dimension rose from the 42nd percentile during the baseline period to the 64th percentile during the performance period. Because Hospital I's performance during the performance period exceeds the achievement threshold of the 50th percentile,

Hospital I's score would be in the achievement range. According to the achievement scale, Hospital I would earn 3 achievement points. However, in this case, the hospital's performance in the performance period has improved from its performance during the baseline period, so Hospital I would be scored based on improvement as well as

achievement. Applying the improvement scale, Hospital I's period-to-period improvement from the 42nd to the 64th percentile would earn it 3.65 improvement points which would be rounded to 4 points. Using the greater of the two scores, Hospital I would receive 4 points for this dimension (rounded to the nearest whole number).

Figure 5. Example of Hospital Earning Points By Achievement or Improvement, HCAHPS Measure Scoring Under the Three-Domain Performance Scoring Model

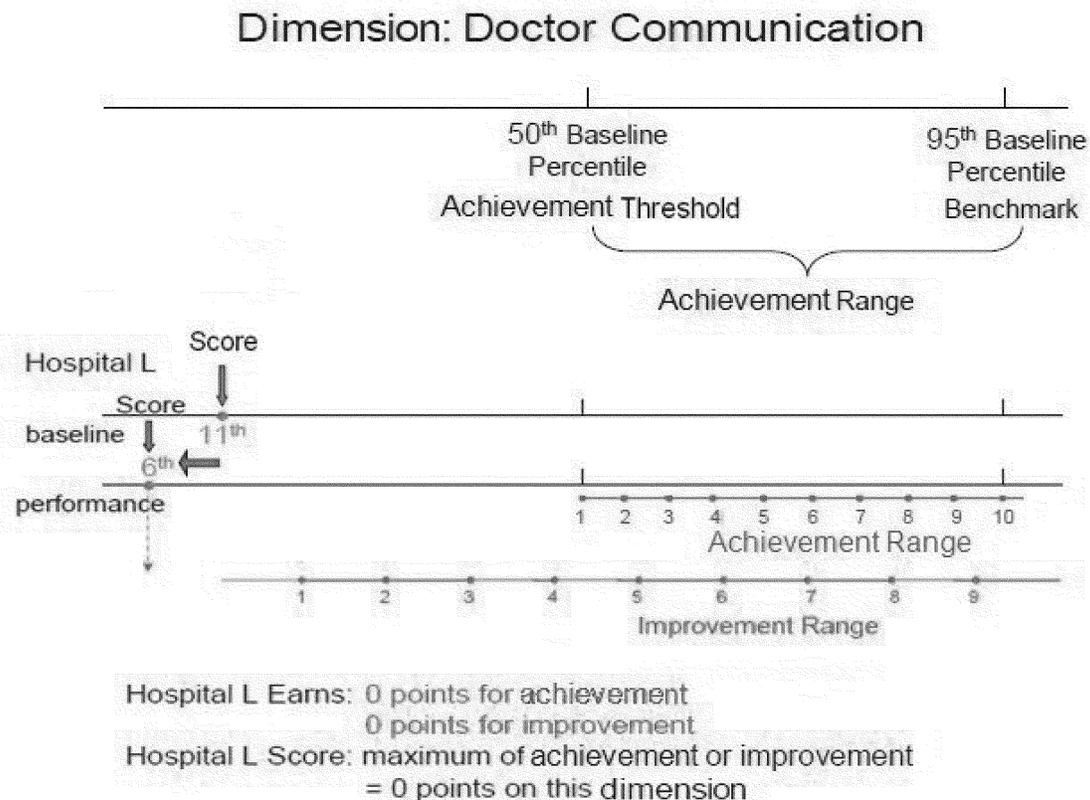


In Figure 6, Hospital L's performance in the baseline period was at the 11th percentile, and its performance declined in the performance period to the 6th percentile. Because Hospital L's

performance during the performance period is lower than the achievement threshold of the 50th percentile, it would receive 0 points based on achievement. Hospital L would also

receive 0 points for improvement because its performance during the performance period is lower than its performance during the baseline period.

Figure 6. Example of Hospital Earning Zero Points, HCAHPS Measure Scoring Under the Three-Domain Performance Scoring Model



e. Calculating the Overall Patient Experience of Care Domain (HCAHPS) Performance Score

The proposed final step under the proposed HCAHPS scoring methodology for the FY 2013 Hospital VBP program is to combine the three proposed component scores into the overall patient experience of care domain (HCAHPS) performance score. We propose to calculate the overall HCAHPS performance score as follows:

1. For each of the eight dimensions, determine the larger of the 0–10 achievement score and the 0–9 improvement score.
2. Sum these eight values to arrive at a 0–80 HCAHPS base score.
3. Calculate the 0–20 HCAHPS consistency score.
4. To arrive at the HCAHPS total earned points, or HCAHPS overall score, sum the HCAHPS base score and the consistency score.

In summary, the overall HCAHPS performance score is calculated as follows:

$$\text{HCAHPS total earned points} = \text{HCAHPS base score} + \text{consistency score.}$$

6. Weighting of Hospital Performance Domains and Calculation of the Hospital VBP Total Performance Score

Section 1886(o)(5)(B)(iii) requires that the methodology developed for assessing the total performance of each hospital must provide for the assignment of weights for categories of measures as the Secretary determines appropriate. As discussed above in section C. of this proposed rule, we have proposed to group the measures for the Hospital VBP program into domains, which we would define as categories of measures by measure type. For purposes of the Hospital VBP program in FY 2013, we propose that two domains will be scored, the clinical process of care and patient experience of care. We believe that hospital quality is multifaceted, requiring adherence to evidence-based practices, achieving good clinical outcomes, and having positive and effectual patient experiences. In determining how to appropriately weight quality measure domains, we considered a number of criteria. Specifically, we considered the number of measures that we have proposed to include in each domain and the reliability of individual measure data. We also considered the systematic

effects of alternative weighting schemes on hospitals according to their location and characteristics (for example, by region, size, and teaching status). We also considered Departmental quality improvement priorities. We strongly believe that outcome measures are important in assessing the overall quality of care provided by hospitals. While we believe that the addition of an outcome domain will make public valuable and important quality information regarding hospital performance, and bring needed attention to patient outcomes, for reasons previously discussed in section II. C. of this proposed rule, we are not proposing to include outcome measures in the FY 2013 Hospital VBP program. Taking all of these considerations into account, we propose the use of a 70 percent clinical process of care and 30 percent patient experience of care (HCAHPS) weighting scheme for the FY 2013 Hospital VBP program. We are proposing this weighting scheme because the 17 proposed clinical process of care measures comprise all but one of the measures we are proposing to include in the FY 2013 Hospital VBP program. We believe assigning a 30 percent weight to the

patient experience of care domain is appropriate because the HCAHPS measure is comprised of eight dimensions that address different aspects of patient satisfaction. For the FY 2014 Hospital VBP program, in addition to proposing to use the 30-day mortality claims-based measures currently displayed on *Hospital Compare*, we propose to adopt the following 8 Hospital Acquired Condition measures and 9 AHRQ Patient Safety Indicator and Inpatient Quality Indicator outcome measures:

- Foreign Object Retained After Surgery
- Air Embolism
- Blood Incompatibility
- Pressure Ulcer Stages III & IV
- Falls and Trauma: (Includes: Fracture, Dislocation, Intracranial Injury, Crushing Injury, Burn, Electric Shock)
- Vascular Catheter-Associated Infections
- Catheter-Associated Urinary Tract Infection (UTI)
- Manifestations of Poor Glycemic Control
- AHRQ Patient Safety Indicators (PSIs), Inpatient Quality Indicators (IQIs), and Composite Measures:
 - PSI 06—Iatrogenic pneumothorax, adult
 - PSI 11—Post Operative Respiratory Failure
 - PSI 12—Post Operative PE or DVT
 - PSI 14—Postoperative wound dehiscence
 - PSI 15—Accidental puncture or laceration
 - IQI 11—Abdominal aortic aneurysm (AAA) repair mortality rate (with or without volume)
 - IQI 19—Hip fracture mortality rate
 - Complication/patient safety for selected indicators (composite)
 - Mortality for selected medical conditions (composite)

We believe that these outcome measures provide important information relating to treatment outcomes and patient safety. All of these measures are currently included in the Hospital IQR program for the FY 2013 payment determination (75 FR 50209). We also believe that adding these outcome measures would significantly improve the correlation between patient outcomes and Hospital VBP performance. We will propose the FY 2014 Hospital VBP performance period end date and performance standards for these outcome measures in future rulemaking. We solicit public comment on what weight would be appropriate to assign to the outcome domain in future rulemaking.

We propose to calculate a hospital's total performance score by multiplying its performance on each domain by the proposed weight for that domain (70 percent clinical process of care, 30 percent patient experience of care), and adding those weighted scores together.

We solicit public comment on the proposed domain weighting approach and calculation of the total performance score, and are particularly interested in receiving comments regarding the utility and appropriateness of alternative methods.

Earlier in this proposed rule, we articulated our principles for value-based purchasing programs. In order to address these principles in our proposed hospital value-based purchasing program, we considered several additional factors when developing our proposed performance scoring methodology for the Hospital Value-Based Purchasing Program. CMS is actively seeking all the comments and proposals about alternative scoring methodologies that may achieve all these principles in better, more efficient, or more straightforward ways. New, innovative ideas are particularly useful to the Agency as we seek to create a payment system fully aligned with the overall health system aims of better health, better health care, and more efficient care through improvement.

Section 1886(o)(5)(B)(iv) states that the Secretary may not set a minimum performance standard in determining the hospital performance score for any hospital. We note that under the proposed Three-Domain Performance Scoring Model, the Secretary does not set the minimum performance standard for any hospital. Rather, the hospital in effect sets its own minimum performance standard based on how well it performed during the baseline period, and any improvement from that performance is sufficient for the hospital to earn improvement points.

7. Alternative Hospital Performance Scoring Models Considered

Since the 2007 Report to Congress, CMS has performed additional research and analyses regarding alternative scoring approaches for hospital value-based purchasing. We primarily focused on the Three-Domain Performance Scoring Model, the Six-Domain Performance Scoring Model, and the Appropriate Care Model (ACM). We are proposing to adopt the Three-Domain Performance Scoring Model as previously described.

The Appropriate Care Model (ACM), also referred to as the "all-or-none" model, is intended to be a more patient-centric method of assessing hospital

performance on the clinical process of care measures. The ACM creates sub-domains by topic for the clinical process measures and is distinguished from the other two models in that it requires complete mastery for each topic area ("all-or-none") in the clinical process of care domain at the patient level.

Under the ACM, the patient encounter, rather than the clinical process of care measure itself, becomes the scored "event," with a hospital receiving 1 point if it successfully provides to a patient the applicable processes under all of the measures within an applicable topic area, or 0 points if it fails to furnish one or more of the applicable processes. The hospital's condition-specific ACM score is the proportion of patients with the condition who receive the appropriate care as captured by the process measures that fall within the topic area.

Within a condition, different sets of clinical processes may apply to a patient. For example, some AMI patients should receive aspirin at arrival but other AMI patients should not; some AMI patients smoke and should receive smoking cessation counseling, while others do not smoke and do not need to receive such counseling. Regardless of the number of clinical process of care measures within a topic that apply to a patient, each patient encounter to which a specific topic area applies weights equally with respect to the hospital's score for the topic area. Patients requiring many clinical processes within a topic are not weighted more heavily than patients requiring only a few clinical processes. There is no "partial credit" given to the hospital for a patient who is provided some, but not all, applicable clinical processes within a topic.

Under the ACM, CMS would determine what percentage of a hospital's patients within each condition or topic area (for example, AMI, HF, PN, and SCIP) received all of the applicable processes covered by all of the measures that fall under that topic. A hospital's performance on each topic area (that is, the percentage of patients that received all the appropriate processes) would then be scored along achievement and improvement ranges similar to those we have proposed for the Three-Domain Performance Scoring Model. These scores across the topic areas would then be equally weighted and combined to create a score for all of the clinical process measures. The hospitals would then be measured on the outcome and patient experience of care domains, just as in the Three-Domain Performance Scoring Model. The total performance score would be

computed as a weighted average across the three domains, calculated by weighting the scores for each of the domains.

With each performance scoring model considered, we commissioned independent researchers at Brandeis University to examine the variation and stability of the clinical process of care domain under different combinations for the number of cases (patients) and number of measures and develop minimum numbers of cases and measures that provide a high level of confidence in the meaningfulness of performance scores across hospitals while at the same time providing scores for the largest possible number of hospitals. Based on this research, we concluded that in order to ensure the statistical reliability of a hospital's score under the ACM model, the hospital would need to have at least 25 patients within a condition (or topic area) to be measured on that condition and have cases corresponding to at least two conditions to receive an overall ACM score.

Under the ACM, for each condition measured in the clinical process of care domain, a hospital may earn points for achievement or for improvement. The method for determining earned points per condition in the ACM is analogous to the way points are determined per measure in the proposed Three-Domain Performance Scoring Model.

Accordingly, the points a hospital earns for each condition is the higher of its points for achievement (that is, performance above the achievement threshold) or improvement (that is, performance better than the hospital's own performance during the baseline period). The hospital's overall ACM score for the clinical process of care domain is the sum of its condition-specific points equally weighted across all conditions measured for the hospital.

Applied to the following five conditions (AMI, HF, PN, SCIP, and HAI), a hospital reporting on all five conditions could earn a maximum of 50 points under the ACM, while a hospital reporting only three conditions could earn at most 30 points. The final overall clinical process of care domain score for a hospital under the ACM would be the fraction of its actual sum of points divided by its maximum possible points (for example, 50 in most cases, but possibly 30, 20, or 10 corresponding to the number of conditions reported).

The Six-Domain Performance Scoring Model, like the ACM, would create and separately score individual sub-domains at the topic level for the clinical process measures. In other words, the clinical process of care domain would be further

broken down into sub-domains characterized by condition (our earlier analysis of the Six-Domain Performance Scoring Model included the HAI measures under the SCIP topic area, using only the four following topic areas, AMI, HF, PN, and SCIP). We would assign intermediate scores to each hospital for each of the clinical process sub-domains (such as, AMI, HF, PN, and SCIP). Like the Three-Domain Performance Scoring Model, hospitals would be scored on each measure in the sub-domain and individual measures (such as, SCIP-Card-2 and AMI-3) would still be weighted equally within a sub-domain. Scores across the topic area sub-domains would then be equally weighted and combined to create an overall clinical process score. The total performance score would be computed as an average across domains, calculated by weighting the scores for each of the three domains. At least two clinical process domains would be needed to calculate a total performance score. Based on the research conducted at Brandeis University discussed above, we concluded that a hospital would need to report at least 1 measure included within a domain (with a minimum of 2 domains) and have 10 opportunities (that is, patients) included in the measure. If an outcome domain was included, a hospital would also need to report on at least one of the available outcome measures.

8. Hospital Performance Scoring Model Comparisons

We assessed each of the models discussed above for purposes of structuring the performance scoring methodology for the Hospital VBP program. Specifically, we considered the following conceptual and empirical criteria:

- Impact on patients: The primary purpose of the Hospital VBP program is to drive improvements in clinical quality, patient-centered care, and efficiency. Thus, consideration of the impact of the various models on quality improvement in patient care is paramount.
- Accuracy of comparisons made between hospitals: The Hospital VBP program should make fair comparisons between hospitals based on total performance scores that are affected predominantly or exclusively by the hospital's performance on the individual measures. However, differences in the TPS between hospitals may also be affected by differences in the scope of services offered, which would determine the mix of measures that comprise the TPS for each hospital. Thus, a critical aspect of

developing and implementing the TPS is facilitating equivalent and accurate comparisons between hospitals.

- Rank Correlation Impact: In light of the fact that the value-based incentive payment amount will vary by hospital, based on the hospital's TPS, we must consider how each model will affect how hospitals rank in terms of their performance.

- Extent of variance across hospitals: In addition to accuracy, the second important property of a TPS is that it has sufficient variance to clearly differentiate between hospitals. The logic and purpose of the scoring is to discriminate among hospitals according to relative performance; hence, the TPS should capture meaningful variation and financial incentives should reflect that variation.

- Number of hospitals that receive a score from the Hospital VBP program: The models for calculating the total performance score use different criteria for hospitals' minimum cases per measure and measures per domain. Consequently, the number of hospitals scored will differ depending on the model used. Other things being equal, a greater number of hospitals receiving scores is preferable in our view.

We analyzed how each of the scoring models discussed above best meet these criteria by modeling hospital performance on each model using data from 2007–2008 for the baseline period and 2008–2009 as the performance period. As discussed above, the primary difference between the Three-Domain Performance Scoring Model and the Six-Domain Performance Scoring Model is that the Six-Domain Performance Scoring model creates intermediate scores at the topic level for the clinical process measures, so that six domains are scored (AMI, HF, PN, SCIP, outcomes, and patient experience) rather than three domains (clinical process of care, outcomes, and patient experience). The Six-Domain model provides an intermediate, condition-specific score for prevalent and/or high-cost conditions in the Medicare population that could provide a useful summary when a more complete set of measures becomes available for those conditions. However, in light of the current set of measures available for use in the Hospital VBP program, we believe that the intermediate scores by condition would convey a false sense of precision about the quality of care for that condition. For this reason, and because hospital total performance scores that we modeled under the Six-Domain Performance Scoring Model were not substantively different from those we modeled under the Three-

Domain Performance Scoring Model, we chose to focus our continued analysis on the Three-Domain Performance Scoring Model and the ACM. We discuss the results of our analysis of the Three-Domain Performance Scoring Model and the ACM below.

The scoring of the clinical process of care and outcome domains in the Three-Domain Performance Scoring Model is based on the Performance Assessment Model presented in the 2007 Report to Congress, but includes and scores the outcome domain as a separate domain. We believe that because each measure is scored independently under the Three-Domain Performance Scoring Model, the model will provide useful information to hospitals on aspects of care that may require improvement. The Three-Domain Performance Scoring Model scores hospitals based on how they performed with respect to each opportunity to provide appropriate care as defined by the measures, in effect weighting hospital scores by service and patient mix. In contrast with the ACM, independent scoring provides opportunities for hospitals to receive credit for each measure for which they meet the performance standard. In addition, hospitals are scored on a curve at the measure level such that they only earn points when their performance on a measure is better than their peers' average performance during the baseline period, or better than their own previous performance, increasing the accuracy of comparisons made between hospitals. This aspect of the Three-Domain Performance Scoring Model differs from the ACM, because ACM scoring results in higher scores for hospitals that only report on "easier" measures (that is, measures for which performance is high for most hospitals), not every clinical process of care measure for each condition will apply to every hospital, and the ACM does not award points for hospitals that furnish most (but not all) recommended care with respect to a clinical process of care topic.

Furthermore, in the Three-Domain Performance Scoring Model, the scoring of the clinical process of care measures in a single clinical process of care domain is consistent with the current level of precision on the measures. We believe that given the current set of measures available for adoption into the

Hospital VBP program at this time, the intermediate scores created at the condition or topic level under the ACM would convey a false sense of precision about the quality of care provided for that condition. There are efforts in the industry to derive sets of measures that capture many aspects of quality for a certain condition. The measures currently in the Hospital IQR program were not developed with that aim; rather, they were developed and implemented as the best single quality measures for various conditions treated in the hospital and, as such, serve better as a proxy for overall quality than as a precise accounting of quality for individual topics. In other words, the measures now available for the Hospital VBP program do not represent all of the processes that constitute best practices for treating the condition in the inpatient setting, but collectively capture an array of clinical processes that are valid indicators representative of the overall quality of care provided in the hospital inpatient setting.

We believe that the Three-Domain Performance Scoring Model and the ACM are similar in several ways. Rank correlations of hospitals' total performance scores based on the two models were extremely high (between 89 percent and 94 percent). With respect to total performance score rank, most hospitals remain in the same quintile regardless of which model is used; only 8 to 18 percent of hospitals changed in rank quintile due to model choice. In addition, the number of hospitals with a sufficient number of cases and measures for inclusion under the ACM criteria (that is, at least 25 patients in 2 conditions) is similar to the number of hospitals qualifying under the criteria that we are proposing below to use for the Three-Domain Performance Scoring Model (that is, at least 10 patients for 4 measures).

The ACM is considered to be "patient focused" rather than "opportunity focused." Since the unit of scoring is the patient encounter, and the hospital earns a clinical process of care domain score of zero for a patient if the hospital fails to provide any of the applicable processes covered by the measures in the applicable topic area, we believe that the hospital is likely to become aware of all of the processes the patient requires in order to treat the condition,

rather than thinking in terms of individual opportunities. The ACM sets a high bar for quality improvement and sends a strong signal about complete mastery for each individual topic area ("all-or-none") at the patient level. On the other hand, we believe that for complex patients or patients for whom one or more processes are not needed, the ACM model may provide a disincentive to providing quality care. Due to its all-or-nothing scoring approach, the ACM loses patient information that would have some effect on the total performance score under the Three-Domain Performance Scoring Model, under which hospitals would receive credit for all of the measures for which it met the performance standard. Furthermore, as a result of all-or-nothing scoring, the ACM approach will capture whether a patient received appropriate care, but it does not describe the extent of lacking care.

With regard to the extent of variation between hospitals, in our analysis, hospital performance scores modeled under the ACM in general tended to be lower than scores modeled under the Three-Domain Performance Scoring Model. These lower scores would, in theory, allow more room for hospitals to improve in future years.

We will continue analyzing alternative performance scoring models, including the ACM, and may consider proposing to implement scoring models other than the Three-Domain Performance Scoring Model in the future. We solicit public comments on the proposed Three Domain Performance Scoring Model as well as other potential performance scoring models.

9. Example of Applying the Three-Domain Performance Scoring Model to a Hospital and Calculating the Total Performance Score

To illustrate the application of the proposed Three-Domain Performance Scoring Model, we offer the following example:

For the performance period, Hospital E reports and receives raw scores on the measures as set forth in Table 5. (This example uses data from 2007 as the baseline period and 2009 as the performance period.)

TABLE 5—EXAMPLES OF HOSPITAL RAW SCORES ON HOSPITAL VBP PERFORMANCE MEASURES

Domain	Condition	Measure name	Achievement threshold	Benchmark	Hospital baseline score	Hospital performance period score
Clinical Process of Care.	HF-1	Discharge Instructions.	0.778	0.989	0.4	0.952

TABLE 5—EXAMPLES OF HOSPITAL RAW SCORES ON HOSPITAL VBP PERFORMANCE MEASURES—Continued

Domain	Condition	Measure name	Achievement threshold	Benchmark	Hospital baseline score	Hospital performance period score
Patient Experience of Care.	HF-2	Evaluation of LVS Function.	0.957	1.0	0.353	0.727
	PN-2	Pneumococcal Vaccination.	0.844	0.985	0.357	0.583
	PN-7	Initial Antibiotic Received Within 6 Hours of Hospital Arrival.	0.949	1.0	0.846	1.0
	HCAHPS Base Score†.	60
	HCAHPS Consistency Score.	9

† The HCAHPS base score is calculated by summing the higher of the achievement or improvement score for each of the 8 HCAHPS dimensions.

Table 6 below depicts the individual measure scores and total performance score Hospital E would receive after applying the proposed scoring methodology described above.

TABLE 6—EXAMPLE OF HOSPITAL VBP SCORE CALCULATION

Domain	Condition	Achievement points	Improvement points	Earned points (higher of achievement or improvement)	Domain score
Clinical Process of Care	HF-1	8	9	9	67.5
	HF-2	0	5	5	
	PN-2	0	3	3	
	PN-7	10	10	10	
Patient Experience of Care (HCAHPS).	HCAHPS Base Score	60	40	60	69
	HCAHPS Consistency Score	9	
Total Performance Score	0.6795

† HCAHPS earned points are calculated by summing the higher of achievement or improvement points across the 8 HCAHPS dimensions.

10. Request for Comments—Proposed FY 2013 Hospital Value-Based Purchasing Performance Score Methodology and Alternatives

As stated in Sections E(1) and E(2) of this proposed rule, we considered both statutorily mandated and additional factors when assessing the proposed FY 2013 Hospital Value-Based Purchasing program performance score methodology and the alternatives outlined in the previous sections. These additional factors include (1) simplicity and transparency of performance score methods to hospitals; (2) alignment of Hospital VBP performance score methodology with other CMS Value-Based Purchasing programs; (3) quantitative characteristics of the measures and hospital-level data; (4) the relative emphasis placed on achievement and improvement in a performance score methodology; (5) elimination of unintended consequences for rewarding inappropriate hospital behaviors and patient outcomes, and (6) use of most

currently available measure data to assess improvement in a performance score methodology.

We solicit comment on the merits and drawbacks about all of these factors on our proposed performance score methodology, and our performance score methodology alternatives described in this proposed rule. We are particularly interested in all suggested new, improved scoring methodology alternatives that may achieve our objectives in better, straightforward, or more effective ways.

F. Applicability of the Value-Based Purchasing Program to Hospitals

Section 1886(o)(1)(C) of the Act specifies the applicability of the value-based purchasing program to hospitals. For purposes of the Hospital VBP program, the term “hospital” is defined under section 1886(o)(1)(C)(i) as a “subsection (d) hospital,” (as defined in section 1886(d)(1)(B) of the Act). Section 1886(d)(1)(B) of the Act defines a “subsection (d) hospital” as a “hospital located in one of the fifty States or the

District of Columbia.” The term therefore does not include hospitals located in the territories or hospitals located in Puerto Rico. Section 1886(d)(9)(A) of the Act separately defines a “subsection (d) Puerto Rico hospital” as a hospital that is located in Puerto Rico and that “would be a subsection (d) hospital if it were located in one of the 50 states.” Therefore, because 1886(o)(1)(C) does not refer to “subsection (d) Puerto Rico hospitals,” the Hospital VBP program would not apply to hospitals located in Puerto Rico. The statutory definition of a subsection (d) hospital under section 1886(d)(1)(B), however, does include inpatient, acute care hospitals located in the State of Maryland. These hospitals are not currently paid under the IPPS in accordance with a special waiver provided by section 1814(b)(3) of the Act. Despite this waiver, the Maryland hospitals continue to meet the definition of a “subsection (d) hospital”

because they are hospitals located in one of the 50 states. Therefore we propose that the Hospital VBP program will apply to acute care hospitals located in the State of Maryland unless the Secretary exercises discretion pursuant to 1886(o)(1)(C)(iv), which states that “the Secretary may exempt such hospitals from the application of this subsection if the State which is paid under such section submits an annual report to the Secretary describing how a similar program in the State for a participating hospital or hospitals achieves or surpasses the measured results in terms of patient health outcomes and cost savings established under this subsection.”

The statutory definition of a subsection (d) hospital also does not apply to hospitals and hospital units excluded from the IPPS under section 1886(d)(1)(B) of the Act, such as psychiatric, rehabilitation, long term care, children’s, and cancer hospitals. In order to identify hospitals, we propose that, for purposes of this provision, we would adjust payments to hospitals as they are distinguished by provider number in hospital cost reports. We propose that payment adjustments for hospitals be calculated based on the provider number used for cost reporting purposes, which is the CMS Certification Number (CCN) of the main provider (also referred to as OSCAR number). Payments to hospitals are made to each provider of record.

Section 1886(o)(1)(C)(ii) sets forth a number of exclusions to the definition of the term “hospital.” First, under section 1886(o)(1)(C)(ii)(I) a hospital is excluded if it is subject to the payment reduction under section 1886(b)(3)(B)(viii)(I) (the Hospital IQR program) for the fiscal year. Therefore, any hospital that is subject to the Hospital IQR payment reduction because it does not meet the requirements for the Hospital IQR program will be excluded from the Hospital VBP program for the fiscal year. We are concerned about the possibility of hospitals deciding to “opt out” of the Hospital VBP program by choosing to not submit data under the Hospital IQR program, thereby avoiding both the base operating DRG payment reduction and the possibility to receive a value-based incentive payment, although we recognize that these hospitals would still be subject to the Hospital IQR program reduction to their annual payment increase for the fiscal year. We intend to track hospital participation in the Hospital IQR program and welcome public comment on this issue.

With respect to hospitals for which we have measure data from the performance period but no measure data from the baseline period (perhaps because these hospitals were either not open during the baseline period or otherwise did not participate in the Hospital IQR program during that period), we are proposing that these hospitals will still be included in the Hospital VBP program, but that they will be scored based only on achievement. We invite public comments on this approach and welcome input on scoring hospitals without baseline performance data using this and other approaches.

Under section 1886(o)(1)(C)(ii)(II), a hospital is excluded if it has been cited by the Secretary for deficiencies during the performance period that pose immediate jeopardy to the health or safety of patients. We are proposing to interpret this to mean that any hospital that is cited by the Centers for Medicare and Medicaid through the Medicare State Survey and Certification process for deficiencies during the proposed performance period (for purposes of the FY 2013 Hospital VBP program, July 1, 2011–March 31, 2012) that pose immediate jeopardy to patients will be excluded from the Hospital VBP program for the fiscal year. We are also proposing to use the definition of the term “immediate jeopardy” that appears in 42 CFR 489.3.

Section 1886(o)(1)(C)(ii)(III) requires the Secretary to exclude for the fiscal year hospitals that do not report a minimum number (as determined by the Secretary) of measures that apply to the hospital for the performance period for the fiscal year.

Section 1886(o)(1)(C)(ii)(IV) requires the Secretary to exclude for the fiscal year hospitals that do not report a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for the fiscal year.

In determining the minimum number of reported measures and cases under sections 1886(o)(1)(C)(ii)(III) and (IV), the Secretary must conduct an independent analysis of what minimum numbers would be appropriate. To fulfill this requirement, we commissioned Brandeis University to perform an independent analysis that examined technical issues concerning the minimum number of cases per measure and the minimum number of measures per hospital needed to derive reliable performance scores. This analysis examined hospital performance scores using data from 2007–2008 and 2008–2009. The researchers tested different minimum numbers of cases

and measures and concluded that the most important factor in setting minimum thresholds for the Hospital VBP program is to determine a combination of thresholds that allows the maximum number of hospitals to be scored reliably. We note that such reliability depends on the combination of the two thresholds. For example, if we allowed the number of cases per measure to be small (for example, 5 cases), we might still have reliable overall scores if there were a sufficiently large number of measures.

The independent analysis indicated that a smaller number of cases would yield less reliable results for any given measure, ultimately affecting results, when the measures were combined to create the domain scores. Because the proposed Hospital VBP scoring methodology aggregates information across all of the proposed measures, the analysis considered various thresholds for the minimum number of cases to include in a measure. We recognized that lowering the minimum number of cases required for each measure would allow a greater number of hospitals to participate in the Hospital VBP program. The analysis explored whether a lower threshold for each individual measure might be sufficient to make composite measures (that is, measures based on aggregations of individual measures), more statistically reliable.

Brandeis researchers checked the reliability of the total performance score for hospitals with only 4 measures. One approach was to randomly select 4, 6, 10, or 14 measures and to compare the reliabilities that are determined using these different sets of measures per hospitals. The research found that using 4 randomly selected measures per hospital did not greatly reduce between-hospital reliability (particularly in terms of rank ordering) from what would have been determined using 10 or 14 measures. Examining hospitals with at least 10 cases for each measure, the analysis compared the reliability of clinical process measure scores for hospitals according to the number of such measures reported. Whisker plots and reliability scores revealed comparable levels of variation in the process scores for hospitals reporting even a small number of measures as long as the minimum of 10 cases per measure was met. Based on this analysis, we propose to establish the minimum number of cases required for each measure under the proposed Three Domain Performance Scoring Model at 10, which we believe will allow us to include more hospitals in the Hospital VBP program.

When examining the minimum number of measures necessary to derive reliable performance scores, the independent analysis revealed that the distribution of performance scores varied depending on the number of measures reported per hospital. The whisker plots and reliability scores demonstrated a clear difference in the distribution of scores for hospitals reporting 4 or more measures compared with those reporting fewer than 4 measures.

We believe that setting the minimum number of measures and cases as low as is reasonable is an essential component of implementing the Hospital VBP program and will help to minimize the number of hospitals unable to participate due to not having the minimum number of cases for a measure, or the minimum number of measures. Therefore, as we stated above, we propose to exclude from hospitals' total performance score calculation any measures on which they report fewer than 10 cases. We also propose to exclude from the Hospital VBP program any hospitals to which less than 4 of the proposed measures apply.

We are also proposing that, for inclusion in the Hospital VBP program for FY 2013, hospitals must report a minimum of 100 HCAHPS surveys during the performance period. The reliability of HCAHPS scores was determined through statistical analyses conducted by RAND, the statistical consultant for HCAHPS. Based on these analyses, we believe that a reliability rate of 85 percent or higher is desired for HCAHPS to ensure that true hospital performance, rather than random "noise," is measured. RAND's analysis indicates that HCAHPS data do not achieve an 85 percent reliability level across all eight HCAHPS dimensions with a sample of less than 100 completed surveys.

As proposed in this section and in section II. E. of this proposed rule, hospitals reporting insufficient data to receive a score on either the clinical

process of care or HCAHPS domains will not receive a total performance score for the FY 2013 Hospital VBP program.

We solicit public comments on our proposals regarding the minimum numbers of cases and measures necessary for hospitals' inclusion in the Hospital VBP program. We note that hospitals excluded from the Hospital VBP program will be exempt from the base operating DRG payment reduction required under section 1886(o)(7) as well as the possibility for value-based incentive payments.

G. The Exchange Function

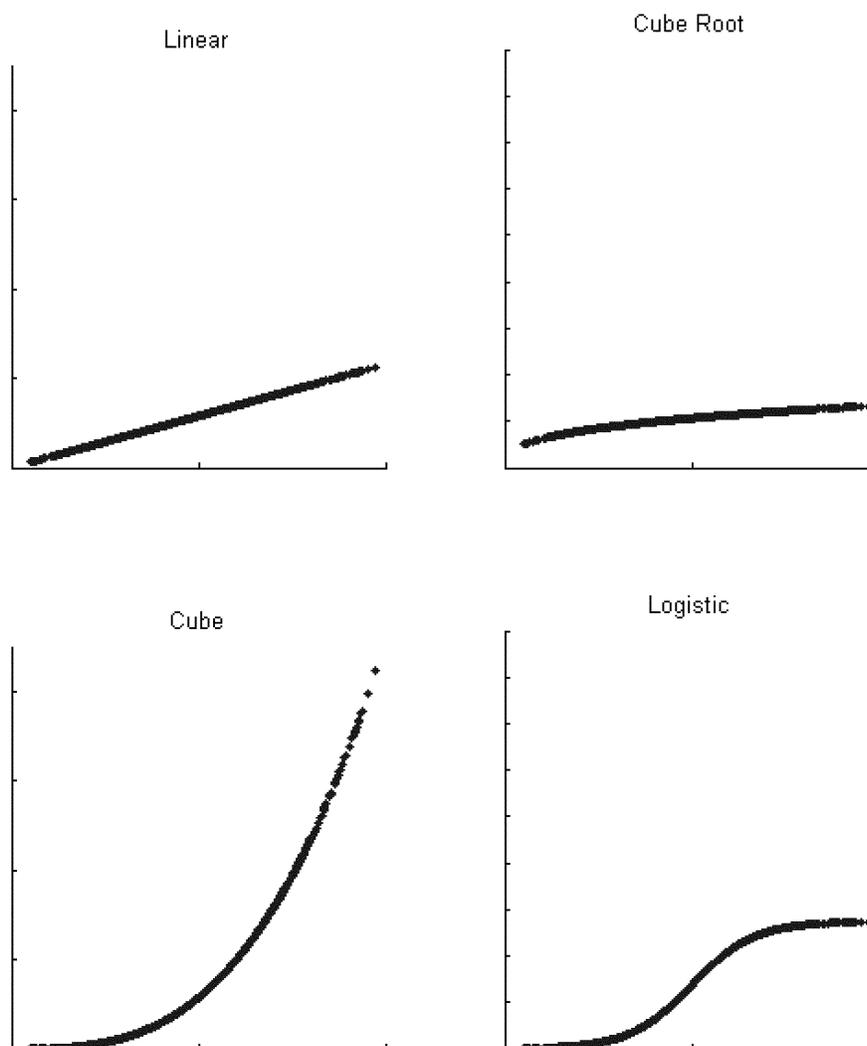
Section 1886(o)(6) of the Act governs the calculation of value-based incentive payments under the Hospital VBP program. Specifically, section 1886(o)(6)(A) requires that in the case of a hospital that meets or exceeds the performance standards for the performance period for a fiscal year, the Secretary shall increase the base operating DRG payment amount (as defined in section 1886(o)(7)(D)), as determined after application of a payment adjustment described in section 1886(o)(7)(B)(i), for a hospital for each discharge occurring in the fiscal year by the value-based incentive payment amount. Section 1886(o)(6)(B) defines the value-based incentive payment amount for each discharge in a fiscal year as the product of (1) the base operating DRG payment amount for the discharge for the hospital for such fiscal year, and (2) the value-based incentive payment percentage for the hospital for such fiscal year. Section 1886(o)(6)(C)(i) provides that the Secretary must specify a value-based incentive payment percentage for each hospital for a fiscal year, and section 1886(o)(6)(C)(ii) provides that in specifying the value-based incentive payment percentage, the Secretary must ensure (1) that the percentage is based on the hospital's performance score, and (2) that the total amount of value-based incentive payments to all hospitals in a

fiscal year is equal to the total amount available for value-based incentive payments for such fiscal year under section 1886(o)(7)(A), as specified by the Secretary.

Section 1886(o)(7) of the Act describes how the value-based incentive payments are to be funded. Under section 1886(o)(7)(A), the total amount available for value-based incentive payments for all hospitals for a fiscal year must be equal to the total amount of reduced payments for all hospitals under section 1886(o)(7)(B), as estimated by the Secretary. Section 1886(o)(7)(B)(i) requires the Secretary to adjust the base operating DRG payment amount for each hospital for each discharge in a fiscal year by an amount equal to the applicable percent of the base operating DRG payment amount for the discharge for the hospital for such fiscal year, and further requires that the Secretary make these reductions for all hospitals in the fiscal year involved, regardless of whether or not the hospital has been determined to have earned a value-based incentive payment for the fiscal year. With respect to fiscal year 2013, the term "applicable percent" is defined as 1.0 percent, but the amount gradually rises to 2 percent by FY 2017 (section 1886(o)(7)(C)).

The 2007 Report to Congress introduced the exchange function as the means to translate a hospital's total performance score into the percentage of the value-based incentive payment earned by the hospital. We believe that the selection of the exact form and slope of the exchange function is of critical importance to how the incentive payments reward performance and encourage hospitals to improve the quality of care they provide.

As illustrated in Figure 7, we considered four mathematical exchange function options: Straight line (linear); concave curve (cube root function); convex curve (cube function); and S-shape (logistic function).

Figure 7. Exchange Function Options.

In determining which of these exchange functions would be most appropriate for translating a hospitals TPS into a value-based incentive payment percentage, we carefully considered four aspects of each option.

First, we considered how each option would distribute the value-based incentive payments among hospitals. Under section 1886(o)(7)(A) of the Act, the total amount available for value-based incentive payments for all hospitals for a fiscal year must be equal to the total amount of reduced payments for all hospitals for such fiscal year, as estimated by the Secretary. We interpret this section to mean that the redistribution of a portion of the IPPS payment to all hospitals under the Hospital VBP program must be accomplished in a way that is estimated to be budget neutral, without increasing or decreasing the aggregate overall IPPS payments made to the hospitals. As a

result, if we award higher value-based incentive payments to higher performing hospitals, less money is available to make value-based incentive payments to lower performing hospitals. The reverse is also true. If we give higher value-based incentive payments to lower performing hospitals, less money is available to reward higher performing hospitals. The form and slope of each exchange function also affects the level of value-based incentive payments available to hospitals at various performance levels. Under both the cube and logistic functions, lower incentive payments are available to lower performing hospitals and aggressively higher payments are available for higher performing hospitals. These functions therefore distribute more incentive payments to higher performing hospitals. Under the cube root function, payments stay at relatively lower levels for higher

performing hospitals; this function distributes more incentive payments to lower performing hospitals. The linear function moves more aggressively to higher levels for higher performing hospitals than the cube root function, but not as aggressively as the logistic and cube functions. It therefore distributes more incentive payments to higher performing hospitals than the cube root function, but not as aggressively as the logistic and cube functions.

Second, we considered the potential differences between the value-based incentive payment amounts for hospitals that do poorly and hospitals that do very well. Due to the fact that the cube root function distributes lower payment amounts to higher performing hospitals, the cube root function creates the narrowest distribution of incentive payments across hospitals. The linear is next, followed by the logistic. The cube

function, which most aggressively moves to higher payment levels for higher performing hospitals, creates the widest distribution.

Third, we considered the different marginal incentives created by the different exchange function shapes. In the case of the linear shape, the marginal incentive does not vary for higher or lower performing hospitals. The slope of the linear function is constant, so any hospital with a TPS that is 0.1 higher than another hospital would receive the same increase in its value-based incentive payment across the entire TPS range. For the other shapes, the slope of the exchange function creates a higher or lower marginal incentive for higher or lower performing hospitals. Steeper slopes at any given point on the function indicate greater marginal incentives for hospitals to improve scores and obtain higher payments at that point, while flatter slopes indicate smaller marginal incentives. If the slope is steeper at the low end of performance scores than at the high end, as with the cube root function, hospitals at the low end have a higher marginal incentive to improve than hospitals at the high end. If the slope is steeper at the high end, as with the cube function, hospitals have a higher marginal incentive to improve at the high end than they do at the low end.

Fourth, we weighed the relative importance of having the exchange function be as simple and straightforward as possible.

Taking all of these factors into account, we propose to adopt a linear exchange function for the purpose of calculating the percentage of the value-based incentive payment earned by each hospital under the Hospital VBP program. The linear function is the simplest and most straightforward of the mathematical exchange functions discussed above. The linear function provides all hospitals the same marginal incentive to continually improve. The linear function more aggressively rewards higher performing hospitals than the cube root function, but not as aggressively as the logistic and cube functions. We propose the function's intercept at zero, meaning that hospitals with scores of zero will not receive any incentive payment. Payment for each hospital with a score above zero will be determined by the slope of the linear exchange function, which will be set to meet the budget neutrality requirement of section 1886(o)(6)(C)(ii)(II) that the total amount of value-based incentive payments equal the estimated amount available under section 1886(o)(7)(A). In other words, we will set the slope of the

linear exchange function for FY 2013 so that the estimated aggregate value-based incentive payments for FY 2013 are equal to 1 percent of the estimated aggregate base operating DRG payment amounts for FY 2013. Analogous estimates will be done for subsequent fiscal years.

We believe that our proposed linear exchange function ensures that all hospitals have strong incentives to continually improve the quality of care they provide to their patients. We may revisit the issue of the most appropriate exchange function in future rulemaking as we gain more experience under the Hospital VBP program. We solicit public comments on our proposed exchange function and the resulting distribution of value-based incentive payments.

We note that, in order to evaluate the different exchange functions, we needed to estimate the value-based incentive payment amount. As noted previously, section 1886(o)(6)(B) of the Act defines the value-based incentive payment amount as equal to the product of the base operating DRG payment amount for each discharge for the hospital for the fiscal year and the value-based incentive payment percentage specified by the Secretary for the hospital for the fiscal year. Section 1886(o)(7)(D)(i) defines the base operating DRG payment with respect to a hospital for a fiscal year as, unless certain special rules apply, "the payment amount that would otherwise be made under subsection (d) (determined without regard to subsection (q)) for a discharge if [subsection (o)] did not apply; reduced by any portion of such payment amount that is attributable to payments under paragraphs (5)(A), (5)(B), (5)(F) and (12) of subsection (d); and such other payments under subsection (d) determined appropriate by the Secretary." Therefore, for estimation purposes, to calculate base operating DRG payments, we estimated the total payments using Medicare Part A claims data and subtracted from this number the estimates of payments made as outlier payments (authorized under section 1886(d)(5)(A)), indirect medical education payments (authorized under section 1886(d)(5)(B)), disproportionate share hospital payments (authorized under section 1886(d)(5)(F)), and low-volume hospital adjustment payments (authorized under section 1886(d)(12)). We note that this approximation of base operating DRG payments made for the purpose of estimating the value-based payment amount to evaluate the different exchange functions is not a policy proposal. We will propose a definition of the term "base operating DRG payment amount" under section

1886(o)(7)(D), as well as how we would implement the special rules for certain hospitals described in section 1886(o)(7)(D)(ii), in future rulemaking. We invite public comment to inform our intended future policymaking on this issue.

Furthermore, section 1886(o)(7)(A) states that the total amount available for value-based incentive payments for all hospitals for a fiscal year shall be equal to the total amount of reduced payments for all hospitals for such fiscal year. To calculate the total amount of reduced payments, section 1886(o)(7)(B) states that the base operating DRG payment amount shall be reduced by an applicable percent as defined under section 1886(o)(7)(C). This applicable percent is 1.0 percent for FY 2013, 1.25 percent for FY 2014, 1.5 percent for FY 2015, 1.75 percent for FY 2016, and 2 percent for FY 2017 and subsequent years. To develop an estimation of the value-based incentive payment amount for the purposes of evaluating the different exchange functions, we used the FY 2013 1.0 as the applicable percent. We multiplied an estimate (described above) of the total aggregate base operating DRG payments for hospitals as defined under 1886(o)(1)(C) by 1.0 percent in order to derive the total amount available for value-based incentive payments that was used in the evaluation of the four exchange functions.

H. Proposed Hospital Notification and Review Procedures

Section 1886(o)(8) requires the Secretary to inform each hospital of the adjustments to payments to the hospital for discharges occurring in a fiscal year as a result of the calculation of the value-based incentive payment amount (section 1886(o)(6)) and the reduction of the base operating diagnosis-related group (DRG) payment amount (section 1886(o)(7)(B)(i)), not later than 60 days prior to the fiscal year involved. We propose to notify hospitals of the 1 percent reduction to their FY 2013 base operating DRG payments for each discharge in the FY 2013 IPPS rule, which will be finalized at least 60 days prior to the beginning of the 2013 fiscal year. We expect to propose to incorporate this reduction into our claims processing system in January, 2013, which will allow the 1 percent reduction to be applied to the FY 2013 discharges, including those that have occurred beginning on October 1, 2012. We will address the operational aspects of the reduction as part of the FY 2013 IPPS rule.

Because the proposed performance period would end only six months prior

to the beginning of FY 2013, CMS will not know each hospital's exact total performance score or final value-based incentive payment adjustment 60 days prior to the start of the 2013 fiscal year on October 1, 2012. Therefore, we propose to inform each hospital through its QualityNet account at least 60 days prior to October 1, 2012 of the estimated amount of its value-based incentive payment for FY 2013 discharges based on estimated performance scoring and value-based incentive payment amounts, which will be derived from the most recently available data. We also propose that each hospital participating in the Hospital VBP program establish a QualityNet account if it does not already have one for purposes of the Hospital IQR program. We further propose to notify each hospital of the exact amount of its value-based incentive payment adjustment for FY 2013 discharges on November 1, 2012. The value-based incentive payment adjustment would be incorporated into our claims processing system in January 2013, which will allow the value-based incentive payment adjustment to be applied to the FY 2013 discharges, including those that have occurred beginning on October 1, 2012.

Section 1886(o)(10)(A)(i) of the Act requires the Secretary to make information available to the public regarding individual hospital performance in the Hospital VBP program, including: (1) Hospital performance on each measure that applies to the hospital; (2) the performance of the hospital with respect to each condition or procedure; and (3) the total hospital performance score. To meet this requirement, we propose to publish hospital scores with respect to each measure, each hospital's condition-specific score (that is, the performance score with respect to each condition or procedure, for example, AMI, HF, PN, SCIP, HAI), each hospital's domain-specific score, and each hospital's total performance score on the *Hospital Compare* website. We note that we are not proposing to use a hospital's condition-specific score for purposes of calculating its total performance score under the proposed Three-Domain Performance Scoring Model.

Section 1886(o)(10)(A)(ii) requires the Secretary to ensure that each hospital has the opportunity to review and submit corrections related to the information to be made public with respect to the hospital under section 1886(o)(10)(A)(i) prior to such information being made public. As stated above, we propose to derive the Hospital VBP measures data directly

from measures data submitted by each hospital under the Hospital IQR program. We propose that the procedures we adopt for the Hospital IQR program will also be the procedures that hospitals must follow in terms of reviewing and submitting corrections related to the information to be made public under section 1886(o)(10).

With respect to the FY 2013 Hospital VBP program, we propose to make each hospital's Hospital VBP performance measure score, condition-specific score, domain-specific score, and total performance score available on the hospital's QualityNet account on November 1, 2012. We propose to remind each hospital via the hospital's secure QualityNet account of the availability of its performance information under the Hospital VBP program on this date. Pursuant to section 1886(o)(10)(A)(ii), we propose to provide hospitals with 30 calendar days to review and submit corrections related to their performance measure scores, condition-specific scores, domain-specific scores and total performance score.

Section 1886(o)(10)(B) requires the Secretary to periodically post on the *Hospital Compare* website aggregate information on the Hospital VBP program, including: (1) The number of hospitals receiving value-based incentive payments under the program as well as the range and total amount of such value-based incentive payments; and (2) the number of hospitals receiving less than the maximum value-based incentive payment available for the fiscal year involved and the range and amount of such payments. We propose to post aggregate Hospital VBP information on the *Hospital Compare* website in accordance with Section 1886(o)(10)(B). We will provide further details on reporting aggregated information in the future.

I. Proposed Reconsideration and Appeal Procedures

Section 1886(o)(11)(A) of the Act requires the Secretary to establish a process by which hospitals may appeal the calculation of a hospital's performance assessment with respect to the performance standards (section 1886(o)(3)(A)) and the hospital performance score (section 1886(o)(5)). Under section 1886(o)(11)(B), there is no administrative or judicial review under section 1869, section 1878, or otherwise of the following: (1) The methodology used to determine the amount of the value-based incentive payment under section 1886(o)(6) and the determination of such amount; (2) the determination of the amount of funding

available for the value-based incentive payments under section 1886(o)(7)(A) and payment reduction under section 1886(o)(7)(B)(i); (3) the establishment of the performance standards under section 1886(o)(3) and the performance period under section 1886(o)(4); (4) the measures specified under section 1886(b)(3)(B)(viii) and the measures selected under section 1886(o)(2); (5) the methodology developed under section 1886(o)(5) that is used to calculate hospital performance scores and the calculation of such scores; or (6) the validation methodology specified in section 1886(b)(3)(B)(viii)(XI).

We will propose an appeals process under section 1886(o)(11) in future rulemaking. We invite public comment, in general, on the structure and procedure of an appropriate appeals process. Specifically, CMS seeks comment on the appropriateness of a process that would establish an agency-level appeals process under which CMS personnel having appropriate expertise in the Hospital VBP program would decide the appeal. We seek insight on what qualifications such personnel should hold. Further, we invite comment on how the appeals process should be structured. Finally, we seek public input on the timeframe in which these appeals should be resolved.

J. Proposed FY 2013 Validation Requirements for Hospital Value-Based Purchasing

In the FY 2011 IPPS final rule (75 FR 50227 through 50229), we adopted a validation process for the FY 2013 Hospital IQR program. We propose that this validation process will also apply to the FY 2013 Hospital VBP program. We believe that using this process for both the Hospital IQR program and the Hospital VBP program is beneficial for both hospitals and CMS because no additional burden will be placed on hospitals to separately return requested medical records for the Hospital VBP program. Because the measure data we are using for the Hospital VBP program is the same as the data we collect for the Hospital IQR program, we believe that we can ensure that the Hospital VBP program measure data are accurate through the Hospital IQR program validation process.

In future rulemaking related to the Hospital IQR program, we will consider proposing refinements to our annual Hospital IQR validation sample selection, targeting, and annual validation period for enhanced alignment and use in the Hospital VBP program. We seek to reduce hospital burden and ensure that the information we collect for both the Hospital IQR

program and the Hospital VBP program is accurate.

K. Additional Information

1. Monitoring and Evaluation

As part of our ongoing effort to ensure that Medicare beneficiaries receive high-quality inpatient care, CMS plans to monitor and evaluate the new Hospital VBP program. Monitoring will focus on whether, following implementation of the Hospital VBP program, we observe changes in access to and the quality of care furnished to beneficiaries, especially within vulnerable populations. We will also evaluate the effects of the new Hospital VBP program in areas such as:

- Access to care for beneficiaries, including categories or subgroups of beneficiaries.
- Changes in care practices that might adversely impact the quality of care furnished to beneficiaries.
- Patterns of care suggesting particular effects of the Hospital VBP program (such as whether there are changes in the percentage of patients receiving appropriate care for conditions covered by the measures); or a change in the rate of hospital acquired conditions.
- Best practices of high-performing hospitals that might be adopted by other hospitals.

We currently collect data on readmission rates for beneficiaries diagnosed with myocardial infarction, heart failure, and pneumonia. We also collect chart abstracted data on a variety of quality of care indicators related to myocardial infarction, heart failure, pneumonia, and surgical care improvement. These sources and other available data will provide the basis for early examination of trends in care delivery, access, and quality. Assessment of the early experience with the Hospital VBP program will allow us to create an active learning system, building the evidence base essential for guiding the design of future Hospital VBP programs and enabling CMS to address any disruptions in access or quality that may arise. These ongoing monitoring and evaluation efforts will be part of CMS's larger efforts to promote improvements in quality and efficiency, both within CMS and between CMS and hospitals in the Hospital VBP program. We welcome public comments regarding approaches to monitoring and evaluating the Hospital VBP program.

2. Electronic Health Records (EHRs)

a. Background

Starting with the FY 2006 IPPS final rule, we have encouraged hospitals to take steps toward the adoption of EHRs (also referred to in previous rulemaking documents as electronic medical records) that will allow for reporting of clinical quality data from the EHRs directly to a CMS data repository (70 FR 47420 through 47421). We encouraged hospitals that are implementing, upgrading, or developing EHR systems to ensure that the technology obtained, upgraded, or developed conforms to standards adopted by HHS. We suggested that hospitals also take due care and diligence to ensure that the EHR systems accurately capture quality data and that, ideally, such systems provide point of care decision support that promotes optimal levels of clinical performance.

We also continue to work with standard setting organizations and other entities to explore processes through which EHRs could speed the collection of data and minimize the resources necessary for quality reporting as we have done in the past.

We note that we have initiated work directed toward enabling EHR submission of quality measures through EHR standards development and adoption. We have sponsored the creation of electronic specifications for quality measures for the hospital inpatient setting, and will also work toward electronically specifying measures selected for the Hospital IQR program and the Hospital VBP program.

b. HITECH Act EHR Provisions

The HITECH Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA) authorizes payment incentives under Medicare for the adoption and use of certified EHR technology beginning in FY 2011. Hospitals are eligible for these payment incentives if they meet requirements for meaningful use of certified EHR technology, which include reporting on quality measures using certified EHR technology. With respect to the selection of quality measures for this purpose, under section 1886(n)(3)(A)(ii) of the Act, as added by section 4102 of the HITECH Act, the Secretary shall select measures, including clinical quality measures, that hospitals must provide to CMS in order to be eligible for the EHR incentive payments. With respect to the clinical quality measures, section 1886(n)(3)(B)(i) of the Act requires the Secretary to give preference to those clinical quality measures that have been selected for the Hospital IQR

program under section 1886(b)(3)(B)(viii) of the Act or that have been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act. Any clinical quality measures selected for the HITECH incentive program for eligible hospitals must be proposed for public comment prior to their selection, except in the case of measures previously selected for the Hospital IQR program under section 1886(b)(3)(B)(viii) of the Act.

Thus, the Hospital IQR program and Hospital VBP Program have important areas of overlap and synergy with respect to the reporting of quality measures under the HITECH Act using EHRs. We believe the financial incentives under the HITECH Act for the adoption and meaningful use of certified HER technology by hospitals will encourage the adoption and use of certified EHRs for the reporting of clinical quality measures under the Hospital IQR program which are subsequently used for the Hospital VBP Program.

We note that the provisions in this proposed rule do not implicate or implement any HITECH statutory provisions. Those provisions are the subject of separate rulemaking and public comment.

L. QIO Quality Data Access

The mission of the Quality Improvement Organization (QIO) Program, as authorized under section 1862(g) and Part B of title XI of the Act, is to promote the effectiveness, efficiency, economy, and quality of services delivered to Medicare beneficiaries. We contract with one organization in each state, as well as the District of Columbia, Puerto Rico, and the U.S. Virgin Islands, to serve as that state/jurisdiction's QIO. QIOs are private, usually not-for-profit organizations, which are staffed mostly by doctors and other health care professionals. These professionals are trained to review medical care and help beneficiaries with complaints about the quality of care and to implement improvements in the quality of care available throughout the spectrum of care. Over time, QIOs have been instrumental in advancing national efforts that motivate providers to improve the quality of Medicare services, and in measuring and improving outcomes of quality.

Data collected by QIOs to accomplish their mission represent an important tool for CMS in our efforts to improve quality. QIOs collect survey, administrative, and medical records data in order to monitor and assess

provider performance. The confidentiality and disclosure requirements associated with QIO information are set forth in Section 1160 of the Act. In particular, this section stipulates that QIOs are not Federal agencies for purposes of the Freedom of Information Act and specifies that “any data or information acquired by [a QIO] in the exercise of its duties and functions shall be held in confidence and shall not be disclosed to any person.” The section then authorizes certain exceptions that allow disclosures, including the authority of the Secretary to prescribe additional exceptions “in such cases and under such circumstances as the Secretary shall by regulations provide * * *.” Implementing regulations governing the QIO confidentiality and disclosure requirements were issued in 1985 (see 50 FR 15347, April 17, 1985). In accordance with section 1881(c)(8), section 1160 and the confidentiality and disclosure requirements also apply to End Stage Renal Disease Networks.

A key aspect of these regulations is the significant restriction placed on a QIO’s ability to disclose QIO information, in particular information related to a Quality Review Study (QRS). A QRS is defined in § 480.101(b) as “an assessment, conducted by or for a QIO, of a patient care problem for the purpose of improving patient care through peer analysis, intervention, resolution of the problem and follow-up.” QIOs are instrumental in collecting, maintaining, and processing certain data associated with the Hospital Inpatient Quality Reporting Program. Such data is considered to be QRS data. As such, these data are subject to the increased restrictions placed on disclosures of QRS information set forth in § 480.140 of the QIO regulations. Section 480.140 even places stringent restrictions on a QIO’s ability to disclose to CMS. While the QIO regulations have gone largely unchanged since 1985, the regulations were recently updated to account for CMS’ expanded role in quality reporting. Specifically, § 480.140 was amended to add a new subparagraph (g), which ensures that CMS has access to QRS information collected as part of the Hospital Inpatient Quality Reporting Program, following hospital review of the data. However, CMS’s access is restricted to the sole purpose of conducting certain activities related to MA organizations, as described in § 422.153. See 75 FR 19678, 19759 (April 15, 2010). CMS continues to be limited in other areas of quality reporting based on the current regulatory restrictions.

In fact, many of the same regulatory restrictions that impact CMS’ ability to properly coordinate quality reporting have also impacted CMS’ ability to oversee and plan other QIO program activities and Departmental initiatives. As previously noted, the QIO regulations were originally issued in 1985. Although these regulations have not undergone significant change, there have been significant changes both within and outside the QIO program directly impacting the way the QIOs and CMS conduct business. In 1985, computers were still in their infancy, and QIO review activities were primarily conducted onsite at the provider’s and/or practitioner’s place of business. Similarly, CMS’ oversight responsibilities were conducted onsite at the QIOs’ offices. The QIO program regulations were written based on this reality. Additionally, the original restrictions were designed to enhance provider and practitioner participation in the QRS process, and in fact, were considered necessary to obtain the frank and open communication needed to improve the quality of health care.

Since 1985 however, we have seen enormous technological advances, including improvements in the ability to electronically exchange large amounts of data safely and securely through the internet. Moreover, several laws, most notably the Health Insurance Portability and Accountability Act (HIPAA) and the Federal Information Security and Management Act (FISMA), have been established to protect sensitive information. In addition, despite the QIOs continued focus on information obtained directly from providers and practitioners, QIOs also obtain a large amount of CMS claims data electronically to complete their review activities. During this same time period, the QIO program has expanded and now includes more emphasis on quality reporting and additional responsibilities, for example, a broader range of beneficiary appeals of provider discharges. In turn, CMS’ responsibilities have also been broadened both in terms of programmatic responsibilities, for example, quality reporting, and its contractor oversight responsibilities. Moreover, there are various initiatives designed to ensure transparency of our programs, as well as the operations of individual providers and practitioners. We have also identified several unintended consequences resulting from these regulatory restrictions, which need to be addressed to ensure better management of the QIOs. This includes

improvements related to CMS’ oversight of QIO physician reviewers.

In light of the above, we are proposing several changes to the QIO regulations. We are amending the definition of the QIO review system in § 480.101(b) to include CMS. The QIO review system currently consists of the QIO and the organizations and individuals who either assist the QIO or are directly responsible for providing care or for making review determinations with respect to that care. Particularly in the area of quality reporting, there is a need for increased coordination between CMS and the QIOs, which includes exchanges of data so that CMS can better manage and respond to new information.

We are also modifying § 480.130 to clarify the Department’s general right to access non-QRS confidential information. We have made it clear that this provision includes Departmental components, including CMS as well as the Center for Disease Control and Prevention including those related to data exchanges associated with the National Health Care Safety Network. Additionally, we are modifying § 480.139(a) to remove limitations on CMS’ access to information regarding the QIO’s internal deliberations (as defined in § 480.101(b)). The current regulation authorizes CMS’ access to information in “deliberations,” but limits that access to onsite “at the QIO office or at a subcontracted organization.” This limitation is unrealistic in light of today’s technologically advanced business environment.

For the same reasons, we have modified § 480.140 to eliminate the onsite restriction to CMS’ access to QRS data. In addition to the reasoning we have presented above, we considered this change necessary in order to create a more consistent approach to how and when we could gain access to QRS information. In our recent addition of subparagraph (g) to § 480.140, the “onsite” limitation was removed only in the context of MA organizations. We now see no reason to confine this change to such a narrow purpose. As a general matter, CMS must have access to QRS information not only for quality reporting purposes but also to ensure proper oversight and management of the QIOs. This includes access for the evaluation of specific contractor performance issues and for the long-term planning of the QIO program. In addition, the current state of technology, the use of electronic exchanges of data and information, and the speed at which data must be exchanged to ensure accomplishment of our work, warrants

the elimination of the restriction that data can only be accessed “onsite” at the QIO. We also considered the fact that the current “onsite” limitation does not establish realistic limits on the use of data CMS views onsite. While actual copies of materials cannot be removed from an onsite location, it is unlikely that the “onsite” restriction adequately prevents CMS from “taking away” information it has learned while viewing that information. Thus, the change presents a more realistic approach to access in light of today’s environment. It will enable CMS to operate more efficiently, and account for the current information exchange methodologies used throughout the world. In fact, we are asking for comments regarding whether the “onsite” restriction should be eliminated entirely from subparagraph (a) of section 480.140. In order to reflect the specific changes we are now proposing in section 480.140, we are making corresponding changes in § 422.153 to ensure consistency between the two provisions.

In general, the changes will not only enable CMS to better monitor its programs and contractors, but will also help to ensure that CMS has access to information in a timely manner to account for any unintended consequences to patient care resulting from its programs. This increased access to QIO information is vital to achieving CMS’ goal of developing a performance-based incentive payment program that rewards providers for high-quality care. Access to this data will enhance CMS’ efforts to create a Hospital VBP program based on quality of care. The changes will also facilitate CMS’ effort to improve coordination with its contractors. Moreover, CMS will be positioned to better leverage opportunities to improve the quality of health care and to oversee its contractor activities with less cost, including costs associated with travel.

In addition to the proposed changes, we are also asking for comments regarding the disclosure of QIO information to researchers. Historically, QIOs have not disclosed confidential QIO information to researchers. However, we recognize the value that research can offer in improving the quality of health care, and researchers frequently contact QIO program representatives to gain access to QIO information. Thus, we are requesting comments on whether researchers should be allowed access to QIO information. This includes access to confidential information associated with quality review studies. Moreover, we are requesting comments on the process

that should be used to evaluate these requests, for example, enabling QIOs to independently assess such requests or using the current CMS Privacy Board structure. Insight regarding criteria to be used in evaluating these requests should also be provided.

III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Statement

A. Statement of Need

The objectives of the Hospital VBP program include to transform how Medicare pays for care and to encourage hospitals to continually improve the quality of care they provide. In accordance with section 1886(o) of the Act, we have proposed to accomplish these goals by providing incentive payments based on hospital performance on quality measures. This proposed rule was developed based on extensive research we conducted on hospital value-based purchasing, some of which formed the basis of the 2007 Report to Congress, as well as extensive stakeholder and public input. The proposed approach reflects the statutory requirements and the intent of Congress to promote increased quality of hospital care for Medicare beneficiaries by aligning a portion of hospital payments with performance.

B. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), 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 Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). To provide funding for value-based incentive payments, beginning in fiscal year 2013 and in each succeeding fiscal year, section 1886(o)(7) of the Act governs the funding for the value-based incentive payments and requires the Secretary to reduce the base operating DRG payment amount for a hospital for each discharge in a fiscal year by an amount equal to the applicable percent of the base operating DRG payment amount for the discharge for the hospital for such fiscal year. We anticipate defining the term “base operating DRG amount” in future rulemaking. For purposes of this proposed rule, we have limited our analysis of the economic impacts to the value-based incentive payments. As required by section 1886(o)(7)(A), total reductions for hospitals under section 1886(o)(7)(B) must be equal to the amount available for value-based incentive payments under section 1886(o)(6), resulting in a net budget-neutral impact. Overall, the distributive impact of this proposed rule is estimated at \$850 million for FY 2013. Therefore, this proposed rule is economically significant and thus a major rule under the Congressional Review Act.

The objectives of the Hospital VBP program include to transform how Medicare pays for care and to encourage hospitals to continually improve the quality of care they provide. In accordance with section 1886(o) of the Act, we have proposed to accomplish these goals by providing incentive payments based on hospital performance on quality measures. This proposed rule was developed based on extensive research we conducted on hospital value-based purchasing, some of which formed the basis of the 2007 Report to Congress, as well as extensive stakeholder and public input. The proposed approach reflects the statutory requirements and the intent of Congress to promote increased quality of hospital care for Medicare beneficiaries by aligning a portion of hospital payments with performance.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are considered to be small entities, either by nonprofit status or by having revenues \$34.5 million or less in any 1 year. Individuals and States are not included in the definition of a small entity.

Guidance issued by the Department of Health and Human Services interpreting the RFA considers effects to be economically significant if they reach a threshold of 3 to 5 percent or more of total revenues or costs. Among the 3,092 hospitals that would be participating in the Hospital VBP program, we estimate that percent increases in payments resulting from this proposed rule will range from 0.0236 percent for the lowest-scoring hospital to 1.817 percent for the highest-scoring hospital. When the reduction in base DRG operating payments to hospitals required under section 1886(o)(7) is taken into account, roughly half of participating hospitals will receive a net increase in payments and half will receive a net decrease in payments. However, we estimate that no participating hospital will receive more than a net 1 percent increase or decrease in payments. This falls well below the threshold for economic significance established by HHS for requiring a more detailed impact assessment under the RFA. Thus, we are not preparing an

analysis under the RFA because the Secretary has determined that this proposed rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. We are not preparing an analysis under 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 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2010, that threshold is approximately \$135 million. This rule would not mandate any requirements for State, local, or tribal governments, nor would it affect private sector costs.

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. As stated above, this final rule would not have a substantial effect on State and local governments.

C. Anticipated Effects

Table 7 displays our analysis of the distribution of possible total performance scores based on 2009 data, providing information on the estimated impact of this proposed rule. Value-based incentive payments for the estimated 3,092 hospitals participating in Hospital VBP are stratified by hospital characteristic, including geographic region, urban/rural designation, capacity (number of beds), and percentage of Medicare utilization. For example, line 4 of Table 7 shows the estimated value-based incentive payments for the East South Central region, which includes the states of Alabama, Kentucky, Mississippi, and Tennessee. Column 2 relates that, of the 3,092 participating hospitals, 301 are located in the East South Central region. Column 3 provides the estimated mean value-based incentive payment to those hospitals, which is 1.021 percent. The next columns provide the distribution of scores by percentile; we see that the value-based incentive percentage payments for hospitals in the East South Central region range from 0.550 at the 5th percentile to 1.482 at the 95th percentile, while the value-based incentive payment at the 50th percentile is 1.023 percent.

TABLE 7—TWO-DOMAIN IMPACT (CLINICAL PROCESS AND HCAHPS); ESTIMATED INCENTIVE RATES BY HOSPITAL CHARACTERISTIC†

Hospital characteristic	N = 3,092	Mean	Percentile								
			5th	10th	25th	50th	75th	90th	95th		
Region:											
New England	138	1.083	0.660	0.751	0.935	1.088	1.276	1.391	1.434		
Middle Atlantic	370	0.955	0.542	0.619	0.766	0.963	1.152	1.288	1.352		
South Atlantic	518	1.041	0.551	0.661	0.822	1.039	1.255	1.420	1.499		
East North Central	475	1.022	0.555	0.652	0.840	1.025	1.214	1.380	1.472		
East South Central	301	1.021	0.550	0.634	0.810	1.023	1.235	1.413	1.482		
West North Central	248	1.083	0.638	0.721	0.866	1.075	1.283	1.470	1.567		
West South Central	457	1.014	0.477	0.597	0.784	0.997	1.248	1.432	1.563		
Mountain	201	0.980	0.584	0.650	0.822	0.986	1.159	1.336	1.396		
Pacific	384	0.935	0.434	0.551	0.755	0.951	1.126	1.290	1.383		
Urban/Rural:											
Large Urban	1,199	1.008	0.552	0.646	0.815	1.014	1.206	1.370	1.449		
Other Urban	1,010	1.016	0.551	0.646	0.817	1.015	1.209	1.379	1.484		
Rural	883	1.007	0.487	0.607	0.788	1.009	1.239	1.398	1.499		
Capacity (by # beds):											
1 to 99 beds	1,045	1.044	0.491	0.617	0.814	1.047	1.284	1.456	1.575		
100 to 199 beds	939	1.002	0.500	0.598	0.815	1.015	1.201	1.360	1.452		
200 to 299 beds	481	0.989	0.586	0.662	0.803	0.996	1.175	1.323	1.392		
300 to 399 beds	279	0.995	0.577	0.668	0.821	1.022	1.167	1.293	1.379		
400 to 499 beds	151	0.985	0.575	0.700	0.837	0.982	1.135	1.307	1.414		
500+ beds	197	0.960	0.562	0.652	0.766	0.960	1.146	1.265	1.314		
Medicare Utilization:											
0 to 25%	237	0.990	0.542	0.639	0.798	1.012	1.164	1.352	1.451		
>25% to 50%	1,508	1.016	0.528	0.642	0.818	1.020	1.224	1.381	1.459		
>50% to 65%	1,148	1.005	0.524	0.637	0.804	1.008	1.206	1.381	1.482		
> 65%	196	1.02	0.52	0.60	0.80	1.02	1.28	1.42	1.53		

†Note: Because sufficient 2009 data was not available at the time of publication of this proposed rule, the measures SCIP-Card-2 and SCIP-Inf-4 were not included in the calculation of estimated incentive rates. However, we believe that no significant change in estimated incentive rates results from the omission of these measures.

Table 8 below shows the estimated percent distribution by hospital characteristic of the 1% reduction (\$850 million) in the base operating DRG payment for fiscal year 2013.

TABLE 8—AVERAGE ESTIMATED PERCENTAGE WITHHOLD AMOUNT (AS REQUIRED BY SECTION 1886(O)(7) OF THE SOCIAL SECURITY ACT) BY HOSPITAL CHARACTERISTIC

Hospital characteristic	N=3,092	Estimated percent withhold amount
Region:		
New England	138	5.9
Middle Atlantic ...	370	15.9
South Atlantic	518	19.5
East North Central	475	17.5
East South Central	301	7.8
West North Central	248	7.2
West South Central	457	10.3
Mountain	201	4.8
Pacific	384	11.2
Urban/Rural:		
Large Urban	1,199	49.8
Other Urban	1,010	38.2
Rural	883	11.1
Capacity (by # beds):		
1 to 99 beds	1,045	8.1
100 to 199 beds	939	21.2
200 to 299 beds	481	20.5
300 to 399 beds	279	16.9
400 to 499 beds	151	11.0
500+ beds	197	23.4
Medicare Utilization:		
0 to 25%	237	3.9
>25 to 50%	1,508	60.0
>50% to 65%	1,148	32.8
>65%	196	3.2

We also analyzed the characteristics of hospitals not receiving a Hospital VBP score based on the program requirements, which is shown below in Table 9. We estimate that 353 hospitals will not receive a Hospital VBP score in fiscal year 2013. We note that these hospitals will not be impacted by the reductions in base DRG operating payments under section 1886(o)(7). IPPS hospitals not included in this analysis were excluded due to the complete absence of cases applicable to the measures included, or due to the absence of a sufficient number of cases to reliably assess the measure.

As might be expected, a significant portion of hospitals not receiving a Hospital VBP score are small providers because such entities are more likely to

lack the minimum number of cases or measures required to participate in the Hospital VBP program. We anticipate conducting future research on methods to include small hospitals in the Hospital VBP program.

TABLE 9—PROJECTED NUMBER OF HOSPITALS NOT RECEIVING A HOSPITAL VBP SCORE IN FY 2013, BY HOSPITAL CHARACTERISTIC

Hospital characteristic	Number of hospitals not receiving hospital VBP Score (N=353)
Region:	
New England	6
Middle Atlantic	18
South Atlantic	14
East North Central	31
East South Central	26
West North Central	17
West South Central	85
Mountain	25
Pacific	26
Puerto Rico	34
Missing Region	71
Urban/Rural:	
Large Urban	116
Other Urban	83
Rural	83
Missing Urban/Rural	71
Capacity (by # beds):	
1 to 99 beds	213
100 to 199 beds	47
200 to 299 beds	11
300 to 399 beds	8
400 to 499 beds	2
500+ beds	0
Missing Capacity	72
Medicare Utilization:	
0 to 25%	78
>25% to 50%	75
>50% to 65%	43
>65%	28
Missing Medicare Utilization	129

We note that a number of hospitals were missing hospital characteristic data, including region, urban/rural classification, size, and Medicare utilization. All 353 hospitals included in Table 9, including those with missing hospital characteristic data, lacked sufficient clinical process of care data or HCAHPS data needed to calculate a total performance score.

D. Alternatives considered

The major alternative performance scoring models considered for this proposed rule were the Six-Domain Performance Scoring Model and the Appropriate Care Model, and both of

these models were discussed in Section II. E. of this proposed rule. Examining these alternative performance scoring models, our analyses showed only modest differences in financial reimbursements across the separate models considered by the various characteristics listed above. We believe that these observed transfers are within the limits of expected variation and do not reflect significant differences in financial reimbursements between the performance scoring models considered.

E. Accounting Statement

As required by OMB Circular A-4 (available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>), we have prepared an accounting statement showing the classification of the impacts associated with the provisions of this proposed rule.

As required by section 1886(o)(7)(A), total reductions for hospitals under section 1886(o)(7)(B) must be equal to the amount available for value-based incentive payments under section 1886(o)(6), resulting in a net budget-neutral impact. Overall, the distributive impacts of this proposed rule, resulting from the incentive payments and the 1% reduction (withhold) in the base operating DRG payment for fiscal year 2013, are estimated at \$850 million for fiscal year 2013 (reflected in 2010 dollars).

TABLE 10—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR FY 2013

Category	Transfers
Annualized Monetized Transfers.	\$0 (distributive impacts resulting from the incentive payments and the 1% reduction (withhold) in the base operating DRG payment are estimated at \$850 million).
From Whom To Whom?	Federal Government to Hospitals.

The analysis above, together with the remainder of this preamble, provides a Regulatory Impact Analysis. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health

maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 480

Health care, Health professions, Health records, Peer Review Organizations (PRO), Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as follows:

PART 422—MEDICARE ADVANTAGE PROGRAM

1. 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 D—Quality Improvement

2. Section 422.153 is revised to read as follows:

§ 422.153 Use of quality improvement organization review information.

CMS will acquire from quality improvement organizations (QIOs) as defined in part 475 of this chapter data collected under section 1886(b)(3)(B)(viii) of the Act and subject to the requirements in § 480.140(g). CMS will acquire this information, as needed, and may use it for the following functions:

- (a) Enable beneficiaries to compare health coverage options and select among them.
- (b) Evaluate plan performance.
- (c) Ensure compliance with plan requirements under this part.
- (d) Develop payment models.
- (e) Other purposes related to MA plans as specified by CMS.

PART 480—ACQUISITION, PROTECTION, AND DISCLOSURE OF QUALITY IMPROVEMENT ORGANIZATION REVIEW INFORMATION

3. The authority citation for part 480 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart B—Utilization and Quality Control Quality Improvement Organizations (QIOs)

4. Section 480.101(b) is amended by revising the definition of “QIO review system” to read as follows:

§ 480.101 Scope and definitions.

* * * * *

QIO review system means the QIO and those organizations and individuals who either assist the QIO or are directly responsible for providing medical care or for making determinations with respect to the medical necessity, appropriate level and quality of health care services that may be reimbursed under the Act. The system includes—

- (1) The QIO and its officers, members and employees;
- (2) QIO subcontractors;
- (3) Health care institutions and practitioners whose services are reviewed;
- (4) QIO reviewers and supporting staff;
- (5) Data support organizations; and
- (6) CMS.

* * * * *

5. Section 483.130 is revised to read as follows:

§ 480.130 Disclosure to the Department.

Except as limited by § 480.139(a) and § 480.140 of this subpart, QIOs must disclose to the Department all information requested by the Department in the manner and form requested. The information can include confidential and non-confidential information and requests can include those made by any component of the Department, such as CMS.

6. Section 480.139 is amended by revising paragraph (a)(1) to read as follows:

§ 480.139 Disclosure of QIO deliberations and decisions.

(a) *QIO deliberations.* (1) A QIO must not disclose its deliberations except to—

- (i) CMS; or

(ii) The Office of the Inspector General, and the General Accounting Office as necessary to carry out statutory responsibilities.

* * * * *

7. Section 480.140 is amended by revising paragraph (a)(1) and paragraph (g) to read as follows:

§ 480.140 Disclosure of quality review study information.

(a) * * *

(1) Representatives of authorized licensure, accreditation or certification agencies as is required by the agencies in carrying out functions which are within the jurisdiction of such agencies under state law; to federal and state agencies responsible for identifying risks to the public health when there is substantial risk to the public health; or to Federal and State fraud and abuse enforcement agencies;

* * * * *

(g) A QIO must disclose quality review study information to CMS with identifiers of patients, practitioners or institutions—

(1) For purposes of quality improvement. Activities include, but are not limited to, data validation, measurement, reporting, and evaluation.

(2) As requested by CMS when CMS deems it necessary for purposes of overseeing and planning QIO program activities.

Authority: Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program.

Dated: December 10, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: December 16, 2010.

Kathleen Sebelius,

Secretary.

[FR Doc. 2011–454 Filed 1–7–11; 4:15 pm]

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Part III

Department of
Agriculture

7 CFR Parts 210 and 220

Nutrition Standards in the National School Lunch and School Breakfast
Programs; Proposed Rule

DEPARTMENT OF AGRICULTURE**Food and Nutrition Service****7 CFR Parts 210 and 220**

[FNS-2007-0038]

RIN 0584-AD59

Nutrition Standards in the National School Lunch and School Breakfast Programs**AGENCY:** Food and Nutrition Service, USDA.**ACTION:** Proposed rule.

SUMMARY: This rule proposes to revise the meal patterns and nutrition requirements for the National School Lunch Program and the School Breakfast Program to align them with the 2005 “Dietary Guidelines for Americans,” as required by the Richard B. Russell National School Lunch Act. The proposed changes are based on recommendations from the National Academies’ Institute of Medicine set forth in the report “School Meals: Building Blocks for Healthy Children.” This proposed rule would increase the availability of fruits, vegetables, whole grains, and fat-free and low-fat fluid milk in school meals; reduce the levels of sodium and saturated fat in meals; and help meet the nutrition needs of school children within their calorie requirements. Implementation of this proposed rule would result in more nutritious school meals that improve the dietary habits of school children and protect their health.

DATES: To be assured of consideration, written comments must be postmarked on or before April 13, 2011.

ADDRESSES: The Food and Nutrition Service, USDA, invites interested persons to submit comments on this proposed rule. Comments may be submitted through one of the following methods:

- *Preferred method:* Federal eRulemaking Portal at <http://www.regulations.gov>. Follow the online instructions for submitting comments.
- *Mail:* Comments should be addressed to Julie Brewer, Chief, Policy and Program Development Branch, Child Nutrition Division, Food and Nutrition Service, Department of Agriculture, 3101 Park Center Drive, Room 640, Alexandria, Virginia 22302-1594.
- *Hand Delivery or Courier:* Deliver comments to the Food and Nutrition Service, Child Nutrition Division, 3101 Park Center Drive, Room 640, Alexandria, Virginia 22302-1594,

during normal business hours of 8:30 a.m.–5 p.m.

All comments submitted in response to this proposed rule will be included in the record and will be made available to the public. Since USDA is anticipating a large volume of comments, we request that commenters submit comments through only one of the methods listed above. Please be advised that the substance of the comments and the identity of the individuals or entities submitting the comments will be subject to public disclosure. FNS will make the comments publicly available on the Internet via <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: William Wagoner or Marisol Benesch, Policy and Program Development Branch, Child Nutrition Division, Food and Nutrition Service at (703) 305-2590.

SUPPLEMENTARY INFORMATION:**I. Overview**

The 2005 “Dietary Guidelines for Americans” (referred to as the Dietary Guidelines from here on) recommend that a person’s diet supply all of the nutrients needed for growth and development, and emphasize the consumption of a variety of nutrient-dense foods. To align the meals served under the National School Lunch Program (NSLP) and the School Breakfast Program (SBP) with the 2005 Dietary Guidelines, this proposed rule would require schools to offer more fruits, vegetables and whole grains; offer only fat-free or low-fat fluid milk; reduce the sodium content of school meals substantially over time; control saturated fat and calorie levels; and minimize trans fat. These proposed changes, based on the 2009 Institute of Medicine (IOM) report “School Meals: Building Blocks for Healthy Children,” are intended to result in school meals that are nutrient-rich and supply appropriate calorie levels. This proposed rule is expected to bring about several positive outcomes:

- Update the NSLP and SBP meal requirements according to the latest nutrition science;
- Increase the availability of key food groups (fruits, vegetables, whole grains, and fat-free and low-fat fluid milk and milk products) in school menus;
- Allow the NSLP and SBP to better meet the nutritional needs of children, improve their eating habits, and safeguard their health;
- Simplify the administration and operation of the NSLP and SBP; and
- Reinforce the nutrition education messages provided by schools.

This proposed rule also alerts the public about possible additional

changes to the school meal requirements based on the upcoming 2010 Dietary Guidelines, and invites public comments on how to incorporate those possible changes into the NSLP and SBP. Three areas addressed by the advisory committee for the 2010 Dietary Guidelines that may have significant impact on the meal requirements are sodium, saturated fat, and vegetable subgroups. The “Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010” (which precedes the release of the Dietary Guidelines’ policy) recommends:

- Lower saturated fat consumption (<7% of total calories),
- Lower sodium consumption (<1500 mg per day), and
- A new red/orange vegetable subgroup.

Because the 2010 Dietary Guidelines policy was not available to IOM for consideration, USDA has decided to issue this proposed rule and seek public comments on ways to incorporate the above possible recommendations (without including them in the proposed regulatory text). Delaying the many critical updates necessary to align school meals with the 2005 Dietary Guidelines would undermine nationwide efforts to improve the health of school children. Public comments on the areas identified above are requested as part of this proposed rulemaking. USDA will also publish a notice in the **Federal Register** when the 2010 Dietary Guidelines official policy is issued to facilitate comment on how it may impact this proposal.

II. Background

The NSLP was established in 1946 upon enactment of the National School Lunch Act (NSLA), now the Richard B. Russell National School Lunch Act, to safeguard the health and well-being of the nation’s children. At that time, nutritional concerns in the United States (U.S.) centered on nutrient deficiencies and issues of under consumption. To facilitate the planning of well-balanced meals in schools across the nation, the U.S. Department of Agriculture (USDA) established meal patterns with minimum food component requirements based on nutrition science at that time. The Type A lunch, designed to provide one-third to one-half of the daily food requirements of a 10- to 12-year-old child, was the primary meal pattern for all children for the first three decades of the lunch program. This meal pattern allowed school foodservice managers to choose from a wide variety of foods, and

served as a tool for teaching children about nutrition and good eating habits.

Over time, the NSLP changed to ensure that children receive adequate nutrition for proper growth and development. The Type A lunch was updated to reflect new knowledge about the nutritional needs of children and their consumption habits. In 1975, the SBP was established as a permanent program. By 1980, USDA phased out the Type A lunch and specified different portion sizes for different age/grade groups of children.

In the late 1980s, scientific evidence showed that diets high in fat, saturated fat, and cholesterol have adverse health consequences. USDA's "School Nutrition Dietary Assessment" (SNDA-I), published in 1993, indicated that the meals served under the NSLP and SBP were effective in delivering micronutrients but exceeded recommended intakes of total fat, saturated fat, cholesterol and sodium. (See the SNDA-I report at <http://www.fns.usda.gov/oane/menu/Published/CNP/cnp-archive.htm>.) Consequently, Section 106(b) of the Healthy Meals for Healthy Americans Act of 1994, Public Law 103-448, added section 9(f)(1) to the NSLA, 42 U.S.C. 1758(f)(1), to require that school meals not only provide a percentage of the Recommended Dietary Allowances (RDAs)¹ but are also consistent with the goals of the most recent Dietary Guidelines. In 2004, the NSLA was again amended by Section 103 of the Child Nutrition and WIC Reauthorization Act of 2004, Public Law 108-265, which added Section 9(a)(4), 42 U.S.C. 1758(a)(4), requiring the Secretary to promulgate rules revising nutrition standards, based on the most recent Dietary Guidelines, that reflect specific recommendations, expressed in serving recommendations, for increased consumption of foods and food ingredients offered in school nutrition. The Dietary Guidelines reflect the current science-based consensus on proper nutrition, a vital element in promoting health and preventing chronic disease, and provide the nutritional basis for Federal domestic nutrition assistance programs such as the NSLP and SBP.

In response to section 9(f)(1) of the NSLA, USDA adopted the School Meals Initiative for Healthy Children (SMI), a comprehensive plan to promote the health of school children. On June 13,

¹ The RDAs, developed by the Food and Nutrition Board of the Institute of Medicine, reflect the average daily dietary nutrient intake levels sufficient for meeting the nutrient requirements of nearly all (97 to 98 percent) healthy individuals in particular age and sex groups.

1995, USDA issued program regulations (60 FR 31188) that required school meals to reflect the 1990 Dietary Guidelines and established three menu planning options that schools may choose from, including two methods based on computerized nutrient analysis (Nutrient Standard Menu Planning and Assisted Nutrient Standard Menu Planning) and a food-based menu planning system. On May 9, 2000, USDA issued program regulations (65 FR 26904) that further expanded the existing menu planning approaches to the five current options. At present, the five menu planning approaches are:

- The traditional and the enhanced food-based menu planning (FBMP) approaches, which follow specific meal patterns;
- The nutrient standard menu planning and the assisted nutrient standard menu planning (NSMP)² approaches, which are based primarily on a computer analysis of the nutrient and energy contributions of planned meals; and
- One alternate menu planning approach that is an individualized modification of either FBMP or NSMP.

Currently, schools using any of the five menu planning approaches must offer lunches and breakfasts that provide one-third and one-fourth, respectively, of the 1989 RDAs. Program regulations require that school meals provide at least minimum calorie and nutrient levels for protein, calcium, iron, vitamin A, and vitamin C. These are key nutrients that promote growth and development and are readily identifiable on the nutrition labels of all food products. In addition, schools must decrease the levels of sodium and cholesterol, increase the amount of dietary fiber, and limit meals to not more than 30 percent of total calories from fat and less than 10 percent of total calories from saturated fat consistent with the 1995 Dietary Guidelines. Compliance with these nutrition standards is determined by averaging nutrients in meals offered over a school week. This allows menu planners flexibility to plan nutritious and appealing meals that vary from day to day, but that provide appropriate levels of nutrients and calories over a five-day school week.

School lunches and breakfasts were not updated when the 2000 Dietary

² The NSMP approach requires a School Food Authority to conduct a weighted analysis to assess the nutrient profile of the meals selected by students. Weighted analysis gives more weight to nutrients supplied by more frequently selected food items and correspondingly less weight to nutrients supplied by items less frequently selected. This requirement is currently waived until September 30, 2010.

Guidelines were issued because those recommendations did not require significant changes to the school meal patterns.

III. Need To Revise the Nutrition and Meal Requirements

The current nutrition standards and meal requirements for the NSLP and SBP are inconsistent with the 2005 Dietary Guidelines. Further, as noted, section 9(a)(4) of the NSLA was amended in 2004 requiring that meals be consistent with the most recent Dietary Guidelines, so modifications are needed to align school meal patterns with the Dietary Guidelines. The 2005 Dietary Guidelines call for significant changes in dietary habits for persons ages 2 years and older, and emphasize the importance of a nutritious diet to maintain health and reduce the risk of chronic diseases, such as overweight and obesity. New dietary concerns have emerged since the establishment of the NSLP. The overt nutritional deficiencies in children's diets that led to the NSLP's inception have largely been eliminated. In turn, overweight and obesity are now major health concerns affecting children and adolescents. Studies indicate that excess food consumption, poor food choices, and decreased physical activity are contributing to childhood overweight and obesity, and related chronic health conditions. According to Centers for Disease Control and Prevention's 2003-2006 National Health and Nutrition Examination Survey (NHANES) data, almost 32 percent of children 6 to 19 years of age are overweight or obese. NHANES data indicate that 17 percent of children age 6-11 are obese, while 17.6 percent of adolescents age 12-19 are obese. Obese children and adolescents are at risk for health problems during their youth and as adults. They are more likely to have risk factors associated with cardiovascular disease (such as high blood pressure, high cholesterol, and Type 2 diabetes) than other children and adolescents.

A basic premise of the 2005 Dietary Guidelines is that nutrient needs should be met primarily by consuming a variety of nutrient-dense foods from the basic food groups. In comparison with the 2005 Dietary Guidelines, current school menus are not required to offer the recommended quantities of fruits, vegetables (including vegetable subgroups), and whole grains. These foods, along with low-fat fluid milk and milk products, supply many of the key nutrients of concern for children: Calcium, fiber, potassium, magnesium and vitamin E.

Current regulations also allow schools to offer whole and reduced-fat (2 percent milk fat) fluid milk as part of a reimbursable school lunch or breakfast. Those types of milk may contribute to high saturated fat in school meals. The SNDA—III report issued by USDA in 2007 indicates that less than one-third of school lunches offered in school year 2004–2005 under the current menu planning approaches met the requirement of less than 10 percent of total calories from saturated fat.

SNDA—III also shows that school lunches are high in sodium. This is consistent with IOM's findings. With regard to fiber intake, the IOM report indicates that children's consumption of whole grains is extremely low in comparison with the Dietary Guidelines recommendation that half of all grains consumed are whole grains, which are excellent sources of fiber.

Another reason for updating the school meals is that new applications for dietary planning are available. RDAs, which are currently used as the basis for requirements in the School Meal Programs, are no longer a primary value for planning the diets of groups and individuals. Beginning in 2000, IOM issued the Dietary Reference Intake (DRI) reports providing new guidance for planning dietary intakes for individuals and groups. The DRI reports for vitamins, minerals, energy, and macronutrients provide recommended intake levels aimed at improving long-term health by preventing typical nutritional deficiencies and reducing the risk of chronic disease through nutrition. The DRIs represent a more comprehensive recommendation for appropriate nutrient levels than the former RDAs and are the recommended tool for dietary planning.³

In light of the changes in nutrition science and current dietary concerns, USDA is seeking significant improvements in the NSLP and SBP to ensure that these programs continue to meet their goal to safeguard the health of school children. The changes proposed in this rule are necessary to align school lunches and breakfasts with the 2005 Dietary Guidelines and be consistent with the DRIs. Implementation of the proposed changes would amend program regulations in 7 CFR 210 for the NSLP

and 7 CFR 220 for the SBP as stated in the regulatory text.

The 2009 IOM report that serves as the basis for the nutritional provisions of this proposed rule provides recommendations for the meals planned for school-aged children only (grades K and above). This rule addresses the proposed meal requirements for school-aged children in § 210.10 and § 220.8 of the regulatory text. However, this proposed rule would retain the current meal requirements for children in preschool (ages 1–2 and 3–4) and infants pending changes to the Child and Adult Care Food Program (CACFP). Consistent with the IOM's selection of a food-based meal pattern for Kindergarten and above, this rule would allow only the traditional FBMP approach to plan meals for preschoolers. This rule allows a school serving meals to school-aged children and preschoolers to use a single menu planning approach to plan meals for all children. The meal requirements for preschoolers are addressed separately in § 210.10(p) and § 220.8(n) of the proposed regulatory text.

IV. IOM Recommendations for Implementing the 2005 Dietary Guidelines

This proposed rule seeks to update the school meals for school-aged children to align them with the 2005 Dietary Guidelines and make them consistent with the DRIs, as described in the IOM final report "School Meals: Building Blocks for Healthy Children," which was published October 20, 2009 (see the report at <http://www.nap.edu>). As recommended by IOM, this proposed rule focuses on revising the meal requirements for the NSLP and SBP. The new meal requirements seek to ensure that the meals planned by school foodservice providers and selected by students reflect the food groups emphasized by the 2005 Dietary Guidelines and meet the nutrient targets identified by IOM.

The IOM final report on school meals was issued in response to USDA's request for recommendations to align lunches and breakfasts with the 2005 Dietary Guidelines. Prior to the IOM study, USDA had explored a range of alternatives to implement the 2005 Dietary Guidelines in the School Meal Programs in a scientifically sound and practical manner. Due to the complexity of this task, USDA decided to seek help from IOM. USDA had previously sought IOM's expertise to update the food package for the Special Supplemental Nutrition Program for Women, Infants and Children and that expertise proved extremely valuable.

To conduct a review of the School Meals Programs, IOM assembled a committee of scientists in various disciplines and school foodservice professionals. The committee conducted an independent review and assessment of the nutritional needs of school-aged children in the U.S. using the 2005 Dietary Guidelines and the DRIs. The committee used that scientific review as the basis for recommending revisions to the NSLP and SBP meal requirements.

In the course of the study, IOM analyzed scientific evidence, deliberated in closed sessions, and held open meetings (July 8, 2009 and January 28, 2009) to obtain stakeholders' input. Representatives from many entities provided oral testimony, including nutrition advocates, health professionals, and many others listed in the final IOM report. In addition to the oral testimony, the committee received written comments from numerous stakeholders.

IOM issued two reports during the study. "Nutrition Standards and Meal Requirements for National School Lunch and Breakfast Programs: Phase I, Proposed Approach for Recommending Revisions" was issued December 17, 2008. The Phase I report describes the approach used by the IOM committee to make recommendations for revising the School Meal Programs. The final report "School Meals: Building Blocks for Healthy Children," dated October 20, 2009, provides the scientific basis for this proposed rule. It contains recommendations for meal requirements, nutrient targets, and implementation and monitoring. In addition, the report explains the rationale for each of the committee's recommendations and includes several appendices that provide technical justification. Appendix D of the final report provides a summary of the public comments received in response to the Phase I report.

V. Proposed Meal Requirements for NSLP and SBP

The IOM final report recommends that emphasis be placed on revising the NSLP and SBP meal requirements to align school lunches and breakfasts with the 2005 Dietary Guidelines. The IOM report addresses standards for menu planning and standards for meals as selected by the student.

Standards for Menu Planning

The proposed standards for menu planning improve the school meals' alignment with the 2005 Dietary Guidelines by offering more fruits at breakfast; increasing the amount and variety of vegetables at lunch; offering

³ The DRIs for vitamins and minerals consist of four reference standards that include the RDAs as well as Estimated Average Requirements (EAR), Adequate Intake levels (AI), and the Tolerable Upper Intake Level (UL). For energy and macronutrients, the DRIs are expressed as Estimated Energy Requirements (EERs) and Acceptable Macronutrient Distribution Ranges (AMDRs), respectively.

more whole-grain rich foods; limiting fluid milk choices to fat-free (unflavored or flavored) and unflavored fluid low-fat milk; establishing minimum and maximum calorie levels for each age/grade group; increasing the emphasis on limiting saturated fat; seeking gradual but major reductions in the sodium content; and minimizing *trans* fat. The intent of these proposed changes is to offer school meals that are nutrient-rich and calorie-appropriate.

In developing its recommendations, IOM set targets for 24 nutrients and other dietary components that serve as a scientific basis for the proposed standards for menu planning. To align the school meals with the Dietary Guidelines, the IOM committee found it necessary to consider a large number of nutrients and replace the concept of nutrition standards with a new concept of "nutrient targets." IOM established nutrient targets for the school meals based on the DRIs.

Compared to the current nutrition standards, the nutrient targets identified by IOM are higher for protein, and selected vitamins and minerals. The recommended nutrient targets were set at 32 percent of the School Meal-Target Median Intake for lunches and at 21.5 percent of the School Meal-Target Median Intake for breakfasts. (These percentages correspond to the means of the values used by IOM for the minimum and maximum calorie levels.) The Target Median Intake method combines information about a population group's nutrient requirements (Estimated Average Requirements or Adequate Intakes) and Tolerable Upper Intake Levels. The selected Target Median Intake distribution aims to minimize predicted prevalence of nutrient inadequacy and excessive intakes. (See chapter 4 of the IOM final report for additional information on the development of the nutrient targets.)

Schools would not use these 24 nutrient targets for planning or monitoring menus. Instead, they would follow the food-based meal patterns developed by IOM, as set forth in the following table. Meals that meet the proposed meal patterns and other meal requirements are expected to supply most of the nutrient targets set by IOM.

The proposed meal patterns designed by IOM and set forth in this proposed rule offer more fruits, vegetables, and whole grains consistent with the recommendations of the Dietary Guidelines. As the following table indicates, the proposed meal pattern for breakfast would consist of fruits, grains, meats/meat alternates, and fluid milk. The proposed meal pattern for lunch would consist of fruits, vegetables, grains, meats/meat alternates, and fluid milk.

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	Proposed Breakfast Meal Pattern			Proposed Lunch Meal Pattern		
	Grades K-5	Grades 6-8	Grades 9-12	Grades K-5	Grades 6-8	Grades 9-12
Meal Pattern	Amount of Food^a Per Week (Minimum Per Day)					
Fruits (cups) ^b	5 (1)	5 (1)	5 (1)	2.5 (0.5)	2.5 (0.5)	5 (1)
Vegetables (cups) ^{bc}	0	0	0	3.75 (0.75)	3.75 (0.75)	5 (1)
Dark green	0	0	0	0.5 ^d	0.5 ^d	0.5 ^d
Orange	0	0	0	0.5 ^d	0.5 ^d	0.5 ^d
Legumes	0	0	0	0.5 ^d	0.5 ^d	0.5 ^d
Starchy	0	0	0	1 ^e	1 ^e	1 ^e
Other	0	0	0	1.25 ^d	1.25 ^d	2.5 ^d
Grains ^f (oz eq)	7-10 (1)	8-10 (1)	9-10 (1)	9-10 (1)	9-10 (1)	12-13 (2)
Meats/Meat Alternates (oz eq)	5 (1)	5 (1)	7-10 (1)	8-10 (1)	9-10 (1)	10-12 (2)
Fluid milk ^g (cups)	5 (1)	5 (1)	5 (1)	5 (1)	5 (1)	5 (1)
Other Specifications: Daily Amount Based on the Average for a 5-Day Week						
Min-max calories (kcal) ^{hi}	350-500	400-550	450-600	550-650	600-700	750-850
Saturated fat (% of total calories) ^h	< 10	< 10	< 10	< 10	< 10	< 10
Sodium (mg) ^j	≤ 430	≤ 470	≤ 500	≤ 640	≤ 710	≤ 740
<u>Trans</u> fat	Nutrition label or manufacturer specifications must indicate zero grams of <u>trans</u> fat per serving.					

^aFood items included in each group and subgroup and amount equivalents. Minimum serving is 1/8 cup.

^bOne cup of fruits and vegetables usually provides 2 servings; 1/4 cup of dried fruit counts as 1/2 cup of fruit; 1 cup of leafy greens counts as 1/2 cup of vegetables. No more than half of the fruit offerings may be in the form of juice. All juice must be 100% full-strength.

^cFor breakfast, 1/2 cup of non-starchy vegetables may be considered equivalent to 1/2 cup fruits.

^dLarger amounts of these vegetables may be served.

^eA maximum of 1 cup of starchy vegetables may be served per week. Starchy vegetables include white potatoes, corn, green peas, and lima beans.

^fUpon implementation, at least half of grains must be whole grain-rich. Aiming for a higher proportion of whole grain-rich foods is encouraged. Two years post implementation, all grains must be whole grain-rich.

See http://teammnutrition.usda.gov/Resources/DGfactsheet_grains.pdf

http://www.fns.usda.gov/tn/HealthierUS/HUSSCkit_pp25-35.pdf

^gFluid milk must be low-fat (1 percent milk fat or less, unflavored) or fat-free (unflavored or flavored).

^hThe average daily amount for a 5-day school week is not to be less than the minimum or exceed the maximum.

ⁱDiscretionary sources of calories (solid fats and added sugars) may be added to the meal pattern if within the specifications for calories, saturated fat, trans fat, and sodium. Foods of minimal nutritional value and fluid milk with fat content greater than 1 percent milk fat are not allowed.

^jSodium targets are to be reached 10 years after implementation of the final rule. Intermediate targets have been established to ensure that action to reduce the sodium content of school meals over the 10-year period maintains student participation rates.

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The greatest change in breakfast foods is the increase in fruits, which doubles from the current requirement. In addition, grains increase by nearly 80

percent over current levels, with a shift to whole grains. For lunch, the greatest change is the increase in fruits and vegetables, an increase of nearly four half-cup servings a week. The following

tables compare the types and amounts of foods required under the current and the proposed meal patterns for breakfast and lunch.

CHANGES IN MINIMUM AMOUNTS AND TYPES OF FOOD: BREAKFAST

	Current requirement	Proposed requirement
Fruit	1/2 cup per day	1 cup per day.
Grains and Meat/Meat Alternate	2 grains or 2 meat/meat alternates or 1 of each per day.	1.4–2 grains per day plus: 1–2 meat/meat alternates per day. (Range reflects difference by grade group.)
Whole Grains	Encouraged	At least half of the grains to be whole grain-rich.
Milk	1 cup	1 cup, fat content of milk to be 1% or less.

CHANGES IN MINIMUM AMOUNTS AND TYPES OF FOOD: LUNCH

	Current requirement	Proposed requirement
Fruit and Vegetables	1/2–1 cup of fruit and vegetables combined per day	3/4–1 cup of vegetables plus 1/2–1 cup of fruit per day.
Vegetables	No specifications as to type of vegetable	Weekly requirement for dark green and orange vegetables and legumes and limits on starchy vegetables.
Meat/Meat Alternate	1.5–3 oz equivalents (daily average over 5-day week).	1.6–2.4 oz equivalents (daily average over 5-day week).
Grains	1.8–3 oz equivalents (daily average over 5-day week).	1.8–2.6 oz equivalents (daily average over 5-day week).
Whole Grains	Encouraged	At least half of the grains to be whole grain-rich.
Milk	1 cup	1 cup, fat content of milk to be 1% or less.

USDA recognizes that these proposed changes are significant and may pose a particular challenge to implement. We solicit comments on how these changes may affect take-up and participation rates.

Menu Planning Approach and Age/Grade Groups

The 2005 Dietary Guidelines stress the importance of increasing the consumption of key food groups: Fruits, vegetables, whole grains, and fat-free/low-fat fluid milk or milk products. Consistent with the Dietary Guidelines' emphasis on food groups, IOM developed a food-based meal pattern for each of the School Meal Programs. This proposed rule would require that all schools follow a food-based menu planning approach to plan school lunches and breakfasts for all children. No alternate menu planning approaches would be allowed.

Currently, approximately 70 percent of schools use the FBMP approach. Using a single FBMP approach would simplify program management, training, and monitoring by State agencies (SAs). It would also give schools a practical and easy tool to plan well-balanced and nutritious meals. More importantly, this change would ensure that all school children participating in the NSLP and SBP nationwide have access to more healthy foods in key food groups that contribute to a nutritious diet and protect health.

Another change proposed in this rule involves the age/grade groups used for menu planning. Today, childhood overweight and obesity are major public health concerns. To avoid excessive calories and provide age-appropriate meals, new age/grade groups recommended by IOM would be established. All schools would be required to use the following age/grade groups to plan lunches and breakfasts:

- Grades K–5 (ages 5–10 years)
- Grades 6–8 (ages 11–13 years)
- Grades 9–12 (ages 14–18 years)

These age/grade groups are consistent with the current age-gender categories used in the DRIs and with widely used school grade configurations. Use of these age/grade groups would enable schools operating under a food-based menu planning system to provide meals that meet the nutrition needs of school children in various grade groups and are conducive to healthy weight.

IOM recognizes that some schools have different grade configurations and numerous logistical problems that may interfere with the reasonable use of the proposed age/grade groups. Those schools would be allowed to use the same breakfast and lunch meal patterns for students in grades K through 8 as food quantity requirements for the proposed age/grade group K–5 and 6–8 are comparable. However, schools choosing to use one meal pattern for students in these two age/grade groups would continue to be responsible for meeting the calorie, saturated fat, and

sodium standards for each of the proposed age/grade groups. This would mean meals would have to meet very precise targets for calories and sodium.

For example, a school could offer all students in grade groups K–5 and 6–8 the same breakfast choices for the fruit, meat/meat alternate, and milk components because the quantity requirements are the same. The requirements for the grains component are not the same but they overlap (for grades K–5 is 7–10 oz eq per week, and for grades 6–8 is 8–10 oz eq per week). A school could offer 8–10 oz eq per week to meet the requirements for both grade groups. Similarly, the calorie requirements for grades K–5 (350–500 average calories per week) and grades 6–8 (400–550 average calories per week) overlap. Therefore, a school could offer both grade groups a range of 400–500 average calories to meet the requirement for each grade group. While the saturated fat and trans fat requirement are the same for both grade groups, the school must carefully consider the sodium requirements. The school would have to comply with a standard of <430 mg, which was developed for grades K–5, but would also meet the requirement for students in grades 6–8.

USDA acknowledges that schools offering the SBP may face barriers when grouping students by age/grade group for breakfast service. Children typically participate in the breakfast service as they arrive at school, rather than by grade level. In addition, some schools

provide breakfasts by methods such as “grab-and-go breakfasts” from kiosks. In instances where schools serve K–12 students on the same line, the IOM committee suggests that the SFA work with the SA to find a solution that ensures that basic elements of the meal requirements are maintained: Inclusion of required food components and food subgroups, moderate calorie levels, and an emphasis on reducing saturated fat and sodium. USDA will provide technical assistance to the SAs to assist them with this issue. Schools in these situations have the option to serve breakfast in the classroom to each grade group, use one meal pattern for grades K to 8 that meets the standards for each age/grade group, or work with the SA to find a feasible solution that meets the meal requirements.

Fruits and Vegetables

The proposed food-based meal patterns for the NSLP and SBP were designed by IOM to improve the nutrient density of school meals and the nutrient intake by students, especially with regard to nutrients of concern. The proposed meal patterns offer fruits and vegetables as separate components and increase the quantities of these key food groups to promote children’s intake of fiber and other important nutrients such as potassium and magnesium.

To facilitate school’s compliance with the fruits requirement, schools would be allowed to offer fruit that is fresh, frozen without sugar, dried, or canned in fruit juice, water, or light syrup. To confer fiber benefits, it is important to meet the fruits component with whole fruit whenever possible. However, schools would be able to offer pasteurized, full-strength (100 percent) fruit juice, as currently defined, to meet up to one-half of the fruits requirement. Products that contain less than 100 percent juice would not be allowed. The volume of products that would be necessary to meet the fruits requirement may be relatively large for consumption by children and can displace the intake of nutrient-rich foods in the meal. Requiring 100 percent fruit juice in the NSLP would be consistent with the current requirements in the SBP and the Child and Adult Care Food Program.

For breakfast, schools would have the option to offer non-starchy vegetables in place of fruits. For some schools, vegetables may be more affordable than whole fruit. For example, schools may add tomatoes and green peppers to a breakfast omelet or a breakfast burrito.

In addition to establishing fruits and vegetables as separate food components in the NSLP, this proposed rule would require that schools offer specific

vegetable subgroups at lunch over the school week to encourage variety in children’s diets. Schools would be required to offer weekly at lunch at least ½ cup equivalent of each of the following vegetable subgroups: Dark green, orange, and legumes (dry beans). As recommended by IOM, starchy vegetables (e.g., white potatoes, corn, lima beans, and green peas) would be limited to 1 cup per week to encourage students to try new vegetables in place of the familiar starchy ones. In addition, schools would be allowed to offer other vegetables (as defined in Appendix A–2 of the 2005 Dietary Guidelines) over the course of the week as specified in the proposed meal pattern. Schools using canned vegetables would have to select products with low sodium to stay within the proposed sodium limits.

Whole Grains

The Dietary Guidelines recommend that all age groups consume at least half their grains as whole grains.⁴ In light of concerns such as whole grain product availability, product labeling, and student acceptability, IOM recommends the following staged approach to align school meals with the Dietary Guidelines’ whole grains recommendation:

- Upon implementation of the proposed rule, at least half of the grains servings offered in the NSLP and SBP should be whole grain-rich.⁵
- Within three years post-implementation, menu planning standards should be revised so that the proportion of whole grains to refined grains will exceed 50 percent.

This proposed rule is consistent with IOM’s recommended temporary criterion for whole grain-rich foods, which encompasses the HealthierUS School Challenge criteria. However, this rule slightly modifies IOM’s suggested timeline to minimize the frequency of changes to menus and vendor requirements. This proposed rule would

⁴ *Whole grains* are (1) grain foods whose grain ingredients are whole grains only (100 percent whole grains), or (2) whole grain ingredients, such as rye flour, and whole wheat flour. (Virginia A. Stallings, Carol West Suito, and Christine L. Taylor, Editors; Committee on Nutrition Standards for National School Lunch and Breakfast Programs; Institute of Medicine. *School Meals: Building Blocks for Healthy Children*.)

⁵ *Whole grain-rich foods* may contain less than 100 percent whole grains but, generally, contain at least 51 percent whole grains. IOM’s recommended criterion requires that whole grain-rich foods meet serving size requirements defined in the Grains/Breads Instruction for Child Nutrition Programs, and can be easily identified as containing at least 51 percent whole grains. Please see Box 7–1 in the IOM report for details on the recommended temporary criterion for *whole grain-rich foods* (available at: http://books.nap.edu/openbook.php?record_id=12751&page=124).

align the whole grains implementation timeline with the phased-in sodium reductions. Therefore, this proposed rule would implement the IOM whole grains recommendation as follows:

- Upon implementation of the final rule, half of the grains offered during the school week must be whole grain-rich.
- Two years post-implementation of the final rule, all grains offered during the school week must be whole grain-rich.

The IOM report also recommends that the FDA take action to require labeling for the whole grain content of food products. USDA will provide support to FDA to help implement the labeling recommendation. In the interim, the criteria used to identify whole grain-rich foods served in school meals would be established in FNS guidance, and could be revised in policy as more information becomes available on the food label by the voluntary addition of whole grain information by industry or by FDA action to require labeling for the whole grain content of food products. USDA will also work with industry and other stakeholders to ensure that program operators can identify and purchase whole grains.

IOM expects that the availability of whole grain-rich products will increase over time nationwide. At the Federal level, USDA commodity foods (now known as USDA Foods) will continue to expand the list of whole grain products available to schools. USDA Foods now include brown rice, and whole grain tortillas, pancakes, and pasta. In addition, USDA will issue an updated Grains/Breads Instruction and develop practical guidance to help schools incorporate more whole grain-rich products into school menus.

This proposed rule would continue to allow schools the option to meet part of the weekly grains requirement with a grain-based dessert. Up to one serving per day of a grains-based dessert would be allowed as part of the grains component. When offered in moderation, grain-based desserts may present an opportunity to add variety to the grains component, incorporate more whole grains into the menu, and encourage student participation. Schools would need to refer to the Grains/Breads Instruction to identify creditable grain-based desserts.

To accommodate cultural food preferences and due to product availability concerns, current regulations allow schools in outlying areas (American Samoa, Puerto Rico, and the Virgin Islands) to serve a vegetable such as yams, plantains, or sweet potatoes to meet the grains requirement. This proposed rule would

continue to permit this meal pattern exception.

Meats/Meat Alternates

The Dietary Guidelines recommend selecting and preparing lean meat and poultry, or low-fat and fat-free meat alternates, and limiting the intake of saturated fats, *trans* fat, and cholesterol. The meal pattern designed by IOM includes meats and meat alternates (such as beans, cheese, whole eggs, nuts, seeds, peanut butter, other nut or seed butters, and yogurt) and the recommendation to control saturated fat and *trans* fat. To meet this food component as well as the dietary specifications for saturated fat and *trans* fat, schools would have to offer lean meats/meat alternates. The use of processed meats would be discouraged because those available at this time are usually high in sodium. If offered, processed meats would have to be low in fat. USDA guidance and technical assistance materials will emphasize strategies for purchasing, planning, and preparing lean meats/meat alternates.

As currently done, the quantity of meats/meat alternates offered daily could vary if at least a minimum amount (1 ounce) is provided daily and the total offered over the school week meets the weekly component requirement. This proposed rule would also retain the current requirement that all creditable meats/meat alternates be offered in the main dish or as part of the main dish and up to one other food item other than a dessert.

USDA is aware of a growing interest to expand the list of allowable meat alternates to include tofu, a whole soybean food. We recognize that soybean foods are increasingly being incorporated in the American diet as nutrient-dense meat alternatives. This rule is not proposing to credit commercially prepared tofu as an allowable meat alternate at this time. However, USDA is interested in receiving comments from the child nutrition community proposing a methodology that could be used for crediting commercially prepared tofu.

A longstanding concern regarding tofu is the lack of an FDA standard of identity. An FDA standard of identity defines what a given food product is, its name, and the ingredients that must be used or may be used in the manufacture of the food product. Without a standard of identity, USDA cannot assure nutritional consistency across brands and types of tofu in a food-based menu planning approach. Although tofu does not have a standard of identity, the USDA National Nutrient Database for Standard Reference, Release 22 (2009)

provides nutrient profiles for different types of tofu.

Other soy-based products are currently allowed as alternate protein products (APP) if they meet the requirements in Appendix A to 7 CFR part 210, and Appendix A to 7 CFR part 220. Examples of allowable APPs include products that are formulated with ingredients such as soy concentrates, soy isolates, soy flours, whey protein concentrate, or casein. Tofu is not an allowable APP because it does not meet the established minimum requirement to consist of at least 18 percent protein by weight when fully hydrated or formulated.

Fluid Milk

As recommended by IOM, only fat-free fluid milk (unflavored or flavored) and unflavored low-fat fluid milk (1 percent milk fat or less) would be allowed in the School Meal Programs in order to reduce the saturated fat and calorie content of school meals. Flavored low-fat fluid milk would not be allowed because it increases both saturated fat and calories. However, flavored fat-free fluid milk would be allowed because calcium is a nutrient of concern for children and the use of flavors to encourage children to drink more fluid milk could help mitigate this problem. USDA anticipates that the proposed calorie maximum would drive schools to select flavored fat-free fluid milk with the lowest sugar content.

This proposed rule would no longer allow schools to offer whole milk or reduced-fat (2 percent milk fat) fluid milk as part of the reimbursable meal. This rule would also remove the existing regulatory requirement that schools offer milk in a variety of fat content. Section 203 of the Healthy, Hunger-Free Act of 2010, which amended the NSLA, requires that schools offer a variety of milk consistent with the Dietary Guidelines recommendations.

Calories, Saturated Fat, Sodium, and Trans Fat

Because the proposed meal pattern alone cannot ensure appropriate amounts of calories, saturated fat, sodium and *trans* fat, IOM recommended specific standards for these dietary components. This proposed rule would implement the IOM-recommended standards for calories, saturated fat, sodium, and *trans* fat as follows:

Calories

When recommending the calorie levels that should be provided by school meals, the IOM committee was mindful

of the childhood obesity trend and the food choices available to school children outside of the NSLP and SBP. The committee recommended minimum and maximum calories for lunches and breakfasts based on evidence about children's intakes at meals and snacks. The proposed minimum and maximum calorie levels to be required for each age grade group on average over the course of the week are:

LUNCH—PROPOSED MINIMUM AND MAXIMUM CALORIE LEVELS

Grades K–5	Grades 6–8	Grades 9–12
550–650	600–700	750–850

^aThe average daily amount for a 5-day school week is not to be less than the minimum or exceed the maximum.

^bDiscretionary sources of calories (solid fats and added sugars) may be added to the meal pattern if within the specifications for calories, saturated fat, *trans* fat, and sodium.

BREAKFAST—PROPOSED MINIMUM AND MAXIMUM CALORIE LEVELS

Grades K–5	Grades 6–8	Grades 9–12
350–500	400–550	450–600

^aThe average daily amount for a 5-day school week is not to be less than the minimum or exceed the maximum.

^bDiscretionary sources of calories (solid fats and added sugars) may be added to the meal pattern if within the specifications for calories, saturated fat, *trans* fat, and sodium.

The intent of this proposed change is not to reduce children's intake of food, but to avoid excessive calories. The meal patterns proposed in this rulemaking would require increased amounts of fruits, vegetables, and whole grains. Combined with calorie maximums, USDA believes that these increased food requirements leave relatively few discretionary calories for fats and added sugars. Therefore, to stay within the calorie ranges specified in this proposed rule, schools would have to offer lean meats/meat alternates, fat-free or low-fat fluid milk, and other nutrient-dense foods, as recommended by the 2005 Dietary Guidelines.

While the 2005 Dietary Guidelines do not recommend discrete limits on added sugars, they do encourage the consumption of foods and beverages low in added sugars.

Saturated Fat

The 2005 Dietary Guidelines continue to recommend that all individuals consume less than 10 percent of total calories from saturated fat. This is the current standard in both the NSLP and SBP and this proposed rule would retain it as recommended by IOM.

Schools have made a recognizable effort to reduce the saturated fat levels of meals. SNDA-III data indicate that, on average, three-quarters of schools offered breakfasts that met the requirement to provide less than 10 percent of total calories from saturated fat. At lunch, however, only one-third of schools offered meals that met this required level.

A variety of food sources contribute to saturated fat levels in school meals; however, fluid milk is a primary contributor. As stated earlier, this proposed rule would no longer allow schools to offer whole fluid milk or reduced-fat fluid milk as part of a reimbursable lunch or breakfast for children ages five and older. To meet the new statutory requirement that schools offer a variety of milk consistent with the Dietary Guidelines (established by the Healthy, Hunger-Free Act of 2010), schools would have to offer

students at least two fluid milk options. For example, schools could offer fat-free milk (both unflavored and flavored), or fat-free milk (unflavored and/or flavored) along with low-fat milk (unflavored). By limiting the choices to fat-free and low-fat milk, schools would limit saturated fat in the school meals while maintaining key nutrients for growth and development found in fluid milk.

Sodium

Reducing the sodium content of school meals is one of the key objectives of this proposed rule. Research suggests that modest population-wide reductions in dietary salt could substantially reduce cardiovascular events and medical costs (see, for example, Smith-Spangler, 2010; Bibbins-Domingo, 2010). More specifically, a forthcoming study suggests that reducing dietary salt in adolescents could yield substantial

health benefits by decreasing the number of teenagers with hypertension and the rates of cardiovascular disease and death as these teenagers reach young and middle age adulthood (Bibbins-Domingo, 2010b).

USDA has encouraged schools to reduce sodium since the implementation of SMI in 1995. According to the SNDA-III study, the average sodium content of school lunches (for all schools) is more than 1400 mg. IOM recommended a gradual but significant reduction in sodium over time and suggested that USDA establish intermediate targets to help schools progress to the final sodium standards developed by the IOM expert committee for each age/grade group. This proposed rule would require that schools meet the final sodium standards established by IOM no later than ten years after the final rule is implemented by reaching intermediate sodium targets as follows:

Proposed Sodium Reduction: Timeline & Amount					
Age/Grade Group	Baseline: Current Average Sodium Levels As Offered¹ (mg)	Target 1: 2 years from implementation of final rule (mg)	Target 2: 4 years from implementation of final rule (mg)	Final Target²: 10 years from implementation of final rule (mg)	% Change (Current Levels vs. Final Targets)
School Breakfast Program					
K-5	573 (elementary)	≤ 540 (28.4% of UL)	≤ 485 (25.5% of UL)	≤ 430 (22.6% of UL)	-25%
6-8	629 (middle)	≤ 600 (27.3% of UL)	≤ 535 (24.3% of UL)	≤ 470 (21.4% of UL)	-25%
9-12	686 (high)	≤ 640 (27.8% of UL)	≤ 570 (24.8% of UL)	≤ 500 (21.7% of UL)	-27%
School Lunch Program					
K-5	1,377 (elementary)	≤ 1,230 (64.8% of UL)	≤ 935 (49.2% of UL)	≤ 640 (33.7% of UL)	-54%
6-8	1,520 (middle)	≤ 1,360 (61.8% of UL)	≤ 1,035 (47.0% of UL)	≤ 710 (32.3% of UL)	-53%
9-12	1,588 (high)	≤ 1,420 (61.7% of UL)	≤ 1,080 (47.0% of UL)	≤ 740 (32.2% of UL)	-53%

¹Current Average Sodium Levels as Offered are from the School Nutrition and Dietary Assessment Study-III. Data were collected in the 2004-05 school year.

²The IOM final targets are based on the Tolerable Upper Intake Limits (ULs) for sodium, established in the Dietary Reference Intakes (DRI) (IOM, 2004). The sodium ULs for school-aged children are 2,300 mg (ages 14-18), 2,200 mg (ages 9-13), and 1,900 mg (ages 4-8). The final sodium targets represent the UL for each age/grade group multiplied by the percentage of nutrients supplied by each meal (approximately 21.5% for breakfast, 32% for lunch), as recommended by IOM. IOM's recommended final sodium targets for the K-5 age/grade group breakfasts and lunches are slightly higher than 21.5% and 32%, respectively, of the UL because this proposed elementary school group spans part of two DRI age groups (ages 4-8 and 9-13 years).

USDA recognizes that there are barriers to reducing the sodium content of meals to the levels recommended by IOM without having an impact on student acceptance and participation, practicality, and cost. The proposed intermediate sodium targets were developed after carefully reviewing scientific literature, consulting with U.S. and international public health professionals involved in sodium reduction efforts, and applying information from expert presentations by industry representatives at the IOM Strategies to Reduce Sodium Intake information gathering session in March 2009. Findings showed that school menu planners can reduce sodium by approximately 10 percent through menu modification. Industry can reduce sodium in school food products by approximately 20 to 30 percent using current technology. The remaining reduction requires innovation.

Establishing intermediate targets was complicated because two intermediate targets set at 10 percent and 20 percent reductions from baseline levels yield reductions for school breakfasts beyond IOM recommendations (school breakfasts require a sodium reduction of approximately 25 percent). If applied to school breakfasts, this strategy also places a disproportionate responsibility for reduction on school menu planners. Industry reductions and innovation necessary to meet school lunch targets will affect all foods served in all school meals, and the intermediate targets must account for this and distribute reductions required more evenly across the 10-year period. Therefore, simply applying 10 percent and 20 percent reductions to baseline levels was not an ideal way to establish intermediate targets.

Instead, USDA applied the same proportional reductions (20 percent and 40 percent, respectively, for the first and second intermediate targets) to the total amount of sodium reduction required for each age/grade group. This method distributes reductions more evenly across the 10-year period and yields reasonable intermediate targets that align with feasible reductions for menu planners (approximately 10 percent) and industry (approximately 20–30 percent), and sodium reduction efforts currently underway.

Taking baseline measures from SNDA III, intermediate targets were established two years and four years post-implementation to initiate change using current resources:

(1) Two years post implementation of the final rule, schools would need to reduce sodium in school lunches by approximately 5–10 percent from

baseline levels (SNDA–III). This is the estimated amount that schools can reduce sodium through menu and recipe modification using currently available foods and technology.

(2) Four years post implementation of the final rule, schools would need to reduce sodium by approximately 15–30 percent from the baseline. This is the estimated amount industry can reduce sodium in foods using currently available technology.

(3) Ten years post implementation of the final rule, school lunches would need to meet the final targets recommended by IOM. This would require schools to reduce sodium in school meals by approximately 25–50 percent from the baseline. A significant amount of time is allotted for this final reduction, which will likely require innovation, such as new technology and/or food products.

These reductions are consistent with public health initiatives aiming to reduce sodium in the nation's food supply over the next 10 years, or a reduction of approximately 5 percent per year. Such reductions are widely supported by the American Public Health Association and by efforts such as New York City's National Sodium Reduction Initiative.

Nearly all schools would need to reduce the sodium content of school meals to meet the proposed intermediate and final sodium targets. The changes necessary will vary by school/district because currently there is no sodium limit for school meals and each school/district will be starting from a different baseline. Schools can use SMI data or review their meals to determine changes needed to meet the sodium targets.

It is important to note that approximately 75 percent of the sodium in foods consumed in the U.S. comes from salt (sodium chloride) added to processed foods. Processed foods and convenience items are often used in the school food service operation to save time and labor. Gradual implementation of the sodium restriction is intended to give schools and industry time to lower the sodium content of the foods used in the school meals.

The availability of high sodium foods in and outside of the School Meal Programs has resulted in a preference for salty foods at a young age. The proposed intermediate standards should help children reduce their salt preference and develop healthier eating habits. However, a simultaneous reduction of sodium levels in foods available outside the NSLP would be important to foster a change in students' taste preference.

USDA plans to develop practical guidance and technical assistance resources to help schools achieve the proposed sodium standards while avoiding a negative impact on student participation. USDA resources would also emphasize strategies for increasing potassium in schools meals. Adequate potassium intake can help offset some of the adverse health effects of high sodium levels.

USDA will continue to make low-sodium USDA Foods available to schools. USDA has targeted specific commodities to be made available at lower sodium levels, including canned items (beef, pork, poultry, salmon, and tuna), chicken fajita strips, and ready-to-eat cereal. Most commodity canned vegetables already meet FDA's requirements for use of the term "healthy," which means that, in addition to meeting other requirements, these foods contain no more than 480 mg sodium per labeled serving. USDA plans to gradually phase-in low sodium canned vegetables for donation to all of the domestic nutrition assistance programs. USDA Foods now offer low sodium canned tomato products and canned dry beans. In school year 2010, the sodium levels in all USDA canned vegetables are being reduced to 140 mg per serving.

While the proposed regulatory requirements discussed above are in line with the 2005 Dietary Guidelines and the IOM final sodium targets, USDA acknowledges further reductions in recommended sodium levels are possible in the upcoming 2010 Dietary Guidelines. The 2010 "Dietary Guidelines Advisory Committee Report" recommends that both children and adults should reduce their sodium intake to 1,500 mg per day (compared to the 2,300 mg per day recommended in the 2005 Guidelines).

USDA is seeking public comment on how to address further reductions in recommended sodium levels, in the event that the 2010 Dietary Guidelines include sodium targets lower than those reflected in this proposed rule. USDA invites public comments on how possible further reductions could be incorporated into the NSLP and SBP, including the timeline for achieving reductions; how intermediate targets, if any, should be established; and the impact that further reductions may have on participation levels, implementation feasibility, and costs.

Tracking Calories, Saturated Fat, and Sodium

Under this proposal, all schools would plan lunches and breakfasts using the food-based meal patterns

developed by IOM. Similar to the current FBMP system, schools would be responsible for offering meals that meet the meal pattern, as well as specific standards for calories, saturated fat, and sodium for each age/grade group on average over the school week. However, this rule would not require that schools conduct a nutrient analysis to determine compliance with the standards for calories, saturated fat, and sodium. SAs would be responsible for monitoring compliance with these three dietary specifications in schools selected for administrative reviews. (Currently, SAs conduct nutrient analysis for FBMP schools to determine the levels of eleven dietary specifications (calories, protein, vitamin A, vitamin C, iron, calcium, total fat, saturated fat, sodium, cholesterol, and dietary fiber). This proposal would support IOM's recommendation to limit and monitor calories, saturated fat, and sodium in school meals without burdening schools or SAs.

Although not required, schools that have the resources to conduct a nutrient analysis would be able to continue to do so to assess how well they are meeting calorie, saturated fat, and sodium standards. SNDA III found that, in school year 2004–2005, about two-thirds of schools were in districts that conducted ongoing nutrient analysis of their menus. This finding suggests that many districts have the capability to conduct nutrient analysis.

USDA intends to develop practical tools to help schools calculate the levels of calories, saturated fat, and sodium in school meals. The SAs are encouraged to develop practical calculation methods and provide technical assistance to schools when they are developing school menus to help align the planned meals with these three dietary specifications.

Trans fat

This proposed rule would require schools to minimize *trans* fat in school meals to be consistent with the 2005 Dietary Guidelines. The IOM report provides a practical method to minimize the *trans* fat content of school meals. To help schools reach the goal of zero grams of *trans* fat per serving, IOM recommended that schools only be allowed to use food products or ingredients that contain zero grams of *trans* fat per serving, as indicated on the nutrition label (FDA defines zero as less than 0.5 grams per serving) or manufacturer's specifications. Foods that contain minimal amounts of naturally-occurring *trans* fat (such as beef and lamb) would be excluded from this requirement. Schools would also be

required to add the *trans* fat specification and request the necessary documentation in their procurement contracts.

If a product or ingredient used to prepare school meals has no nutrition labeling (e.g., institutional products) schools would be responsible for obtaining information, such as manufacturer or nutrition specifications, that confirms that the product contains zero grams of *trans* fat per serving. The *trans* fat information would be examined during an administrative review.

Standards for Meals Selected by the Student (Offer Versus Serve)

To achieve a reasonable balance between the goals of reducing food waste and preserving the nutritional integrity of school meals, the IOM committee recommended standards for meals as selected by the student. The committee formulated two offer versus serve options: A preferred option and a secondary option.

Under IOM's preferred option, a student may decline 1 food item at breakfast but must select 1 fruit or juice. For lunch, the student may decline 2 food items but must select 1 fruit or vegetable.

The secondary option formulated by IOM also requires the student to select 1 fruit or juice at breakfast and 1 fruit or vegetable at lunch but allows the student to decline more food items. Under the secondary option, the student may decline 2 food items at breakfast and 3 food items at lunch.

Although both options formulated by IOM promote the selection of fruits and vegetables, the preferred option is more conducive to preserving the nutritional integrity of the school meal. We are concerned that the secondary option allows the student to decline more food items than the current offer versus serve regulations. Therefore, this proposed rule would adopt IOM's preferred option for offer versus serve with a slight modification that would allow a reimbursable breakfast to include a serving of fruit or a vegetable offered in place of fruit:

- Student may decline 1 food item at breakfast but must select 1 fruit or vegetable.
- Student may decline 2 food items at lunch but must select 1 fruit or vegetable.

This slight modification is consistent with the Dietary Guidelines emphasis on increasing the consumption of fruits and vegetables.

Offer versus serve would be required at the high school level, as is currently the case, and it would continue to be

available to middle and elementary schools at the discretion of the SFA or the SA.

Summary of Proposed Meal Requirements

Implementation of the proposed meal requirements (standards for menu planning and standards for meals selected by the student) would affect the following changes in the NSLP and SBP:

- On a daily basis:
 - Meals offered to each age/grade group would meet the meal pattern designed by IOM;
 - Fluid milk offered would be fat-free (unflavored or flavored) or unflavored low-fat (1 percent milk fat or less) and would include variety that is consistent with the Dietary Guidelines;
 - Food products and ingredients used to prepare school meals would contain zero grams of *trans* fat per serving (less than 0.5 grams per serving) according to the nutrition labeling or manufacturer's specifications; and
 - Meals selected by the students would include at least a fruit or vegetable, and students would not be able to decline more than two food items at lunch and one food item at breakfast.

- Over a 5-day school week:
 - Average calorie content of the meals offered to each age/grade group would fall within the minimum and maximum calorie levels specified by IOM;
 - Average saturated fat content of the meals offered to each age/grade group would be less than 10 percent of total calories; and
 - Average sodium content of the meals offered to each age/grade group would meet the intermediate targets established by USDA and not exceed the maximum level specified by IOM ten years post implementation of the final rule.

This proposed rule includes several existing meal requirements that are restated without change in the proposed regulatory language. Such requirements include the provisions on meal choices, lunch periods, meal exceptions and variations, and fluid milk substitutes. In addition, some requirements for specific food components, such as meats/meat alternates, are retained in the proposed regulatory text.

The meal patterns and nutrition standards for preschoolers and infants also remain unchanged; however, only the traditional FBMP approach would be allowed to plan meals for preschoolers. The State agencies would not be required to analyze the menus for preschoolers pending changes to the CACFP regulations.

Proposed Changes in Monitoring Procedures

This proposed rule would establish new procedures for monitoring implementation of, and compliance with, the new meal requirements and the dietary specifications for calories, saturated fat, sodium, and *trans* fat. As recommended by IOM, monitoring would focus on meeting the relevant Dietary Guidelines through the proposed meal requirements. The new monitoring procedures would also allow the opportunity to provide information and technical assistance to school foodservice staff for continuous quality improvement.

Currently, SAs conduct two reviews to ensure compliance with program requirements. The SMI nutrition review assesses the nutritional quality of school meals. The Coordinated Review Effort (CRE) focuses on eligibility certification, meal counting and claiming, and meal elements. This proposed rule would discontinue the SMI reviews under § 210.19 and strengthen CRE administrative reviews under § 210.18 to enable SAs to monitor the quality of school meals and assist schools in continually improving performance. As part of the CRE Performance Standard 2, the SAs would be required to monitor compliance with the meal patterns, including ensuring that sufficient quantities of each component are offered. The SAs would also be responsible for calculating the levels of calories, saturated fat, and sodium for the meals offered by the school(s) selected for review and ensuring that the food products and ingredients used to prepare school meals contain zero grams of *trans* fats. To accomplish this, the following changes are proposed:

(1) *Establish a three-year review cycle*—The IOM report recommends frequent monitoring to assess how well the new meal requirements are being implemented at the local level. This proposed rule would expand the ability of the SAs to monitor the quality of the meals offered at the local level by changing the review cycle from 5 years to 3 years, and by requiring SAs to monitor compliance with the meal pattern and the requirements for calories, saturated fat, sodium, and *trans* fats. More frequent monitoring would also expand opportunities to provide technical assistance and mentoring to local operators as recommended by IOM.

(2) *Establish a two-week review period*—In order to give the SAs a more complete view of the meals offered at the local level, this proposed rule would expand the review period from one to

two weeks. SAs would review menu and production records for a two-week period to assess compliance with the meal pattern; conduct a weighted nutrient analysis to determine the average levels of calories, sodium, and saturated fat in the planned meals; and confirm that food products and ingredients used to prepare school meals contain zero grams of *trans* fat.

(3) *Include breakfasts in the CRE review*—This proposed rule would require SAs to review the breakfast meal during the 2-week CRE review. Due to the many important meal requirements that IOM recommended for both the NSLP and the SBP, USDA believes that it is desirable to monitor the quality of breakfasts as part of the CRE review.

In addition, SAs would continue to monitor the serving line and lunches counted at point of service to determine if the meals offered and selected the day of the onsite review contain the required food components and food quantities. If food quantities offered by the reviewed school appear to be insufficient or excessive, SAs would provide technical assistance and guidance, apply corrective action, and follow up to assess improvement in the quality of meals. The on-site visit, the nutrient analysis, and other information obtained from direct observation during the review period would give the SA a comprehensive view of the quality of the school meals and compliance with the meal requirements.

USDA anticipates that the State monitoring activities will focus on technical assistance and corrective action following implementation of the new meal requirements. As currently done, SAs would be required to apply immediate fiscal action if the meals offered are completely missing one of the food components established in the new meal pattern. In addition, SAs would be required to take fiscal action for repeated violations of the vegetable subgroups and milk type requirements when (1) technical assistance has been provided and (2) corrective action has not resolved these specific violations. These requirements are easily understood by school food authorities and can be quickly identified by visual inspection without having specialized nutrition knowledge or training. However, because not all schools currently have knowledge or accurate tools to calculate the average levels of calories, saturated fat, sodium and *trans* fat in the meals offered during the week, this proposed rule would give SAs discretion to take fiscal action for such violations, as well as for food quantity and whole grain violations, provided that technical assistance and corrective

action have taken place. The SAs would also be required to first use technical assistance and corrective action to address these deficiencies.

Since the new requirements for calories, saturated fat, sodium, and *trans* fat would only apply to the meals for school-aged children, the SAs would not have to conduct a nutrient analysis of the meals offered to preschoolers (ages 1–2 and 3–4) in a school selected for an administrative review pending changes to the CACFP regulations. Likewise, the proposed whole grains and fluid milk requirements would not apply to preschoolers' meals.

Technical Assistance

IOM recommended technical assistance to help school foodservice staff develop and continuously improve menus, order appropriate foods, and control costs while maintaining quality. USDA intends to provide training and develop technical assistance resources to facilitate the transition to the new meal requirements. This would be accomplished by updating USDA menu planning resources; guidance materials on fruits, vegetables, and whole grain foods; the Child Nutrition Database; and requirements for nutrient analysis software. USDA will continue to collaborate with the National Food Service Management Institute to develop and provide appropriate training. In addition, USDA would disseminate information about the new requirements in public forums, such as the School Nutrition Association and American Dietetic Association meetings, and other national, regional and state conferences; and through the USDA Regional nutritionists who work with the School Meal Programs.

Miscellaneous Proposed Changes

USDA is using this opportunity to propose additional program changes that would support IOM's recommendations or enhance the overall school nutrition program.

Identification of a Reimbursable Meal

USDA is proposing to require schools to identify the foods composing the reimbursable meal(s) for the day at or near the beginning of the serving line(s). Students and parents often do not know what food or menu items are included in the NSLP or SBP meal. Identifying the Program meal may avoid higher costs to the students from their unintentional purchase of a la carte foods, rather than the unit-priced school meal. This additional information would promote nutrition education by teaching students what foods are included in a balanced meal. Schools

would have discretion to identify the best way to provide this information on the meal serving line(s).

Crediting

Foods served as part of the School Meal Programs should be wholesome and easily recognized by children as part of a food group that contributes to a healthy diet. To support the Dietary Guidelines' emphasis on whole fruits and vegetables, this proposal would disallow the crediting of any snack-type fruit or vegetable products (such as fruit strips and fruit drops), regardless of their nutrient content, toward the fruits component or the vegetables component. USDA does not currently allow snack-type foods such as potato chips or banana chips to be credited toward meeting the fruits/vegetables requirement; however, certain snack-type fruit products have been allowed to be credited by calculating the whole-fruit equivalency of the processed fruit in the product using the FDA's standards of identity for canned fruit nectars (21 CFR 146.113). The standard of identity for canned fruit nectars, however, has since been removed from the CFR. Therefore, this rationale for allowing certain snack-type fruit products to be credited in the meal pattern is no longer established in regulation.

In addition, this proposal would require that all fruits and vegetables (and their concentrates, purees, and pastes) be credited based on volume as served with two exceptions: (1) Dried whole fruit and dried whole fruit pieces would be credited for twice the volume served; and (2) leafy salad greens would be credited for half the volume served. These exceptions are highlighted in the IOM report and the 2005 Dietary Guidelines. This proposal would specifically change the current practice of crediting tomato paste and puree. Currently tomato paste and puree are credited as a calculated volume based on their whole-food equivalency using the percent natural tomato soluble solids in paste and puree, while other fruit paste and purees (such as blackberries puree) are credited based on actual volume as served. Under this proposal, schools would credit tomato paste and puree based on actual volume as served. Schools would not be allowed to credit a volume of fruit or vegetables that is more than the actual serving size.

Fortification

A basic premise of the Dietary Guidelines is that nutrients should come primarily from the consumption of whole foods that are not highly processed or heavily fortified. Current

nutrition science suggests that a variety of factors in whole foods work together to generate health benefits. While certain nutrients in foods have been identified as being linked to specific health benefits, the effects are not always comparable when the nutrient is isolated from the food in which it is naturally present.

This proposed rule seeks to reduce schools' reliance on highly fortified foods. To promote consumption of naturally nutrient-dense foods, such as whole grains, fruits and vegetables, this proposed rule would eliminate the use of formulated grain-fruit products as defined in Appendix A to 7 CFR Part 220. Formulated grain-fruit products are (1) grain-type products that have grain as the primary ingredient, and (2) grain-fruit type products that have fruit as the primary ingredient. Both types of products must have at least 25 percent of their weight derived from grain. These food products typically contain high levels of fortification, rather than naturally occurring nutrients, and are high in sugar and fat. Such products do not support the Dietary Guidelines' recommendation to consume fruits as a separate and important food group. Furthermore, formulated grain-fruit products are no longer necessary in the school meal programs. This product specification was originally adopted in response to the limited access that some schools faced in procuring or storing traditional breakfast foods. Today, schools can procure other breakfast options with similar shelf-life (e.g., ready-to-eat cereals and whole grain or enriched grain products) that would meet the operational needs of the school and the nutrient needs of children.

USDA recognizes that fortification of some foods is an accepted practice to enhance or add nutrients. Often in such cases, fortification is an effective way to preserve nutrients lost during preparation or processing, or to increase the nutrient intake in consumer diets that normally may be lacking the added nutrients. Examples of such foods are enriched grain products, fortified cereals, and fluid milk (with added vitamins A and D). In most other instances, however, the use of highly-fortified food products is inconsistent with the Dietary Guidelines.

Technical Changes to Appendices A and B

This proposed rule would update Appendices A and B to 7 CFR Parts 210 and 220. USDA is proposing to amend Appendix A to Part 220 by removing Formulated Grain-Fruit Products in its entirety for the reasons previously stated in the discussion of Fortification.

Appendix B to Part 210 would be amended by removing the statement that affirms that Appendix B will be updated to exclude individual foods that have been determined to be exempted from the categories of Foods of Minimal Nutritional Value. Although USDA has published Notices in the past to inform the public of exempted foods, Appendix B has not been amended subsequently to reflect these exemptions. A list of these exempted foods is maintained and available to all State agencies participating in the Programs. There have been no changes to the categories of exempted foods and USDA will maintain the requirement to publish a Notice and update the regulations to reflect any changes to the categories.

Implementation of Proposed Changes

Until the final rule is implemented, meal reimbursement will be based on compliance with current program regulations in 7 CFR Part 210 and Part 220. However, schools are strongly encouraged to take steps within current Program regulations to provide meals that are consistent with the 2005 Dietary Guidelines, such as reducing sodium and saturated fat, and increasing the availability of fruits, vegetables, whole grains, and fat-free and low-fat fluid milk in the menus. Team Nutrition has developed practical guidance to help schools provide meals that reflect the Dietary Guidelines. (See http://teamnutrition.usda.gov/Resources/dgfactsheet_hsm.html.)

Since the 2005 Dietary Guidelines were issued, USDA has provided technical assistance and guidance to help schools offer meals that reflect the recommendations of the Dietary Guidelines. USDA recognizes that changing children's dietary habits is indeed a challenge for schools. Nutrition education is essential to help children accept new foods, change preferences, and make healthy choices. USDA's Team Nutrition initiative will continue to assist SAs with their nutrition education efforts.

The HealthierUS School Challenge is a voluntary certification initiative that recognizes schools that are providing nutritious food and beverage choices and nutrition education, physical education and opportunities for physical activity. The Challenge criteria help schools move closer to the new meal pattern requirements related to whole grains, fruits, vegetables, and low-fat and fat-free fluid milk. USDA is working with partner organizations and stakeholders to double the number of HealthierUS schools during school year

2010–2011 and to add 1,000 schools per year for two years thereafter.

Team Nutrition and the HealthierUS School Challenge, and our joint efforts with the National Food Service Management Institute, have helped schools move in the right direction. USDA is confident that State and local program operators have made and will continue to make progress to further improve the quality of school meals and the dietary habits of school children.

I. Procedural Matters

Executive Order 12866

This proposed rule has been determined to be economically significant and was reviewed by the Office Management and Budget in conformance with Executive Order 12866.

Regulatory Impact Analysis

As required for all rules that have been designated as significant by the Office of Management and Budget, a Regulatory Impact Analysis (RIA) was developed for this proposed rule and is included in the preamble. The following summarizes the conclusions of the RIA:

Need for action: Section 9(a)(4) of the NSLA, 42 U.S.C. 1758(a)(4), added to the statute in 2004, requires the Secretary of Agriculture to issue regulations that increase the availability of foods recommended by the most recent “Dietary Guidelines for Americans” in the Federal school meals programs. In addition, Section 9(f)(1) of the NSLA, 42 U.S.C. 1758(f)(1), requires schools that participate in the NSLP or SBP to offer lunches and breakfasts that are consistent with the goals of the most recent Dietary Guidelines. This proposed rule implements recommendations of the National

Academy of Science’s Institute of Medicine (IOM). Under contract to the United States Department of Agriculture (USDA), the IOM proposed changes to NSLP and SBP meal pattern requirements consistent with the 2005 Dietary Guidelines and the IOM’s Dietary Reference Intakes.

Benefits: The proposed rule implements recommendations of the IOM that are designed to better align school meal patterns and nutrition standards with the IOM’s Dietary Reference Intakes and the goals of the Dietary Guidelines. In developing its recommendations, the IOM sought to address low intakes of fruits, vegetables, and whole grains among school-age children, and excessive intakes of sodium and discretionary calories from solid fats and added sugar. The proposed rule addresses these concerns by increasing the amount of fruit, the amount and the variety of vegetables, and the amount of whole grains offered each week to students who participate in the school meals programs. The rule would also replace higher fat fluid milk with low fat and skim fluid milk in school meals. And it would limit the levels of calories, sodium, and saturated fat in those meals.

The linkage between poor diets and health problems such as childhood obesity are also a matter of particular policy concern, given their significant social costs. One in every three children (31.7%) ages 2–19 is overweight or obese.⁶ Along with the effects on our children’s health, childhood overweight and obesity imposes substantial economic costs, and the epidemic is associated with an estimated \$3 billion in direct medical costs.⁷ Perhaps more significantly, obese children and adolescents are more likely to become

obese as adults.⁸ In 2008, medical spending on adults that was attributed to obesity increased to an estimated \$147 billion.⁹ In addition, a recent study suggests reducing dietary salt in adolescents could yield substantial health benefits by decreasing the number of teenagers with hypertension and the rates of cardiovascular disease and death as these teenagers reach young and middle age adulthood. Because of the complexity of factors that contribute both to overall food consumption and to obesity, we are not able to define a level of disease or cost reduction that is attributable to the changes in meals expected to result from implementation of the rule.

As the rule is projected to make substantial improvements in meals served to more than half of all school-aged children on an average school day, we judge that the likelihood is reasonable that the benefits of the rule exceed the costs, and that the proposal thus represents a cost-effective means of conforming NSLP and SBP regulations to the statutory requirements for school meals. Beyond these changes a number of qualitative benefits—including alignment between Federal program benefits and national nutrition policy, improved confidence of parents and families in the nutritional quality of school meals, and the contribution that improved school meals can make to the overall school nutrition environment, are expected from the rule.

Costs: FNS estimates that the total costs of compliance with this rule will reach \$6.8 billion over the five years ending in FY 2016. Year by year costs in millions, assuming implementation of a final rule at the start of SY 2012–2013 are summarized below.

Costs (millions)	Fiscal year					
	2012	2013	2014	2015	2016	Total
Food Costs	\$91.8	\$626.5	\$704.9	\$968.9	\$1,028.2	\$3,420.4
Labor Costs	89.6	611.4	687.9	945.6	1,003.4	3,337.9
Total	181.3	1,237.9	1,392.8	1,914.5	2,031.7	6,758.2

The increases reflect increased costs to purchase the types of foods required by the proposed rule beyond those required to comply with current program rules—

primarily increased fruits, vegetables, and whole grains—as well as increased labor costs due to more on-site food preparation, training for food service

professionals, and some additional administrative costs.

Alternatives:

⁶Ogden, C.L., Carroll, M., Curtin, L., Lamb, M., Flegal, K. (2010). Prevalence of High Body Mass Index in U.S. Children and Adolescents 2007–2008. *Journal of American Medical Association*, 303(3), 242–249.

⁷Trasande, L., Chatterjee, S. (2009). Corrigendum: The Impact of Obesity on Health Service Utilization and Costs in Childhood. *Obesity*, 17(9).

⁸Whitaker, R.C., Wright, J.A., Pepe, M.S., Seidel, K.D., Dietz W.H. Predicting obesity in young adulthood from childhood and parental obesity. *N Engl J Med* 1997; 37(13):869–873; Serdula, M.K., Ivery, D., Coates, R.J., Freedman, D.S., Williamson, D.F., Byers, T. Do obese children become obese adults? A review of the literature. *Prev Med* 1993;22:167–177.

⁹Finkelstein, E., Trogon, J., Cohen J., Dietz, W. (2009). Annual Medical Spending Attributable to Obesity: Payer-And Service-Specific Estimates. *Health Affairs*, 28(5).

In response to NSLA Section 9(a)(4) amended into law in 2004, USDA contracted with IOM to assemble an expert panel to undertake a review of the nutritional needs of children, the recommendations of the Dietary Guidelines, and IOM's Dietary Reference Intakes. USDA asked IOM to develop recommendations for updating NSLP and SBP meal patterns and nutrition requirements based on that review of need and nutrition science, with consideration given to operational feasibility and cost.

The USDA contract with IOM called for the creation of a panel with representatives from the fields of public health, epidemiology, pediatrics, child nutrition and child nutrition behavior, statistics, and economics. The contract also called for representatives with knowledge of cultural differences in food preference and eating habits, experience in menu planning, and experience in managing and operating a school lunch and breakfast program. IOM held workshops at which the panel heard presentations from invited speakers, and solicited public input. The panel also accepted public comment on its planned approach to the project.

The process undertaken by IOM was designed to consider different perspectives and competing priorities. The panel necessarily weighed the merits of alternatives as it developed a preferred option. USDA's commitment was to implement IOM's recommendations where feasible. This commitment is driven by the statutory requirement that schools serve meals that are consistent with the goals of the Dietary Guidelines.

We did not consider alternatives that depart significantly from IOM's recommendations and cannot satisfy our statutory obligation. Nevertheless, the proposed rule makes a few small changes to IOM's recommendations. In addition, the rule contains a handful of provisions that are not addressed by IOM. The RIA provides a discussion of alternatives considered, including a Phase-In Implementation of IOM Recommendations.

Regulatory Flexibility Act

This proposed rule has been reviewed with regard to the requirements of the Regulatory Flexibility Act of 1980 (5 U.S.C. 601–612). Pursuant to that review, it has been determined that this proposed rule would have a significant impact on a substantial number of small entities. The proposed requirements would apply to school districts, which meet the definitions of “small governmental jurisdiction” and “small

entity” in the Regulatory Flexibility Act. A Regulatory Flexibility Act analysis is included in the preamble.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. Under section 202 of the UMRA, USDA generally must prepare a written statement, including a cost/benefit analysis, for proposed and final rules with Federal mandates that may result in expenditures by State, local, or Tribal governments, in the aggregate, or to the private sector, of \$100 million or more in any one year. When such a statement is needed for a rule, section 205 of the UMRA generally requires USDA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, more cost-effective or least burdensome alternative that achieves the objectives of the rule. The Regulatory Impact Analysis conducted by FNS in connection with this proposed rule includes a cost/benefit analysis and explains the options considered to implement the 2005 Dietary Guidelines in the school meal programs.

Prior to developing this proposed rule, FNS sought the assistance of the Institute of Medicine (IOM) of the National Academies to implement the 2005 Dietary Guidelines in the NSLP and SBP in the least burdensome and costly manner. However, this proposed rule contains Federal mandates (under the regulatory provisions of Title II of the UMRA) that could result in costs to State, local, or Tribal governments or to the private sector of \$100 million or more in any one year if State and local operators do not develop strategies to absorb the cost increases associated with increasing the availability of fruits, vegetables, and whole grains in the school menu. To meet the proposed requirements in a cost-effective manner, program operators would need to optimize the use of USDA Foods and adopt other cost-savings strategies in various areas of the food service operation, including procurement, menu planning, and meal production. Program operators have flexibility within the Federal requirements to run the School Meal Programs in a manner that fits local circumstances.

Because childhood overweight and obesity are growing public health issues in the United States, schools should take a leadership role in helping students adopt healthy diets. Many schools are already providing more

fruits, vegetables and whole grains as part of their efforts to enhance the school nutrition environment. Over 840 schools nationwide have been recognized by FNS as part of the HealthierUS School Challenge (HealthierUS) for improvement in the quality of the meals served and the food choices. HealthierUS schools offer fresh fruits or raw vegetables, whole grain foods, legumes, and low-fat or fat-free fluid milk, and provide students with nutrition education and opportunity for physical activity.

Executive Order 12372

The NSLP is listed in the Catalog of Federal Domestic Assistance under No. 10.555 and the SBP is listed under No. 10.553. For the reasons set forth in the final rule in 7 CFR part 3015, Subpart V and related Notice published at 48 FR 29114, June 24, 1983, this Program is included in the scope of Executive Order 12372, which requires intergovernmental consultation with State and local officials.

Since the NSLP and SBP are State-administered, Federally funded programs, FNS headquarters staff and regional offices have formal and informal discussions with State and local officials on an ongoing basis regarding program requirements and operation. This structure allows FNS to receive regular input which contributes to the development of meaningful and feasible Program requirements.

Federalism Summary Impact Statement

Executive Order 13132 requires Federal agencies to consider the impact of their regulatory actions on State and local governments. Where such actions have federalism implications, agencies are directed to provide a statement for inclusion in the preamble to the regulations describing the agency's considerations in terms of the three categories called for under section (6)(b)(2)(B) of Executive Order 13132.

Prior Consultation With State Officials

Prior to drafting this proposed rule, FNS staff received informal input from various stakeholders while participating in various State, regional, national, and professional conferences. The School Nutrition Association, School Food Industry Roundtable, National Alliance for Nutrition and Activity, Association of State and Territorial Public Health Nutrition Directors, and the Center for Science in the Public Interest shared their views about changes to the school meals in writing. Numerous stakeholders also provided input at the public meetings held by IOM in connection with its school meals study.

Based on its independent research and information gathered from stakeholders, IOM issued recommendations which are the basis for this proposed rule.

Nature of Concerns and the Need To Issue This Rule

State Agencies and school food authorities want to provide the best possible school meals through the NSLP and SBP but are concerned about program costs and increasing program requirements. While FNS is aware of these concerns, section 9(a)(4) and section 9(f)(1) of the National School Lunch Act, 42 U.S.C. 1758(a)(4) and (f)(1), require that school meals reflect the most recent "Dietary Guidelines for Americans" and promote the intake of the food groups recommended by the Dietary Guidelines.

Extent To Which We Meet Those Concerns

FNS sought the assistance of the Institute of Medicine to update the school meals in a practical and sound manner. FNS has considered the impact of this proposed rule on State and local program operators and has attempted to develop a proposal that would implement the 2005 Dietary Guidelines in the most effective and least burdensome manner. This proposed rule would simplify management and operation of the School Meal Programs by establishing a single food-based menu planning approach and the same age/grade groups in the NSLP and SBP, as recommended by the Institute of Medicine. The food-based menu planning system is currently used by approximately 70 percent of program operators. This proposed rule would retain the requirement that school meals meet nutrient requirements on average over the course of the week, and the offer versus serve provision, which helps schools control food cost and minimize food waste. This rule would also retain other existing regulatory provisions to the extent possible.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, "Civil Justice Reform." This rule, when published as a final rule, is intended to have preemptive effect with respect to any State or local laws, regulations or policies which conflict with its provisions. As proposed, the rule would permit State or local agencies operating the National School Lunch and School Breakfast Programs to establish more rigorous nutrition requirements or additional requirements for school meals that are not inconsistent with the nutritional provisions of the rule. Such

additional requirements would be permissible as part of an effort by a State or local agency to enhance the school meals and/or the school nutrition environment. To illustrate, State or local agencies would be permitted to establish more restrictive saturated fat and sodium limits. For these components, quantities are stated as maximums (e.g., ≤) and could not be exceeded; however, lesser amounts than the maximum could be served. Likewise, State or local agencies could accelerate implementation of the final sodium targets stated in this proposed rule in an effort to reduce sodium levels in school meals at an earlier date. However, State or local agencies would not, for example, be permitted to decrease the minimum calorie level or increase the maximum calorie level established for each grade group in this proposed rule as that would be inconsistent with the rule's provisions. This rule is not intended to have a retroactive effect. Prior to any judicial challenge to the provisions of this rule or the application of its provisions, all applicable administrative procedures under § 210.18(q) or § 235.11(f) must be exhausted.

Civil Rights Impact Analysis

FNS has reviewed this proposed rule in accordance with USDA Regulation 4300-4, "Civil Rights Impact Analysis," to identify any major civil rights impacts the rule might have on program participants on the basis of age, race, color, national origin, sex or disability. After a careful review of the rule's intent and provisions, FNS has determined that this proposed rule is not expected to affect the participation of protected individuals in the NSLP and SBP. This proposed rule is intended to improve the nutritional quality of school meals and is not expected to limit program access or otherwise adversely impact the protected classes.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

USDA will undertake, within 6 months after this rule becomes effective, a series of Tribal consultation sessions to gain input by elected Tribal officials or their designees concerning the impact of this rule on Tribal governments, communities and individuals. These sessions will establish a baseline of consultation for future actions, should any be necessary, regarding this rule. Reports from these sessions for consultation will be made part of the USDA annual reporting on Tribal Consultation and Collaboration. USDA will respond in a timely and meaningful

manner to all Tribal government requests for consultation concerning this rule and will provide additional venues, such as webinars and teleconferences, to periodically host collaborative conversations with Tribal leaders and their representatives concerning ways to improve this rule in Indian country.

We are unaware of any current Tribal laws that could be in conflict with the proposed rule. We request that commenters address any concerns in this regard in their responses.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. Chap. 35; see 5 CFR 1320), requires that the Office of Management and Budget (OMB) approve all collections of information by a Federal agency from the public before they can be implemented. Respondents are not required to respond to any collection of information unless it displays a current, valid OMB control number. This is a new collection. The new provisions in this rule, which do increase burden hours, affect the information collection requirements that will be merged into the National School Lunch Program, OMB Control Number #0584-0006, expiration date 5/31/2012. The current collection burden inventory for the National School Lunch Program is 11,806,566 hours. These changes are contingent upon OMB approval under the Paperwork Reduction Act of 1995. When the information collection requirements have been approved, FNS will publish a separate action in the **Federal Register** announcing OMB's approval.

Comments on the information collection in this proposed rule must be received by March 14, 2011.

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

ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

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

Title: Nutrition Standards in the National School Lunch and School Breakfast Programs.

OMB Number: 0584—NEW.

Expiration Date: Not Yet Determined.

Type of Request: New Collection.

Abstract: This proposed rule would implement the recommendations of the 2005 “Dietary Guidelines for Americans” in the National School Lunch Program (NSLP) and School Breakfast Program (SBP), as required by section 9(a)(4) and section 9(f)(1) of the Richard B. Russell National School

Lunch Act, 42 U.S.C. 1758(9)(a) and (f). This rule is based on the final report “School Meals: Building Blocks for Healthy Children,” issued by the Institute of Medicine of the National Academies on October 20, 2009 to help FNS implement the 2005 Dietary Guidelines in the NSLP and SBP. This proposed rule would revise the lunch and breakfast meal patterns to increase the availability of fruits, vegetables, whole grains, and fat-free/low-fat fluid milk in the school menu. It would also increase the frequency of administrative reviews by State agencies from the current five-year cycle to a three-year cycle, and change the requirements for these reviews. This rule would impact the reporting and/or recordkeeping burden on school food authorities and State agencies. However, this rule would not increase or decrease the existing burden on local schools participating in the NSLP because they are already required to maintain menu and production records. This proposed rule would require State agencies to examine menu and production records

during administrative reviews, and to maintain documentation related to fiscal action.

Those respondents participating in the School Breakfast Program also participate in the National School Lunch Program, thus the burden associated with the School Breakfast Program will be carried in the National School Lunch Program. The average burden per response and the annual burden hours are explained below and summarized in the charts which follow.

Respondents for this Proposed Rule: State Education Agencies (57) and School Food Authorities (6,983).

Estimated Number of Respondents for this Proposed Rule: 7,040.

Estimated Number of Responses per Respondent for this Proposed Rule: 3.87217.

Estimated Total Annual Responses: 27,260.

Estimated Total Annual Burden on Respondents for this Proposed Rule: 75,842.

BILLING CODE 3410-30-P

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

Reporting						
	Section	Estimated Number of Respondents	Frequency of Response	Average Annual Responses	Average Burden per response	Annual Burden Hours
SA shall verify compliance with critical and general areas of review.	7 CFR 210.18(g) & 210.18(h)	57	1	57	40	2,280
SFA shall submit to SA documented corrective action, no later than 30 days from the deadline for completion, for violations of critical or general areas identified on administrative follow-up review.	7 CFR 210.18(k)(2)	6,983	1	6,983	6	41,898
Total Reporting for DGA Proposed rule		7,040		7,040	6.27528	44,178
Total Existing Reporting Burden for Part 210						2,912,745
Total Reporting Burden for Part 210 with DGA proposed rule						2,956,923

Recordkeeping						
	Section	Estimated Number of Respondents	Frequency of Response	Average Annual Responses	Average Burden per Response	Annual Burden Hours
SA establishes guidelines and approves School Food Authorities menu planning alternatives. (Burden removed by proposed rule)	7 CFR 210.10 (1)	0	0	0	0	(57)*
SA modifies menu planning alternatives or develops menu planning alternatives. (Burden removed by proposed rule)	7 CFR 210.10 (1)	0	0	0	0	(100)*
SA records document the details of all reviews and the degree of compliance with the critical and general areas of review. Documents on file are available to FNS for review.	7 CFR 210.18 (k), 210.18 (p), & 210.20 (b)(6)	57	93.23	5,314	2.3	12,222
SA documents fiscal action taken to disallow improper claims submitted by SFAs, as determined through claims processing, CRE reviews, and USDA audits. Contracts awarded by SFAs to FSMCs.	7 CFR 210.19 (c) & 210.18 (p)	57	139	7,923	0.50	3,962
SFA adopts menu planning alternatives, modifies menu planning alternatives or develops menu planning alternatives and submits them to the State agency for approval at SFA level. (Burden removed by proposed rule.)	7 CFR 210.10(1)	0	0	0	0	(26,261)*
SFA documents corrective action taken on program violations disclosed by review or audit.	7 CFR 210.18 (k)(2)	6,983	1	6,983	6	41,898
Total Recordkeeping for New Burden		7,040		20,220	1.56596	31,664
Total Existing Recordkeeping Burden for 0584-0006, Part 210						8,893,821
Total Recordkeeping Burden for 0584-0006, Part 210 with proposed rule						8,925,485
*Indicates reduced burden hours due to changes in proposed rule.						

Section 7 CFR 210.15 and 210.20 require that, in order to participate in the National School Lunch Program, school food authorities and State agencies must maintain records to demonstrate compliance with Program requirements. Section 7 CFR 210.23 further requires State agencies and school food authorities to maintain records for a period of three years.

SUMMARY OF BURDEN (OMB #0584-NEW)	
TOTAL NO. RESPONDENTS	7,040
AVERAGE NO. RESPONSES PER RESPONDENT	3.87217
TOTAL ANNUAL RESPONSES	27,260
AVERAGE HOURS PER RESPONSE	2.78216
TOTAL BURDEN HOURS FOR PART 210 WITH PROPOSED RULE	11,882,408
CURRENT OMB INVENTORY FOR PART 210	11,806,566
DIFFERENCE (NEW BURDEN REQUESTED WITH PROPOSED RULE)	75,842

BILLING CODE 3410-30-C

E-Government Act Compliance

FNS is committed to complying with the E-Government Act 2002, to promote

the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Regulatory Impact Analysis

Agency: Food and Nutrition Service, USDA.

Title: Nutrition Standards in the National School Lunch and School Breakfast Programs.

Action

a. *Nature:* Proposed Rule.

b. *Need:* Section 103 of the Child Nutrition and WIC Reauthorization Act of 2004 inserted Section 9(a)(4) into the National School Lunch Act requiring the Secretary to promulgate rules revising nutrition requirements, based on the most recent *Dietary Guidelines for Americans*, that reflect specific recommendations, expressed in serving recommendations, for increased consumption of foods and food ingredients offered in school nutrition. This proposed rule amends Sections 210 and 220 of the regulations that govern the National School Lunch Program (NSLP) and the School Breakfast Program (SBP). The proposed rule implements recommendations of the National Academies' Institute of Medicine (IOM). Under contract to the United States Department of Agriculture (USDA), IOM proposed changes to NSLP and SBP meal pattern requirements consistent with the 2005 *Dietary Guidelines* and IOM's Dietary Reference Intakes. The proposed rule advances the mission of the Food and Nutrition Service (FNS) to provide children access to food, a healthful diet, and nutrition education in a manner that promotes American agriculture and inspires public confidence.

c. *Affected Parties:* The programs affected by this rule are the NSLP and the SBP. The parties affected by this regulation are USDA's Food and Nutrition Service, State education agencies, local school food authorities, schools, students, and the food production, distribution and service industry.

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Abbreviations

The following abbreviations are used throughout this document:

- CN Child Nutrition Programs
- CPI Consumer Price Index
- CRE Coordinated Review Effort
- DRI Dietary Reference Intake

- FNS Food and Nutrition Service
- FY Fiscal Year
- IOM Institute of Medicine
- NSLA National School Lunch Act
- NSLP National School Lunch Program
- RDA Recommended Dietary Allowance
- SA State Agency
- SBP School Breakfast Program
- SY School Year
- SFA School Food Authority
- SLBCS-II School Lunch and Breakfast Cost Study II
- SMI USDA School Meals Initiative for Healthy Children
- SNDA-III School Nutrition Dietary Assessment III
- USDA United States Department of Agriculture

I. Background

The National School Lunch Program (NSLP) is available to over 50 million children each school day; an average of 31.6 million children per day ate a reimbursable lunch in fiscal year (FY) 2010. The School Breakfast Program (SBP) served an average of 11.6 million children daily. Schools that participate in the NSLP and SBP receive Federal reimbursement and USDA Foods (donated commodities) for lunches and breakfasts that meet program requirements. In exchange for this assistance schools serve meals at no cost or at reduced price to income-eligible children. Federal meal reimbursements and USDA Foods totaled \$13.3 billion in FY 2010. FNS projections of the number of meals served and Federal program costs are summarized in Table 1.¹⁰

TABLE 1—PROJECTED NUMBER OF MEALS SERVED AND TOTAL FEDERAL PROGRAM COSTS
[In millions]

	Fiscal year					
	2011	2012	2013	2014	2015	2016
NSLP:						
Lunches Served	5,409.6	5,477.2	5,532.0	5,581.8	5,626.5	5,671.5
Program Cost	\$12,116.9	\$12,513.5	\$12,737.0	\$12,834.8	\$12,851.4	\$12,940.2
SBP:						
Breakfasts Served	2,062.4	2,124.3	2,166.7	2,201.4	2,236.6	2,272.4
Program Cost	\$3,117.9	\$3,270.0	\$3,383.8	\$3,460.0	\$3,552.2	\$3,669.3

In FY 2010, schools served 2.9 billion free NSLP lunches, 0.5 billion reduced price lunches, and 1.8 billion full price or “paid” lunches. Schools served 1.5 billion free breakfasts, 0.2 billion reduced price breakfasts, and 0.3 billion

paid breakfasts. These figures do not include non-Federally reimbursable a la carte meals or other non-program foods.¹¹

Reimbursement rates for meals served under the current meal patterns are

established by law and are adjusted annually for inflation.¹² In school year (SY) 2010–2011, the Federal reimbursement for a free breakfast for schools in the contiguous United States and “not in severe need” was \$1.48; the

¹⁰ The figures in Table 1 are USDA projections of the number of program meals served and the value of USDA reimbursements for those meals. These figures are baseline Federal government costs of the NSLP and the SBP estimated for the President's budget proposal for FY 2011. Elsewhere in this document, baseline costs refer to the cost to schools

of serving meals that satisfy current program requirements.

¹¹ USDA program data.

¹² Reimbursement rates and annual inflation adjustments are set by statute, not regulation. The proposed rule does not alter current reimbursement rates. Reimbursement rates for school lunch under

current nutrition standards are specified in Sections 4(b)(2) and 11(a)(2) of the NSLA (42 USC 1753(b)(2) and 42 USC 1759a(a)(2)). Breakfast reimbursement rates are specified in Section 4(b)(1)(B) of the Child Nutrition Act (42 USC 1773(b)(1)(B)). Both lunch and breakfast reimbursement rates are subject to the annual inflation adjustment prescribed by Section 11(a)(3) of the NSLA (42 USC 1759a(a)(3)).

Federal reimbursement for a free lunch to schools in SFAs in the contiguous United States that served fewer than 60 percent free and reduced price lunches was \$2.72. Schools that participate in

the NSLP also receive USDA Foods for each free, reduced price, and paid lunch served, as provided by Section 6 of the Richard B. Russell National School Lunch Act (NSLA). Table 2 provides a

breakdown of breakfast and lunch reimbursements in SY 201–2011, including USDA Foods.

Table 2: Federal Per-Meal Reimbursement and Minimum Value of USDA Foods, SY 2010-2011¹³

	Breakfast Reimbursement		Lunch Reimbursement		Minimum Value of Donated Foods
	Schools in "Severe Need"	Schools not in "Severe Need"	SFAs that serve at least 60% of lunches free or at reduced price	SFAs that serve fewer than 60% of lunches free or at reduced price	Additional Federal assistance for each NSLP lunch served
Contiguous States					
Free	\$1.76	\$1.48	\$2.74	\$2.72	\$0.2025
Reduced Price	1.46	1.18	2.34	2.32	0.2025
Paid	0.26	0.26	0.28	0.26	0.2025
Alaska					
Free	\$2.82	\$2.36	\$4.43	\$4.41	\$0.2025
Reduced Price	2.52	2.06	4.03	4.01	0.2025
Paid	0.39	0.39	0.44	0.42	0.2025
Hawaii					
Free	\$2.05	\$1.72	\$3.20	\$3.18	\$0.2025
Reduced Price	1.75	1.42	2.80	2.78	0.2025
Paid	0.30	0.30	0.32	0.30	0.2025

Under Section 9(a)(4) and Section 9(f)(1) of the NSLA, schools that participate in the NSLP or SBP must offer lunches and breakfasts that are consistent with the goals of the most recent *Dietary Guidelines for Americans*. School lunches must provide one-third of the Recommended Dietary Allowances (RDA) for protein, calcium, iron, and vitamins A and C, on average over the course of a week; school breakfasts must satisfy one-fourth of the RDAs for the same nutrients. Current nutrition requirements for school lunches and breakfasts are based on the 1995 *Dietary Guidelines* and the 1989 RDAs. (School lunches and breakfasts were not updated when the 2000 *Dietary Guidelines* were issued because those recommendations did not require

significant changes to the school meal patterns.) The 2005 *Dietary Guidelines*, provide more prescriptive and specific nutrition guidance than earlier releases, and require significant changes to school meal requirements.

The United States Department of Agriculture's Food and Nutrition Service (FNS) contracted with the National Academies' Institute of Medicine (IOM) in 2008 to examine current NSLP and SBP nutrition requirements. IOM formed an expert committee tasked with comparing current school meal requirements to the 2005 *Dietary Guidelines* and to current Dietary Reference Intakes. The committee released its recommendations in late 2009 (IOM 2009). For a summary discussion of the scientific standards that guided the

committee, and the development of recommended targets for micro- and macronutrients, see the preamble to the proposed rule.

II. Summary of Proposed Meal Requirements

The proposed rule adopts the IOM recommendations with only minor modifications (see section IV). In general, IOM recommended new requirements for menu planning that:

- Increase the amount and variety of fruits, vegetables, and whole grains;
- Set a minimum and maximum level of calories; and
- Increase the focus on reducing the amounts of saturated fat and sodium provided in school meals.

¹³ School year 2010–NSLP and SBP reimbursement rates, and the minimum value of

donated foods, can be found in the July 19, 2010

Federal Register, Vol. 75, No. 137, pp. 41797 and 41798.

Table 3: Summary of Proposed Meal Requirements¹⁴

Meal Pattern	Breakfast			Lunch		
	Grades K-5	Grades 6-8	Grades 9-12	Grades K-5	Grades 6-8	Grades 9-12
	Amount of Food ^a Per Week (Minimum Per Day)					
Fruits (cups) ^b	5 (1)	5 (1)	5 (1)	2.5 (0.5)	2.5 (0.5)	5 (1)
Vegetables (cups) ^{bc}	0	0	0	3.75 (0.75)	3.75 (0.75)	5 (1)
Dark green	0	0	0	0.5 ^d	0.5 ^d	0.5 ^d
Orange	0	0	0	0.5 ^d	0.5 ^d	0.5 ^d
Legumes	0	0	0	0.5 ^d	0.5 ^d	0.5 ^d
Starchy	0	0	0	1	1	1
Other	0	0	0	1.25 ^d	1.25 ^d	2.5 ^d
Grains ^e (oz eq)	7-10 (1)	8-10 (1)	9-10 (1)	9-10 (1)	9-10 (1)	12-13 (2)
Meats/Meat Alternates (oz eq)	5 (1)	5 (1)	7-10 (1)	8-10 (1)	9-10 (1)	10-12 (2)
Milk ^f (cups)	5 (1)	5 (1)	5 (1)	5 (1)	5 (1)	5 (1)
Other Specifications: Daily Amount Based on the Average for a 5-Day Week						
Min-max calories (kcal) ^{gh}	350-500	400-550	450-600	550-650	600-700	750-850
Saturated fat (% of total calories) g	< 10	< 10	< 10	< 10	< 10	< 10
Sodium (mg) ⁱ	≤ 430	≤ 470	≤ 500	≤ 640	≤ 710	≤ 740
Trans fat	Nutrition label must specify zero grams of trans fat per serving.					

^aFood items included in each group and subgroup and amount equivalents. Minimum serving is 1/4 cup.

^bOne cup of fruits and vegetables usually provides 2 servings; 1/4 cup of dried fruit counts as 1/2 cup of fruit; 1 cup of leafy greens counts as 1/2 cup of vegetables. No more than half of the fruit offerings may be in the form of juice.

^cFor breakfast, 1/2 cup of non-starchy vegetables may be considered equivalent to 1/2 cup fruits. No minimum amount of vegetables is required for breakfast.

^dLarger amounts of these vegetables may be served.

^eAt least half of grains must be whole grain-rich. Aiming for a higher proportion of whole grain-rich foods is encouraged.

^fMilk must be low-fat (1 percent milk fat or less, unflavored) or fat-free (unflavored or flavored).

^gThe average daily amount for a 5-day school week is not to be less than the minimum or exceed the maximum.

^hDiscretionary sources of calories (solid fats and added sugars) may be added to the meal pattern if within the specifications for calories, saturated fat, trans fat, and sodium. Foods of minimal nutritional value and fluid milk with fat content greater than 1 percent milk fat are not allowed.

Tables 4 and 5¹⁵ compare the meal pattern recommendations proposed in

¹⁴Information in this table is summarized from the preamble to the proposed rule.

¹⁵Tables 4 and 5 appear as Tables 8-1 and 8-2 in IOM's report on the school meals programs, *School Meals: Building Blocks for Healthy Children* (IOM 2009). The recommendations in these tables are adopted by the proposed rule with one small exception: non-starchy vegetables may be

this rule to current requirements for breakfast and lunch respectively.¹⁶ Key differences include:

substituted for fruit at breakfast (see Table 3, note c).

¹⁶The food group recommendations presented in Tables 4 and 5 are based on a set of nutrient targets developed by IOM (see IOM 2009 for a detailed discussion of that process). Tables 7-2, O-2, and O-3 of the IOM report compare IOM's nutrient targets

to the RDA targets that underlie the current meal patterns. Readers of the IOM report may notice that differences in current rule and recommended food group quantities (Tables 4 and 5) do not always track differences between IOM's nutrient targets and current rule RDA targets (IOM report tables 7-2, O-2, and O-3). For instance, IOM's nutrient targets for protein are twice as great as the RDA protein targets for elementary and high school students; IOM's protein targets are close to three times as great as the RDA targets for middle school students. By comparison, IOM's recommended

number of meat servings are little different than the number of servings under current program rules. The reason for the discrepancy is that student intakes of protein currently exceed RDA targets (see Tables VI.2 and VII.2 in FNS 2007). IOM nutrient targets for protein are fully satisfied by the meat and legume recommendations in Tables 4 and 5 (see the discussion on pages 164 and 165 of IOM 2009). Readers of the IOM report should compare the IOM's nutrient targets to the RDA values in report Tables 7-2, O-3, and O-4, rather than to the RDA values in report table E-4. Table E-4 figures are based on the 1989 RDAs. RDA values in Tables 7-2, O-3, and O-4 are current. Pages 118-120 of the IOM report (IOM 2009) discuss how the IOM

- The number of fruit and vegetable servings offered to students over the course of a week would double at breakfast and would rise substantially at lunch.

- Schools would no longer be permitted to substitute between fruits and vegetables; each has its own requirement, ensuring that students are

nutrient targets compare to the minimum RDA standards for school meals specified by Section 9(b)(1) of the NSLA (42 USC 1758(f)(1)).

offered both fruits and vegetables every day.

- A minimum number of vegetable servings would be required from each of four vegetable subgroups.

- Initially, half of grains offered to students would have to be whole grain rich. Two years after implementation, all grain products offered would have to be whole grain rich.

- Schools would be required to substitute low fat and skim milk for higher fat content milk.

Table 4: School Breakfast Program - Current Requirements Compared to Recommendations for a 5-Day School Week^a

Grade Levels	Current Requirements			
	K-12	K-5	6-8	9-12
Fruit (cups)	2.5	5	5	5
Vegetable (cups)	0	0	0	0
Grain/Bread (oz eq)	0-10 ^{b,c}	7-10 ^d	8-10 ^d	9-10 ^d
Meat/Meat Alternates (oz eq)	0-10 ^c	5	5	7-10
Milk (cups)	5	5	5	5

NOTE: oz eq = ounce equivalent.

^a Requirements and recommendations are for meals *as offered* for a 5-day school week. Requirements are minimum portion sizes based on the Traditional Food-Based Menu planning approach.

^b Must be enriched or whole grain.

^c Requirements call for two grains, two meats, or one of each.

^d At least half of which must be whole grain-rich.

Table 5: National School Lunch Program: Current Requirements Compared to Recommendations for a 5-Day School Week^a

Grade Levels	Current Requirements: Traditional Food-Based Approach			Current Requirements: Enhanced Food-Based Approach			Recommendations		
	K-3 ^b	4-12 ^b	7-12 ^{c,d}	K-3 ^{b,d}	K-6 ^b	7-12	K-5	6-8	9-12
Fruit (cups)	2.5 ^e	3.75 ^e	3.75 ^e	3.75 ^e	4.25 ^g	5 ^e	2.5	2.5	5
Vegetable (cups)							3.75	3.75	5
Dark Green	NS	NS	NS	NS	NS	NS	0.5	0.5	0.5
Orange	NS	NS	NS	NS	NS	NS	0.5	0.5	0.5
Legumes	NS	NS	NS	NS	NS	NS	0.5	0.5	0.5
Starchy	NS	NS	NS	NS	NS	NS	1	1	1
Other	NS	NS	NS	NS	NS	NS	1.25	1.25	2.5
Grain/Bread (oz eq)	8 (min 1/day) ^f	8 (min 1/day) ^f	10 (min 1/day) ^f	10 (min 1/day) ^f	12 (min 1/day) ^f	15 (min 1/day) ^f	9-10 ^h	9-10 ^h	12-13 ^h
Meat/Meat Alternates (oz eq)	7.5	10	15	7.5	10	10	8-10	9-10	10-12
Milk (cups)	5	5	5	5	5	5	5	5	5

NOTES: min = minimum; NS = not specified; oz eq = ounce equivalents.

^a Requirements and recommendations are for meals *as offered* for a 5-day school week.

^b Minimum portion sizes.

^c Recommended portion sizes under the Traditional Food-Based Menu planning approach.

^d Optional grade configuration.

^e Two or more servings of fruit, vegetables, or both a day.

^f Must be enriched or whole grain.

^g Two or more servings of fruit, vegetables, or both a day, plus an extra half-cup over the 5-day school week.

^h At least half of which must be whole grain-rich

The proposed rule differs slightly from the IOM recommendations in that it proposes a quicker transition to a whole grain requirement consistent with the *Dietary Guidelines*. IOM recommended that the proportion of whole grains to refined grains on school menus exceed 50 percent within “approximately 3 years” of

implementation of revised meal patterns.¹⁷

In contrast, the proposed rule accelerates the transition to *Dietary*

¹⁷ “With regard to increasing whole grains and especially to reducing the sodium content of meals, the committee acknowledges the need for a gradual phase-in to accustom children to the changes in school meals and also to give the market time to respond to changes in demands (expressed as purchase specifications) from school food service directors.” (IOM 2009, pp. 172, 199)

Guidelines recommendations to the second year after implementation of the rule. At that time, it requires that schools offer only grain products that are whole grain rich, rather than permit schools to offer half of all grains in the form of 100 percent whole grain foods and the other half as refined grains (one of the options suggested by IOM).

The proposed rule adopts with a slight modification IOM’s recommendation for “offer vs. serve”

requirements as part of a reimbursable meal. Under this requirement, a student may decline 1 food item from the meal pattern at breakfast but must select 1 fruit or vegetable. For lunch, the student may decline 2 food items but must select 1 fruit or vegetable. Our estimates of the impact of the proposed rule reflect this flexibility in estimating the quantities of foods actually served to students.

III. Cost/Benefit Assessment

A. Summary

1. Costs

The proposed rule will more closely align school meal pattern requirements with the science-based recommendations of the 2005 *Dietary Guidelines*. These changes will increase the amount of fruits, vegetables, and whole grains offered to participants in the NSLP and SBP.¹⁸ The proposed meal patterns will also limit certain fats and reduce calories and sodium in school meals. Because some foods that meet these requirements are more expensive than foods served in the school meal programs today, the food cost component of preparing and serving school meals will increase.

The biggest contributors to this increase are the costs of serving more

vegetables and more fruit, and replacing refined grains with whole grains. We estimate that food costs may increase by 3.4 cents per lunch served and 18.8 cents per breakfast served on initial implementation of the proposed requirements. Two years after implementation, when all grains served must be whole grain rich, the food costs may increase to 7.2 cents per lunch served and 25.3 cents per breakfast.¹⁹ In aggregate, we estimate that the proposed rule may increase SFA food costs by \$3.4 billion from FY 2012 through FY 2016. The annual increase in food costs, once the 100 percent whole grain requirement takes effect, may be about \$1 billion.

Compliance with this rule is also likely to increase labor costs. Serving healthier school meals that are acceptable to students may require more on-site preparation, and less reliance on prepared foods. IOM did not estimate the overall required increase in labor costs to implement its recommended changes in meal requirements, but noted an analysis of data from some Minnesota school districts that showed that “healthier” meals had higher labor costs—principally because of increased use of on-site preparation.²⁰

For purposes of this impact analysis, labor costs are assumed to grow so as to maintain a constant ratio with food costs, consistent with findings from a national study of school lunch and breakfast meal costs (USDA 2008). In practice, this suggests that food and labor costs may increase by nearly equal amounts relative to current costs. Additional costs of compliance with the rule are discussed in subsections III C and III D of this analysis.²¹

The estimated overall costs of compliance are summarized in Table 6. For purposes of this analysis, the rule is assumed to take effect on July 1, 2012, the start of school year (SY) 2012–2013. The additional requirement to offer only whole grain rich grain products is assumed to begin in SY 2014–2015.

The analysis estimates that total costs may increase by \$6.8 billion through fiscal year (FY) 2016, or roughly 12 percent when fully implemented in FY 2015. The estimated increases in food and labor costs are equivalent to about 14 cents for each reimbursable school lunch and about 50 cents for each reimbursable breakfast in FY 2015. These costs would be incurred by the local and State agencies that control school food service accounts.

TABLE 6—PROJECTED COST OF PROPOSED RULE
[Dollars in millions]

	Fiscal year					
	2012	2013	2014	2015	2016	Total
Food Costs	\$91.8	\$626.5	\$704.9	\$968.9	\$1,028.2	\$3,420.4
Labor Costs	89.6	611.4	687.9	945.6	1,003.4	3,337.9
State Agency Administrative Costs	0.1	8.9	9.0	9.3	9.6	36.9
Total	181.5	1,246.8	1,401.9	1,923.8	2,041.3	6,795.2
Percent Change Over Baseline	8.3	8.5	9.1	12.0	12.2	10.5

2. Benefits

The primary benefit of this proposed rule is to align the regulations with the requirements placed on schools under NSLA to ensure that meals are consistent with the goals of the most recent *Dietary Guidelines* and the Dietary Reference Intakes. In increasing

access to children for such meals it will address key inconsistencies between the diets of school children and *Dietary Guidelines* by (1) increasing servings of fruits and vegetables, (2) replacing refined-grain foods with whole-grain rich foods, and (3) replacing higher-fat dairy products with low-fat varieties. It

also results in a number of additional benefits, including alignment between Federal program benefits and national nutrition policy, improved confidence by parents and families in the nutritional quality of school meals, and the contribution that improved school

¹⁸ The proposed rule would make no change to the meal requirements for pre-kindergarten (pre-K) children. But, the rule would require that schools serving meals to pre-K children adopt food-based menu planning (FBMP) for consistency with the rule’s FBMP requirement for meals served to older children. Because the rule proposes no substantive change to the pre-K meal requirements we assume that the rule has no impact on the cost of serving meals to these children. More than 2/3 of elementary schools used traditional or enhanced FBMP in SY 2004–2005 (USDA 2008, vol. 1, p. 36) and would

need to make no changes at all to comply with the rule’s pre-K menu planning requirement. For elementary schools that serve meals to pre-K children using a nutrient based menu planning system, the rule would require a change to FBMP. But that change is required for meals served to older children as well, and the administrative cost of that change is incorporated into the labor cost estimate of this analysis.

¹⁹ Some of the difference between the 3.4 cent and 7.2 cent lunch figures and the 18.8 cent and

25.3 cent breakfast figures are due to food inflation, not to the change in the whole grain requirement. The lower numbers are estimates for the end of FY 2012 (the start of SY 2012–2013). The higher numbers are for FY 2015.

²⁰ IOM 2009, p. 148.

²¹ The SLBCS–II found that costs other than food and labor accounted for 9.9 percent of reported SFA costs. These costs include “supplies, contract services, capital expenditures, indirect charges by the school district, etc.” (USDA 2008, pp. 3–5)

meals can make to the overall school nutrition environment.

B. Food and Labor Costs

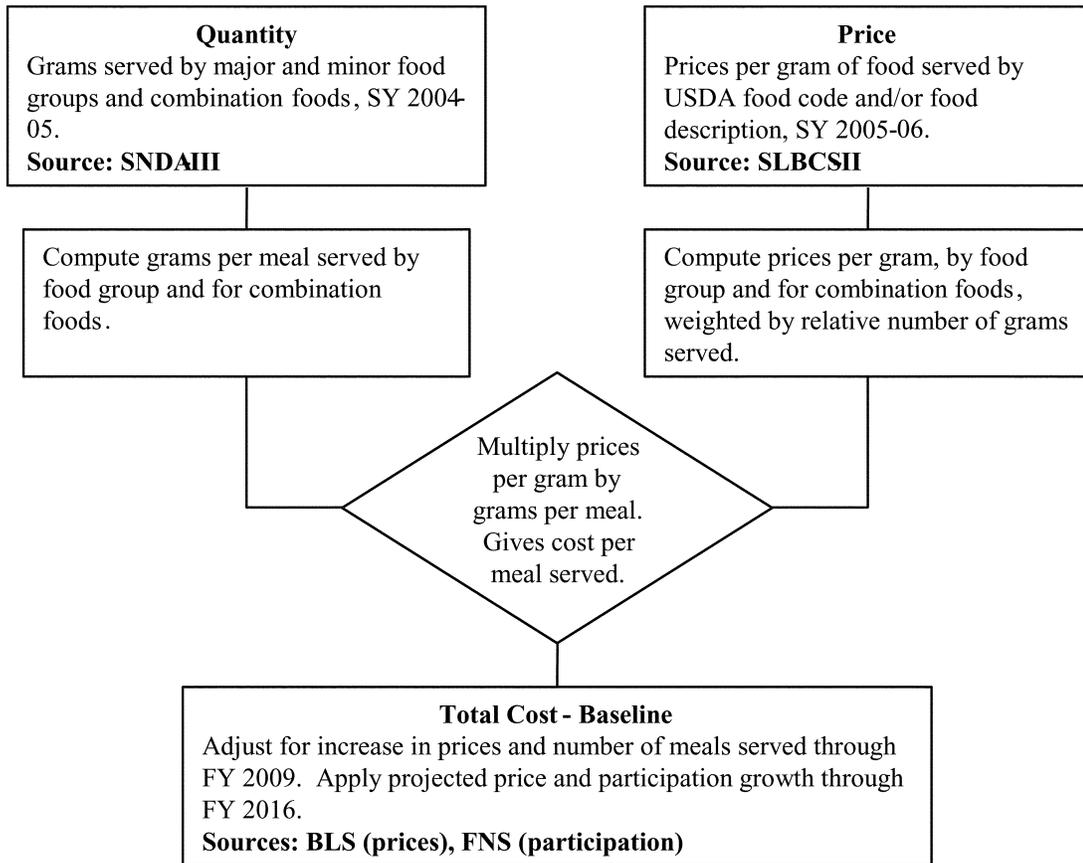
1. Baseline Cost Estimate

Food Costs: The analysis begins with an assessment of the cost of purchasing food to meet the rule’s food-based meal requirements. The estimated increase in

food cost is the difference between the cost of serving the quantities and types of foods used to meet current requirements and the cost of serving the quantities and types of foods outlined in the proposed rule.

Figure 1: Baseline Food Cost Estimate under Current Requirements and Practices

Objective: Use price and quantity data collected from schools to compute the total cost of NSLP and SBP meals served under current program rules.



The data sources that we use in this analysis, and their contribution to our

food cost estimate, are summarized in Table 7.

Table 7: Summary of Food Cost Estimate Data Sources

Data Source	Contribution to Food Cost Estimate
School Nutrition Dietary Assessment Study III (USDA 2007)	<ul style="list-style-type: none"> • Food codes and descriptions and food quantities served to students in SY 2004-05. Prices are applied to these food quantities to determine baseline food costs. • Meals served, quantities served, and quantities offered ("offer weights") by food type, by school type (elementary, middle, and high). Used to determine students' inclinations to take an offered menu item ("take rates"). Take rates are applied to the types and quantities of food that must be offered to students under the proposed rule to estimate quantities served.
School Lunch and Breakfast Cost Study II (USDA 2008)	<ul style="list-style-type: none"> • Food codes and descriptions, number of servings, average gram weight per serving, total grams served, cost per serving. These are used, along with other data sources, to estimate the cost per cup or ounce equivalent of each of the proposed rule's required food types and combination entrées. • Also used to estimate the relative cost of food group subtypes: whole versus refined grain products, and the various vegetable varieties with separate serving requirements under the proposed rule.
USDA Child Nutrition Food Labels	<ul style="list-style-type: none"> • USDA food labels contain information on food group crediting for child nutrition program administrators. USDA maintains a collection of food labels for thousands of commercially-prepared entrees. Food group crediting information is used to determine the cup or ounce equivalents of meat, meat alternate, grain, vegetable, and fruit that may be credited by schools for a particular entrée. • Food group crediting is used to determine how much of the proposed rule's food group requirements are satisfied by prepared foods offered by schools, and how much remains to be met with single food or non-entrée items.
USDA, National Food Service Management Institute, Recipe Database	<ul style="list-style-type: none"> • The recipe database is used to supplement the information from USDA food labels. The recipe records, like the food labels, contain food group crediting information used to determine how much of the proposed rule's food group requirements are satisfied by particular food items.
USDA Food Buying Guide	<ul style="list-style-type: none"> • The Food Buying Guide also contains information on food group crediting. The crediting information for various grain products is used in this estimate.
USDA, Agricultural Research Service, National Nutrient Database for Standard Reference, SR22	<ul style="list-style-type: none"> • The SR22 is used to supplement the other food group crediting resources listed above. SR22 information was used to estimate food credits for food items without a CN food label, or a USDA recipe. SR22 provides protein and fiber content per given volume of a particular food. That information is used to estimate the food group credits for foods that are similar, but not identical, to foods with CN labels or USDA recipe records. • SR22 data is also used to compute the proper conversion factor from grams to cups for various school foods.

Data Source	Contribution to Food Cost Estimate
USDA, Agricultural Research Service, <i>MyPyramid</i> Equivalents Database for USDA Food Codes, Version 1.0	<ul style="list-style-type: none"> Used to determine the relative share of vegetables in combination foods and entrées by each of the varieties with separate serving requirements under the proposed rule.
School Nutrition Dietary Assessment Study II (USDA 2001)	<ul style="list-style-type: none"> Average food group crediting information for school salad bars is taken from SNDA-II.

We first totaled the value of food served by food group, as reported by schools in a national school nutrition assessment (SNDA-III), separately for lunch and breakfast. SNDA-III provides an estimate of the amount or quantity (in grams) of foods offered and served in the school lunch and breakfast programs for SY 2004–2005, based on a nationally representative sample of all participating public schools.²² SNDA-III provides quantities of both minimally processed single foods (such as whole fruit, fruit juice, milk, and vegetables) and combination foods or entrees (such as beef stew, macaroni and cheese, and breakfast burritos). We summed the quantities of foods served to generate total gram weights for each single food and combination food category. We then divided these sums by SNDA-III’s count of total meals served to generate average

per-meal gram amounts for the same broad food categories. We estimated the cost per gram within each food category using detailed price and quantity information collected as part of another nationally representative sample of public schools in SY 2005–2006 (SLBCS-II). SLBCS-II provides information on the number of servings, the average gram weight per serving, total grams served, and the cost per serving for a comprehensive list of single foods and combination entrees. The SLBCS-II dataset provides sufficient information to estimate weighted average prices for the same broad food categories identified in SNDA-III. We computed preliminary per-meal baseline costs for breakfast and lunch as the product of the food quantities reported in SNDA-III and the unit prices computed from the SLBCS-II.

Because the food prices available for this analysis are from SY 2005–2006, we inflated our estimates by the actual and projected increase in prices since that time. We computed a set of food group inflators weighted by SNDA-III’s relative mix of foods served by schools in SY 2004–2005. We used the Consumer Price Index (CPI-U) for the specific food items in our weighted group averages. Because the mix of foods served in school breakfasts differs from the mix served at lunch (the grain group, for example, is weighted more heavily with bread at lunch, and more heavily with cereal at breakfast) we computed two sets of food group inflators. For years through 2009, these inflators are constructed with actual CPI values. For years after 2009, the food group inflators rely on historic 5-year averages. Food group inflation factors are summarized in Table 8.

²² If patterns of student selection of foods is different in private schools than it is in public schools, then the reliance on public school data alone may bias our results. However, enrollment in public schools accounts for 97 percent of total

enrollment in NSLP participating schools. Public schools account for more than 98 percent of total enrollment in SBP participating schools (USDA program data). Because public schools account for such a large share of total enrollment by

participating schools, we expect that any differences in selection patterns between public and private schools would have little impact on our analysis.

Table 8: Food Group Price Inflat²³

	Cumulative Increase 2006 to 2009	5-year Historic Average (for years after 2009)
Lunch		
Milk	5.88%	1.65%
Meat or Meat Alternate	11.20%	2.73%
Fruit Juice	19.01%	3.99%
Fruit (non-juice)	12.02%	3.90%
Vegetables	17.39%	5.37%
Refined & Whole Grains	24.21%	5.27%
Combination Foods/Entrees	12.65%	3.23%
Breakfast		
Milk	5.88%	1.65%
Meat or Meat Alternate	11.68%	2.82%
Fruit Juice	19.01%	3.99%
Fruit (non-juice)	9.97%	3.67%
Vegetables	20.87%	7.00%
Refined & Whole Grains	15.94%	3.26%
Combination Foods/Entrees	12.65%	3.23%

The value of USDA Foods and the value of cash in lieu of such food donations enters into both our baseline and proposed rule cost estimates; we treat them as food “costs” in both estimates. This is the same approach used in the SLBCS–II to estimate the cost of preparing and serving school meals.

We assume in the analysis that the types of commodities offered to schools in future years may satisfy the food group requirements of the proposed rule as effectively as they do now. USDA’s annual commodity purchase plan, developed by FNS in consultation with the Agricultural Marketing Service,

Farm Service Agency, and others, is driven by school demand for particular products as well as by current prices, available funds, and the variable nature of agricultural surpluses.

In large measure the variety of USDA Foods offered to schools are already well positioned to support the proposed requirements. In recent years USDA has purchased relatively more canned foods and meats with reduced levels of fat, sodium, and sugar for school distribution. As products such as butter and shortening have been removed from the USDA Foods available to schools, new products such as whole grain pasta have been added. The proposed rule is

likely to move school demand towards a greater emphasis on these new offerings as schools introduce new menus. We assume that the contribution of USDA Foods to the cost of preparing school meals will not change after implementation of the rule.

The final step in constructing the baseline cost estimate was to multiply the per-meal cost estimates by the projected number of breakfasts and lunches served through our 5-year forecast period. Projected growth in the number of NSLP and SBP meals served in the absence of the proposed rule is shown in Table 9.

TABLE 9—PROJECTED BASELINE GROWTH IN REIMBURSABLE MEALS SERVED²⁴

		Fiscal year					
		2011	2012	2013	2014	2015	2016
Lunches	meals (billions)	5.4	5.5	5.5	5.6	5.6	5.7
	percent change	2.9	1.2	1.0	0.9	0.8	0.8
Breakfasts	meals (billions)	2.1	2.1	2.2	2.2	2.2	2.3
	percent change	5.3	3.0	2.0	1.6	1.6	1.6

Appendix A contains a set of tables that detail the calculations described

above. The appendix tables present baseline and proposed rule food prices,

food quantities, and meals served for

²³ Computed by USDA from CPI figures from the Bureau of Labor Statistics. The figures for combination foods are based on the CPI values for the Food at Home series.

²⁴ The projected growth above in meals served through FY 2011 reflects the difference between FNS estimates for FY 2011 prepared for the 2011 President’s Budget and actual meals served in FY

2010. The remaining percentages are FNS projections prepared for the FY 2011 President’s Budget.

each year from FY 2012 through FY 2016.

Note that our baseline per-meal cost estimates are averages. They reflect the variety of meals served across all NSLP and SBP participating schools. Some schools may be much closer than others to serving meals that meet the requirements of the proposed rule, and the costs of compliance with the proposed rule may therefore vary at the school level. The use of an average baseline cost estimate is appropriate, however, for estimating the aggregate cost of compliance across all schools.

2. Proposed Rule Cost Estimate

Food Costs: Both our baseline and proposed rule food cost estimates rely on quantity and price information reported by schools in SNDA–III and SLBCS–II. These datasets contain detailed information on the quantity, variety, and unit prices of foods offered and served to students. Many of the records on these datasets describe single item foods that are served alone or are

used in school recipes. But other records describe prepared or heat-and-serve entrees and other “combination foods.” As described above, we developed our baseline cost estimate by multiplying the gram weight of food items served by their cost per gram. For both single item foods and combination foods, prices and quantities are given in SLBCS–II and SNDA–III; our baseline cost estimate required limited processing of these datasets.

For the proposed rule we continue to rely on prices per gram from SLBCS–II. But for quantities served we need to look to the requirements of the rule rather than to SNDA–III. We use the midpoints of the rule’s food group requirements, expressed in servings rather than grams, to estimate the quantities of food that schools must purchase.²⁵ For single foods, the

²⁵ The rule’s food group requirements are expressed in servings per week. Because we are developing an average cost per meal we divide these weekly figures by 5. Some of the rule’s requirements are given in ranges of servings, such

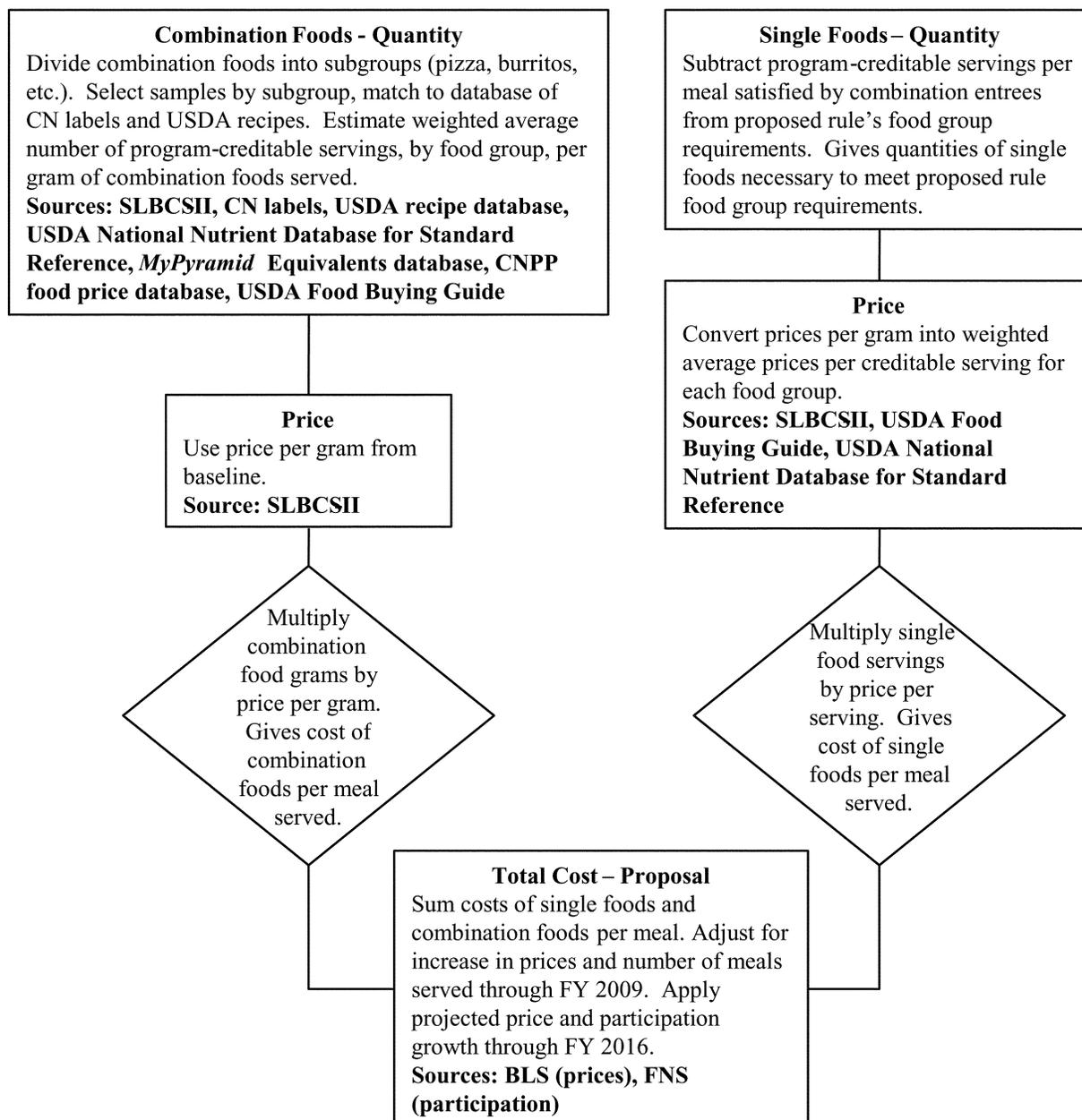
number of program-creditable food group servings per gram is a function of the foods themselves (density and fat content, for example) and whether the foods (primarily vegetables) are served raw or cooked. We relied on several sources for this information, including the USDA Food Buying Guide and the National Nutrient Database for Standard Reference. For combination foods we relied on the USDA’s child nutrition food labels and the USDA’s recipe database; these sources contain the result of analyses performed by food manufacturers and USDA. Because the sources for program-creditable servings per gram are different for single foods and combination foods, we need to separate single foods from combination foods and estimate their costs separately.

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as 10–12 meat or meat alternate servings (for lunches) per high school child per week (*see* Table 3). FNS’s primary cost estimate targets the midpoints of the rule’s food group requirements where requirements are expressed as ranges.

Figure 2: Food Costs under Proposed Rule

Objective: Use price data collected from schools, and meal pattern requirements from the proposed rule, to estimate the cost of serving meals under the proposed rule.

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A basic assumption underlying the estimated cost of reimbursable meals under the proposed rule is that schools will continue to serve entrees that have proven popular with students on current school menus. Some of these entrees may be modified to replace a portion of their refined grains with whole grains, or starchy vegetables with other vegetable varieties. But, because pizza, burritos, and salad bars are successful items today, this impact analysis assumes that they will remain

on school menus under the proposed rule.

We separated combination foods from single food items in the SNDA-III and SLBCS-II datasets.²⁶ Using USDA food codes and the descriptive food labels found on the records of both datasets, we divided the combination foods into sub-categories such as chili, beef dishes, lasagna, chicken sandwiches, macaroni

²⁶ As with the baseline estimate, we prepared separate estimates of meals served under the proposed rule for breakfast and lunch.

and cheese, and peanut butter and jelly. Recognizing that there is variation within these groups, we selected a sample of the most commonly served varieties, and retrieved paper food labels with matching USDA food codes from USDA's Child Nutrition food label collection (CN labels).

CN labels are affixed to many of the commercially prepared and processed foods purchased by school food authorities. The labels provide information on serving size and the

number of cup and ounce equivalents of meat, meat alternate (such as cheese, eggs, legumes, or soy protein), grains, or vegetables that schools may credit toward current reimbursable meal pattern requirements.²⁷ We averaged the crediting information for several varieties within each combination food category to generate representative food credits for the category.

CN labels are not available for some combination foods. However, foods with similar descriptions are often found in USDA's recipe database. The USDA recipe database provides the same type of food crediting information found on CN labels. We used the crediting information from the recipe database when CN labels were unavailable for sampled combination foods. FNS averaged the crediting information from labels and recipes when both sources returned data for particular combination foods.

CN labels and USDA recipes do not indicate whether creditable grain servings are refined or whole grains, nor do they specify what fraction of creditable vegetable servings are satisfied by dark green, deep yellow, starchy, or other varieties. But, USDA's *MyPyramid* database breaks down total grain and vegetable content for given foods into those subcategories or varieties. We matched USDA food codes for the sample of combination foods against the *MyPyramid* database in order to estimate relative shares of whole and refined grains, and vegetable varieties for the combination foods served.²⁸

With these average food credits, and with unit prices from the SLBCS-II, we estimated a price per creditable ounce or cup equivalent of meat, grain, vegetable, and fruit for each combination food served. We then computed a weighted average price per food credit for combination foods as a whole, using the SLBCS-II's relative gram weight of each item. Finally, we multiplied the average price and food credit per gram by SNDA-III's total gram weight of combination foods served per reimbursable meal at the elementary, middle, and high school levels.

These steps generate a price, and a set of food group credits, contributed by combination foods to the average

elementary, middle, and high school lunch and breakfast.

We subtracted the food credits accrued by combination foods from a set of school-level food group targets that represent the requirements of the proposed rule after adjustment for student selection. Under the proposed rule, as under current program rules, students need not take all of the food items offered to them in order for their lunch or breakfast to qualify for Federal reimbursement. The difference between what is offered to students and what they select is the "take rate." We computed average take rates by school level for milk, meat/meat alternate, fruit, vegetables, and grains from SNDA-III and applied those rates, unchanged, to the proposed rule's food group requirements from Tables 4 and 5.²⁹ These adjusted requirements are estimates of what elementary, middle, and high schools are likely to *serve* to students after implementation of the proposed rule. The unadjusted requirements are what schools must *offer* to their students to be in compliance.

The take-rate adjusted requirements not satisfied by combination foods must be met with single offerings of meat or meat alternates, grains, fruit, vegetables, and milk. We computed weighted average prices for these broad food groups, and for dark green, deep yellow and other vegetable varieties, from the SLBCS-II dataset. We estimated the cost of whole grains relative to all grain and bread products with information contained in a food price database developed by USDA's Center for Nutrition Policy and Promotion. The prices per unit of these foods, multiplied by the balance of the proposed rule's requirements that are not met by combination foods, give a total cost per meal for single item foods.

Note that this analytic framework uses an identical set of combination foods in the baseline and proposed rule cost estimates; we do not attempt to construct a reformulated set of combination foods to satisfy the proposed rule's requirements for whole grains or dark green, yellow, and other vegetable varieties. The deficits in whole grains and in dark green and other vegetable varieties are satisfied

entirely through increased offerings of single foods.³⁰ As a result, the cost per unit of combination foods served is unchanged in the baseline and under the proposal, and the entire cost of meeting the new rule's requirements is reflected in the cost of single foods.

In practice, we expect manufacturers may offer reformulated versions of popular combination foods, and that schools may incorporate more whole grains and vegetable varieties in their entree recipes, so that students may not be expected to consume all of their whole grains and healthier vegetables as single foods. Implicit in this modeling approach is the assumption that the cost of serving more whole grains and vegetable varieties is similar, whether those foods are part of combination recipes or single items. The reasoning behind this assumption is that the likely effect of these reformulations on the cost of combination foods is uncertain. While some varieties of combination foods may help schools meet the new requirements at lower cost than single foods, others may be developed to provide greater student acceptance or ease of preparation than single items. These products could command higher prices. We thus assume that, on average, these two propensities combine to result in no net difference in the cost of whole grains and vegetable varieties as combination foods or as single items.³¹

The proposed rule encourages schools to meet the fruit requirement with whole fruit rather than juice "whenever possible" in order to increase fiber consumption. Schools may therefore find it necessary to offer more whole or cut-up fruit relative to fruit juice than they offer today. For this reason, this cost estimate assumes that the proposed rule's entire increase in the fruit group requirement may be satisfied by schools through additional servings of whole or cut-up fruit; the estimate assumes that schools may serve no more fruit juice to students under the proposed rule than they serve today. As a result, there is no added cost for fruit juice in Table 11.

The methodology outlined above generates a set of per-meal cost estimates for breakfast and lunch under the requirements of the proposed rule. Like our baseline estimates, these are multiplied by weighted food group

²⁷ Many large commercial food vendors prepare their own CN labels to help market their foods to SFAs. Other labels are developed by USDA.

²⁸ Because CN crediting values and *MyPyramid* equivalents are not the same, information from the *MyPyramid* database was used only to determine relative shares of vegetable or grain subtypes. FNS also used the *MyPyramid* database to determine if particular combination foods contained any dark green vegetables, orange vegetables, etc.

²⁹ Our take rates are weighted averages computed from all school level records on SNDA-III. We cap individual school take rates for any food group at 100%. We assume that these take rates remain unchanged after implementation of the proposed rule for two primary reasons: lack of an evidence-based alternative, and to avoid understating the costs of the rule. We discuss our assumption of constant take rates, and examine the cost implications of altering that assumption, in section III.B.5.

³⁰ The amount of refined grains in combination foods in excess of proposed rule requirements are offset by subtracting the value of an equivalent amount of single food refined grain products from the proposed rule's per-meal cost.

³¹ Note that we are only referring to the incremental cost of foods above the quantities already purchased by schools (singly or in combination items), not the overall cost of all foods in the proposed meal patterns.

inflation factors, then multiplied by the projected number of meals served to generate projected aggregate costs through FY 2016.

Labor costs: Compliance with this rule is also likely to increase labor costs because of the need for more on-site preparation, and less reliance on prepared foods, than current requirements. The challenge faced by schools in reducing the sodium content of school meals, one element of both the IOM recommendations and the proposed rule, illustrates the need for additional labor hours by school kitchen staff.

[M]ore local food preparation and the use of a greater proportion of fresh foods and frozen vegetables could result in acceptable school meals with a lower sodium content. However, many food production kitchens are designed to heat and hold food items rather than to prepare them.³²

In addition to the implied need for new kitchen equipment, IOM notes that “switching from heat and hold to food production requires the addition of staff. Those districts that estimate meals per labor hour (MPLH) to monitor productivity may see an unfavorable decrease in their numbers.”³³

If schools choose to prepare more meals on-site to meet new requirements, IOM sees the need for “greater managerial skill,” and “more skilled labor and/or training.”³⁴ At the same time, lesser reliance on prepared foods offers some opportunity for offsetting savings.

An empirical analysis of data from 330 Minnesota school districts found that “healthier” meals had higher labor costs (for on-site preparation) but lower costs for processed foods (Wagner, *et al.*, 2007). The authors call for funds to be made available for labor training and kitchen upgrades. They suggest that higher Federal meal reimbursement rates may be unnecessary (under the assumption that the meals do not cost more to produce because lower food costs offset higher labor costs).³⁵

The effect of the proposed rule’s meal requirements on the mix of food and

labor costs is unclear. The proposed rule requires schools to offer relatively more foods with higher unit costs than schools now offer to their students. The rule requires, for example, that schools replace many of their refined grain foods with whole grain substitutes. Because prices for whole grain products tend to exceed the prices of similar products made with refined grains, savings from eliminating a particular refined grain product is more than offset by the cost of its whole grain counterpart. Where pre-baked whole grain foods are simply substituted for pre-baked refined grain products, or whole grain flour is substituted for refined flour in existing recipes, the added cost of serving these new foods is strictly a food cost; labor costs may not increase at all.

But the rule includes other provisions that are likely to increase both food and labor costs. One is the requirement that schools offer more vegetables, from a variety of vegetable subgroups, than schools tend to offer today. Some schools may choose to meet those targets by offering vegetables in school salad bars. It is not difficult to imagine that the cost of installing and maintaining a salad bar could increase the overall cost of school meal production. Similarly, to meet the proposed rule’s calorie and fat requirements, schools may find it necessary to rely less on pre-purchased entrees, and hire more central kitchen or cafeteria workers to prepare healthier meals from scratch.

SLBCS–II data show that the cost of purchasing food accounted for 45.6 percent of SFA reported costs, on average. Labor accounted for an additional 44.5 percent of reported SFA costs. The remaining 9.9 percent of reported costs are attributable to “supplies, contract services, capital expenditures, indirect charges by the school district, *etc.*”³⁶ Labor costs are broadly defined in the SLBCS–II to include the costs of foodservice administrative tasks such as planning, budgeting, and management, and

foodservice equipment maintenance.³⁷ Some of these tasks are detailed in section III.C.1. These tasks include training food preparation staff, servers, and cashiers. They also include the work of individuals who plan menus and prepare recipes.

For purposes of this analysis, we assume that the relative contributions of food and labor to the total cost of preparing reimbursable school meals will remain fixed at the levels observed in the SLBCS–II. As a result, we estimate that labor costs increase on a nearly dollar for dollar basis with estimated food costs.³⁸ We estimate that the proposed rule may increase schools’ food costs by about 12 percent. Although labor costs relative to food costs have held steady over many years,³⁹ this approach may overstate labor costs. We explore the potential effect of labor costs growing at a somewhat lower rate in section III.B.5.

Food and Labor Cost Summary: Table 10 summarizes the estimated increase in food and labor costs associated with the proposed rule through FY 2016.⁴⁰ (The final two rows of Table 10 also include the estimated administrative costs to State agencies.) Overall, we estimate that the proposed rule would increase the total cost of reimbursable school meals by \$6.8 billion over five years; the cost of food would increase by \$3.4 billion, and the cost of labor would increase by \$3.3 billion. In the first year of full implementation (FY 2015),⁴¹ the combined cost of food and labor is expected to be about 12 percent higher under the proposed rule than under existing requirements. The estimated additional cost of *food* for a reimbursable lunch increases from about 3.4 cents in 2012 to 7.7 cents in 2016; the equivalent increase in food costs for a reimbursable breakfast grows from 18.8 cents to 26.1 cents. These rates roughly double—to 15.1 cents and 51.6 cents—when the estimated cost of labor is included.

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³² IOM 2009, p. 110.

³³ *Ibid.*

³⁴ IOM 2009, p. 148.

³⁵ *Ibid.*

³⁶ USDA 2008, p. 3–5.

³⁷ USDA 2008, p. 3–9.

³⁸ The estimates contained in this analysis assume labor costs equal to food costs multiplied by (44.5/45.6), the ratio of reported labor to food costs in the SLBCS–II.

³⁹ Labor costs as a share of the total costs of preparing school meals were found to be 43.8

percent in FNS’s SY 1992–1993 School Lunch and Breakfast Cost Study I, and 44.5 percent in the SY 2005–2006 School Lunch and Breakfast Cost Study II (a statistically insignificant difference). Food costs as a percent of total costs grew slightly from 45.6 percent in SY 1992–1993 to 48.3 percent in SY 2005–2006. But this change, too, is statistically insignificant. USDA 2008, p. 9–2.

⁴⁰ For purposes of this analysis, the new standards are assumed to take effect at the start of SY 2012–2013. Because the 2012–2013 school year begins in July 2012, there is just a small cost in

Federal FY 2012. Note that these figures assume no effect on student participation. We discuss the possible effects of the proposed rule on student participation in section III.F. We examine the effect of alternate participation assumptions in section III.B.5.

⁴¹ Two years after implementation of the rule, all grains servings offered to meet meal pattern requirements must be whole grain rich. If the rule is implemented in SY 2012–2013, then the 100 percent whole grain requirement takes effect in SY 2014–2015 or FY 2015.

Table 10: Food and Labor Cost Summary

	Fiscal Year					
	2012	2013	2014	2015	2016	Total
Food Costs						
Lunch						
Total Cost (millions)	\$29.5	\$206.6	\$248.8	\$403.5	\$434.7	\$1,323.2
Per Meal	0.034	0.037	0.045	0.072	0.077	
Breakfast						
Total Cost (millions)	\$62.3	\$419.9	\$456.1	\$565.4	\$593.5	\$2,097.1
Per Meal	0.188	0.194	0.207	0.253	0.261	
Lunch + Breakfast						
Total Cost (millions)	\$91.8	\$626.5	\$704.9	\$968.9	\$1,028.2	\$3,420.4
Per Meal	0.077	0.081	0.091	0.123	0.129	
Food + Labor Costs						
Lunch						
Total Cost (millions)	\$58.3	\$408.3	\$491.6	\$797.4	\$859.0	\$2,614.5
Per Meal	0.068	0.074	0.088	0.142	0.151	
Breakfast						
Total Cost (millions)	\$123.0	\$829.7	\$901.2	\$1,117.1	\$1,172.7	\$4,143.7
Per Meal	0.371	0.383	0.409	0.499	0.516	
Lunch + Breakfast						
Total Cost (millions)	\$181.3	\$1,237.9	\$1,392.8	\$1,914.5	\$2,031.7	\$6,758.2
Per Meal	0.153	0.161	0.179	0.243	0.256	
Food + Labor + State Administrative Costs						
Lunch + Breakfast						
Total Cost (millions)	\$181.5	\$1,246.8	\$1,401.9	\$1,923.8	\$2,041.3	\$6,795.2
Per Meal	0.153	0.162	0.180	0.245	0.257	

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3. Food Cost Drivers

Table 11 provides a breakdown in the estimated food costs of the proposed rule by seven broad food categories.

Consistent with the *Dietary Guidelines*, the proposed rule will require schools to offer more fruits, vegetables, and whole grains than they currently offer today.

Changes in school demand also impact food producers. The figures in

Table 11 indicate that the economic costs and benefits of the proposed rule may not be shared equally by producer groups.

TABLE 11—ESTIMATED FOOD COSTS BY FOOD CATEGORY
[Dollars in millions]

Food group	Fiscal year					
	2012	2013	2014	2015	2016	Total
Milk	-\$4.4	-\$29.0	-\$29.8	-\$30.5	-\$31.3	-\$125.1
Meat or Meat Alternate	3.1	22.5	24.9	27.6	30.5	108.6
Fruit Juice	0.0	0.0	0.0	0.0	0.0	0.0
Fruit (non-juice)	42.3	286.1	301.4	317.1	334.1	1,281.0
Vegetables	75.6	515.2	547.8	581.2	617.5	2,337.3
Refined Grains	-116.0	-787.5	-964.7	-1,766.5	-1,869.1	-5,503.8
Whole Grains	91.2	619.3	825.3	1,840.0	1,946.5	5,322.3

TABLE 11—ESTIMATED FOOD COSTS BY FOOD CATEGORY—Continued
[Dollars in millions]

Food group	Fiscal year					Total
	2012	2013	2014	2015	2016	
Total Cost of Proposal	91.8	626.5	704.9	968.9	1,028.2	3,420.4

Milk: This impact analysis estimates that the amount of milk served to students may not change after implementation of the proposed rule.⁴² However, the rule does require schools to serve only low-fat or fat-free milk in the school meals programs. Because the per-unit cost of low-fat and fat-free milk is less than the average per-unit cost of the mix of milk products now served in schools, the cost of serving milk under the proposed rule is reduced.

Fruit Juice: The estimate assumes that schools may satisfy the rule's increased fruit requirement entirely through additional servings of whole or cut-up fruit, not fruit juice. We expect that schools may have to encourage consumption of additional whole or cut-up fruit in order to satisfy this requirement. The cost estimate assumes that the amount of fruit juice served to students may not increase above the levels assumed in the baseline estimate. As a result, the relative share of whole or cut-up fruit to fruit juice servings offered to (and taken by) students may increase after implementation of the rule.

Grains: The proposed rule initially requires that half of grains offered to students be whole grain rich. Beginning in SY 2014–2015, the rule requires that all grains served be whole grain rich. This change is reflected in the large changes in both the whole and refined grains figures between FY 2014 and FY 2016.

Note that the total amount of grain products served under the proposed rule may be less than the amount served in the baseline (the per-meal amount taken in SNDA–III). The effect of this net reduction in total grains served is reflected in figures for fiscal years 2012 to 2014, where the cost decrease for refined grains exceeds the cost increase for whole grains. Throughout the estimation period, we assume that the unit cost of whole grains exceeds the unit cost of comparable refined grain

products. Despite this, the net reduction in total grain products served through FY 2014 more than offsets the increased unit cost of whole grains. After FY 2014, when the rule's 100 percent whole grain rich requirement takes effect, the higher relative cost of whole grains to refined grains exceeds the savings from the net reduction in grain products served.

4. Comparison of FNS and IOM Cost Estimates

IOM prepared its own food cost estimate for its recommended meal pattern changes. The methodology behind that estimate is discussed in *School Meals: Building Blocks for Healthy Children* (IOM 2009). While IOM relies on SLBCS–II and SNDA–III, the same primary sources used by FNS, to estimate unit costs and baseline quantities served, its methodology differs from ours in several ways.

Perhaps the most significant difference is in the establishment of baselines. We used all records on the SNDA–III dataset to estimate baseline quantities of food served and student take rates. IOM limited its analysis to a set of six representative baseline menus selected from the SNDA–III dataset. IOM selected one 5-day lunch menu and one 5-day breakfast menu for each of three age-grade groups (elementary, middle, and high school) at random from a subset that excluded practices identified as uncommon.⁴³ The goal of both methodologies is to estimate a baseline food cost representative of all schools that participate in the Federal school meals programs. We have not attempted to isolate and quantify the effect of this methodological difference on our cost estimates.

Another important difference between the IOM and FNS estimates is our use of different student take rates in preparing food cost estimates for the recommended meal patterns. We computed take rates from SNDA–III and applied them, largely unchanged, to the food group serving requirements of the

proposed rule.⁴⁴ We do not increase take rates in anticipation of greater demand for better meals, nor reduce take rates in anticipation of a decline in student acceptance of new vegetable varieties, whole grains, or low fat milk relative to the starchy vegetables, refined grains, and higher fat milk on current school menus.⁴⁵ IOM modified observed take rates from SNDA–III where the expert judgment of committee members and school meal practitioners deemed it appropriate.⁴⁶ Additional differences in FNS and IOM take rates can be attributed to IOM's use of six representative school menus in its analysis; IOM computed its take rates from those schools alone. FNS take rates are computed from all schools on the SNDA–III dataset.

IOM estimated that food costs would increase by 4 to 9 percent for lunch, depending on student take rates for fruits and vegetables. For breakfast, IOM estimated an increase in food costs of 18 to 23 percent. Both of these ranges are based on unadjusted SY 2005–2006 prices from the SLBCS–II. In addition, both are for the requirements recommended for the first year of implementation, not including the more stringent whole grain requirement recommended for later introduction. The comparable FNS figures are 3 percent for lunch and 26 percent for breakfast.

5. Uncertainties

We made several simplifying assumptions in developing this cost estimate, reflecting gaps in available data and evidence. The most significant simplifications are discussed in Table 12. In most cases, our primary estimate reflects conservative assumptions, to avoid understating the costs of the proposal. In this section, we describe the impact of several alternative assumptions on the estimate. The cost impacts of these alternatives are presented in Table 14.

⁴² See section III.B.5. for an examination of the cost implications of altering this assumption.

⁴³ IOM excluded menus that did not offer a reduced fat or fat free unflavored milk, offered only one entree, offered 15 or more entree options, offered juice drinks rather than 100% fruit juice, or offered dessert every day. IOM 2009, p. 307

⁴⁴ FNS caps individual school take rates at the food group category to 100 percent.

⁴⁵ As discussed elsewhere in this impact analysis, our take rate assumptions are intended to avoid understating the cost of the proposed rule given the uncertain response of both students and school foodservice workers to the new meal pattern

requirements. We test the cost implications of adopting different take rates in section III.B.5.

⁴⁶ IOM 2009, p. 136.

TABLE 12—SIMPLIFYING ASSUMPTIONS

Item	Explanation and implications of simplifying assumptions
Take Rates	For each of several food groups, we used SNDA–III data to compute average “take rates” equal to the percentage of food servings taken by students for each serving offered to them. Take rates under current program rules vary by school, grade level, and menu planning system. They are, at best, a rough predictor of student behavior under the proposed rule, which imposes a single food-based meal planning system across all schools, and requires schools to offer a mix of foods somewhat different than many students are accustomed to. We apply these take rates to generate a primary cost estimate. But, recognizing the uncertainty of these take rates, the cost implications of different take rate assumptions are examined in the uncertainties section of the impact analysis.
Student Participation	The cost estimate assumes no change in student participation following introduction of the rule’s new meal pattern requirements. However, we recognize that participation may increase due to better meals or decrease when favorite school foods are replaced with unfamiliar or less appealing options. We chose not to estimate a participation effect given the uncertainty about how schools may incorporate new foods into their menus, and what changes schools may make to a la carte and other non-NSLP/SBP “competitive” foods, factors known to affect NSLP/SBP participation. Schools have a financial interest in preserving the revenue stream that comes with serving Federally-reimbursable school meals. It is also unclear whether participation effects, if any, may prove temporary or permanent. We estimate the cost of the rule under an assumption of increased and reduced student participation in the uncertainties section.
USDA Foods	We include USDA Foods (formerly USDA commodities) in both the quantity and value of food served in its baseline and proposed cost estimates. This treatment of USDA Foods is consistent with the SLBCS–II which includes the value of USDA Foods in its computation of the cost of producing a school meal. We assume that USDA Foods will contribute comparably to the overall cost of preparing school meals under current and proposed program rules. We believe it is reasonable to ignore the value of USDA Foods in computing the estimated cost increase of the proposal.
Whole Grains	We apply a single take rate to both whole grain rich and refined grain products. A less conservative approach would have applied a lower take rate to whole grain foods, at least when offered singly, rather than as part of a combination entree. Further, this take rate is the same take rate observed in SNDA–III where the relative share of whole grain rich products is lower than the 50 percent share that schools must offer in the first two years of implementation, and much lower than the 100 percent share that must be offered thereafter. Testimony before the IOM expert committee by University of Minnesota Professor Leonard Marquart documented steps SFAs can take to phase in whole grains in a manner that promotes high take rates.
Labor Rates	We assume that the relative contributions of food and labor to the total cost of preparing reimbursable school meals will remain fixed at the levels observed in the SLBCS–II study. The study found that the cost of purchasing food accounted for 45.6 percent of SFA reported costs on average, while labor accounted for 44.5 percent of reported costs. We therefore estimate that labor costs may increase on a nearly dollar for dollar basis with estimated food costs. Our assumption leads to a substantial increase in estimated labor costs, one that assumes schools may rely less on prepared foods and more on on-site preparation. We re-estimate the cost of the proposed rule assuming a smaller increase in labor costs in the uncertainties section.
Macronutrient Requirements and Calories.	<p>The cost estimate developed in this impact analysis is based entirely on the cost of adding or deleting foods from particular food groups.</p> <p>The cost estimate accounts for current price differences in whole grains compared to refined grain products, low fat milk compared to 2 percent or whole milk, whole fruit compared to fruit juice, and vegetables by subcategory. But it does not account directly for differences in the costs of comparable combination entrees with different levels of sodium, fat, or calories. SNDA–III found that school lunches offered to students in SY 2004–2005 provided, on average, about 11 percent of calories from saturated fat. The proposed rule would limit this to 10 percent—a relatively modest reduction.</p> <p>Our cost estimate does take into account the added cost of more fruits and vegetables. It also takes into account the cost of shifting away from starchy vegetables, which reduces the relative share of french fries in the proposed rule estimate.</p> <p>Finally, the estimate accounts for the replacement of higher fat content milk with low fat and skim milk. All of these steps implicitly incorporate the cost of offering lower calorie and lower fat content meals into our estimate. We make an explicit assumption that a reduction in sodium can be achieved at minimal cost, at least over the short term, when proposed sodium requirements are only partially phased-in. This is one of the very few assumptions that, if wrong, tend to understate the cost of the proposed rule. But, given the decision to err on the side of overstating costs when making most other assumptions, we believe that the upside risk to an error on this assumption is small.</p>

FNS and IOM Food Group Take Rates: For all food groups, we assume that observed (baseline) take rates from SNDA–III will continue to characterize student behavior after implementation of the proposed rule’s meal requirements.⁴⁷ These take rates are weighted averages across schools that operated under nutrient-based, traditional food-based, and enhanced-

food based systems in SY 2004–2005, calculated as follows:

$$\text{Take rate} = \frac{\text{number of servings taken}^1}{(\text{Servings offered}^2/\text{meal} * \text{number of meals}^3)}$$

¹ Based on SNDA–III analysis of observed meals taken by students.

² Based on SNDA–III analysis of school menus/recipes.

³ Based on SNDA–III observations of daily meal counts.

Data are not available to assess how student behavior across all schools may change in response to menus that simply offer more fruits, vegetables, and whole grains. One approach to model that response would be to apply take rates from schools that offered higher than average amounts of these foods in SY 2004–2005, but this occurred in a relatively small subset of schools sampled in SNDA–III; conclusions drawn based on their behavior may be

⁴⁷ We cap individual food group take rates at 100 percent in our proposed rule cost estimate.

misleading. In addition, upon implementation of the rule, schools may attempt to influence student behavior by developing appealing new menu items, or by taking other steps to encourage increased consumption of the fruits, vegetables, low-fat milk products, and whole grains emphasized by the rule.

Because of these unknowns, FNS adopted a static take-rate assumption in developing its primary cost estimate. IOM departed from observed take rates in developing its assumptions for its own cost estimate, drawing on expert opinion from school meal practitioners about likely student behavior. IOM's assumed take rates, "which are based on

data from SNDA-III but are adjusted to consider the recommended Meal Requirements, represent estimates that the committee considers realistic."⁴⁸

Tables 13a and 13b compare the take rates applied by IOM and by FNS in developing their respective cost estimates.⁴⁹

TABLE 13a—IOM AND FNS BREAKFAST TAKE RATES AFTER IMPLEMENTATION OF IOM RECOMMENDATIONS AND FNS PROPOSED RULE

Food group	IOM Breakfast take-up rates			FNS Breakfast take rates		
	Elementary	Middle	High	Elementary	Middle	High
Fluid Milk	98%	92%	96%	90%	81%	81%
Meat/Meat Alternate	62% or more	68% or more	62% or more	85%	84%	82%
Fruit	70%	70%	75%	84%	82%	77%
Grain	100%	100%	100%	89%	81%	83%

TABLE 13b—IOM AND FNS LUNCH TAKE RATES AFTER IMPLEMENTATION OF IOM RECOMMENDATIONS AND FNS PROPOSED RULE

Food group	IOM Lunch take-up rates			USDA Lunch take rates		
	Elementary	Middle	High	Elementary	Middle	High
Fluid Milk	98%	97%	88%	91%	81%	78%
Meat/Meat Alternate	100%	100%	100%	91%	91%	90%
Fruit	80%	80%	60%	70%	58%	50%
Vegetables	55%	60%	65%	85%	83%	86%
Grain	65%–100%	65%–100%	70–100%	86%	86%	79%

Subsections a through c, below, explain three alternative applications of IOM take rate assumptions.

a. Fruit and Vegetable Take Rates—Use IOM Estimates

In Table 14, Section A, we substitute the fruit and vegetable take rates used by IOM to model student behavior after implementation of new meal patterns for the take rates used in FNS's primary cost estimate under the proposed rule.⁵⁰ IOM applied lower take rates than FNS for vegetables, but applied higher take rates for fruit. The reduced cost estimate presented in Table 14, Section A simply substitutes the post-implementation fruit and vegetable take rates assumed by IOM for the post-implementation take rates assumed by FNS. The net result of using IOM's assumptions would reduce the estimated cost of implementing the proposed rule by \$3.5 billion.

b. IOM Fruit and Vegetable Take Rates with Labor Cost Adjustment

The effect of using IOM's vegetable take rates is to reduce the change in

food cost for lunch in implementing the proposed rule to zero. Under our approach, labor costs are assumed to remain fixed, relative to food costs, at the ratio estimated in the SLBCS-II. As a result, the figures in Table 14, Section A assume no increase in the labor costs of preparing lunches under the proposed rule. However, the work required to prepare lunches (and breakfasts) that meet the new food group, macronutrient, and calorie requirements could increase even if the costs of purchasing food for those meals is about equal under current and proposed rules.

Table 14, Section B reflects estimated food costs using IOM's estimated fruit and vegetable take rates, and the labor costs estimated by FNS for its primary estimate (from Table 6). This revised estimate assumes that the relationship between food and labor costs diverges from the relationship observed in SLBCS-II and the net effect of this assumption would reduce the estimated cost of implementing the proposed rule by \$1.8 billion.

⁴⁸ IOM 2009, p. 307

⁴⁹ See IOM 2009, pp. 309–315, for all of IOM's food group take rate assumptions. Note that some of IOM's assumed take rates are presented as ranges.

⁵⁰ IOM take rates appear in tables L-1 through L-6 of IOM's School Meals report. IOM 2009, pp. 309–315.

c. Using All IOM Take Rates

As described in section III.B.4, IOM and FNS took different approaches to anticipating students' response to the proposed meal pattern changes. IOM relied on observed take rates from SNDA-III as well as the best judgment of school foodservice practitioners. While some of IOM's take rates are higher than the ones used in our primary estimate, others are lower. The net effect of substituting IOM post-implementation take rates for FNS post-implementation take rates for all food groups (milk, meat, meat alternate, fruit/fruit juice, vegetables, and grain products) is displayed in Table 14, Section C. The net effect is a cost estimate that differs from our primary estimate by about 10 percent, a reduction in our primary cost estimate of \$676 million.⁵¹

d. Cost of Whole Grains—Reduction over Time

The proposed rule requires schools to replace refined grains with whole grain rich foods. In the first two years of

⁵¹ It is worth recognizing that the differences between IOM's estimate and our primary estimate also reflect differences in baseline assumptions. We did not alter our baseline take rates for this test.

implementation, whole grain rich products must make up half of all grain products offered to students. By the third year, schools must offer only whole grain rich products. At present, whole grain rich products cost more than similar refined grain products. The primary cost estimate developed above assumes that the relative price of whole grain rich to refined grain products will remain constant at FY 2009 levels throughout the five year forecast period. Part of the price difference, however, may be due to low supply of whole grain products in the market—in turn influenced by current low demand by schools. As IOM explains:

Of greater concern is the relative lack of available whole grain-rich processed products on the market and acceptable in the school meals program. Hence some cost increases would be expected for the less available processed whole grain-rich products in the market. Several new whole grain products are being introduced through the USDA Foods program; over time, the availability of whole grain-rich products is expected to expand.⁵²

The difference in price between whole grain rich and refined grain products may diminish over time. Table 14, Section D provides estimates of the cost of the proposed rule under the assumption that the difference in price between whole grain rich and refined grain products will disappear entirely at a rate of one-third per year from FY 2013 to FY 2015. The net result of this assumption would reduce the estimated cost of implementing the proposed rule by \$2.5 billion.

e. Change in Participation—2 Percent Increase

As discussed in Table 12 above, we assumed that student participation would not change following the introduction of new meal requirements. Table 14 Sections E and F model the effects of altering that assumption.

Section E estimates the effect of a two percent increase in student participation on the cost of the rule relative to our primary cost estimate in Table 6. The dollar figures in Section E are the estimated cost to schools of preparing all meals served under our baseline assumption plus an additional 2 percent. Per meal costs for all of these additional meals are taken from Table 10. The additional meals are eligible for USDA reimbursement at the appropriate free, reduced price, or paid rates. However, the figures shown in Section E are not offset by these increased Federal reimbursements. The net cost to schools, after accounting for Federal reimbursements, would be lower.

Because these costs reflect the provision of improved meals to additional children, we would expect a commensurate increase in the benefits resulting from addition of more fruits, vegetables, and whole grains to the diets of participating children. This participation assumption would result in a \$1.4 billion increase over the cost of our primary estimate.

f. Change in Participation—2 Percent Decrease

Table 14, Section F models the effect of a two percent decrease in participation upon implementation of the new rule. A reduction in participation reduces the cost of compliance with the rule, relative to the primary cost estimate in Table 6.⁵³ Again, because the cost reduction reflects the provision of improved meals to fewer children, we would expect a proportionate decrease in the rule's benefits for participating children. The net effect of this assumption would be to decrease the cost of implementing the final rule by \$1.4 billion.

g. Lower Rate of Increase in Labor Costs Than Food Costs

Our primary cost estimate assumes that the ratio of labor to food costs will remain fixed at the ratio observed in the SLBCS-II. Because we estimate a substantial increase in school food costs, our fixed labor to food cost assumption leads to a substantial increase in labor costs.

Some increase in labor costs is likely. Schools may find it necessary to prepare more meals on site to incorporate added vegetables and whole grains, and to reduce levels of sodium and fat. In addition, schools are likely to incur additional expense to train foodservice workers on the new meal requirements. However, commercial suppliers can be expected to develop and introduce healthier products for the school market ahead of implementation of a final rule; other products may be introduced after implementation. Schools may find that new training replaces some training planned in existing budgets.

It is also uncertain that more expensive foods are proportionately more expensive to prepare than less expensive foods. Long-term stability in the relationship between food and labor costs is unremarkable if the primary factor driving both is an increase in the number of participants and meals served. Though the limited data available shows that this ratio remained stable between SY 1992–1993 and SY

2005–2006—a period that included program changes under the School Meals Initiative—there are reasons to suspect that this relationship may not hold in response to a sudden increase in food costs unrelated to the number meals served.

Table 14, Section G models an increase in labor costs that is 75 percent of the level in our primary estimate, to reflect a shift in the balance between food and labor costs under the proposed rule. This assumption would result in an \$834 million decrease of our primary cost estimate of implementing the proposed rule.

h. Extent of School Compliance With New Requirements

Results from SNDA-III indicate that most schools do not fully comply with the current nutrition requirements for meals served and reimbursed through the school lunch and breakfast programs. Although a large majority of schools (more than 80 percent) served lunches in SY 2004–2005 that met requirements for protein, calcium, and iron, and more than 70 percent served lunches that met requirements for vitamins A and C, fewer than half met minimum calorie requirements, just 30 percent met the standard for saturated fat, and only 21 percent met the standard for total fat. Overall, while most schools met most of the requirements for a nutritious school meal, just 7 percent of schools served reimbursable lunches that met every requirement.⁵⁴

Despite the challenge of meeting these requirements, it is relatively uncommon for schools to serve meals for Federal reimbursement that lack required food group or meal components. FNS' study of improper payments in the school meal programs found no point-of-sale error in identifying reimbursable lunches at 45 percent of schools in SY 2005–2006, and high error rates (more than 20 percent) in just 2 percent of schools. These errors were somewhat more prevalent in breakfast service, but still far below the level of noncompliance with nutrient standards.⁵⁵

Taken together, these results indicate that schools make a relatively successful effort to comply with food group and meal component requirements, but serve too many high fat options in satisfaction of those requirements.

⁵⁴ USDA 2007, vol. I, p.169. For breakfast, schools tend to perform better, though just 30 percent offered meals that met the SMI standard for calories; see p. 204.

⁵⁵ USDA 2007b, vol. I, p. 116. The comparable rates for breakfast were 48 percent with no error, and 11 percent with error rates above 20 percent.

⁵² IOM 2009, p. 8–22

⁵³ This reduction in cost comes at the expense of reduced Federal meal reimbursements.

The proposed rule is intended to facilitate meeting most micro- and macronutrient targets by focusing on a set of food group requirements. This plays to the strengths of the current system which tends to produce meals that satisfy food item or meal component requirements, but is less successful at monitoring the nutrient content of those foods. The cost estimate we developed above is the cost of serving more fruits and vegetables, substituting whole grains for refined grains, and limiting the fat content of fluid milk, as required by the proposed rule's food group requirements; the estimate assumes, we believe reasonably, that schools may comply with those food level changes.

Although schools are expected to satisfy most nutrient requirements through compliance with the rule's proposed food group standards, IOM recognized the need to retain four separate nutrient targets for saturated fat, *trans* fat, calories, and sodium. While schools may have difficulty meeting those requirements, at least in the short term, they may eventually meet them within the same food group requirements that are effective on initial implementation of the rule. For this reason, we believe that less than full compliance with these four nutrient standards offers little cost savings to schools.

We estimate that a committed effort by schools to serve meals consistent with the proposed rule's food-based requirements may increase costs as summarized in Table 6. Nevertheless, it remains possible that some schools may find it operationally difficult, or too costly, to prepare and serve meals that satisfy the new food group and subgroup requirements of the rule. If some schools fall short of the proposed food group requirements in the initial years after implementation by not serving enough of certain foods, the aggregate cost of the rule may be lower than estimated.

The nature of noncompliance with the proposed rule, if observed, is likely to resemble compliance with current standards as illustrated by SNDA-III. That is, most schools can be expected to work toward and achieve compliance with most provisions of the rule. We would expect some variation across schools in the degree to which individual food group requirements are met, given differences in current menus, what students in different schools are accustomed to eating, and variations in school policy on a la carte foods, other non-program choices, implementation of offer versus serve, *etc.* But it is also possible that some schools may be

unable to make any changes to current menus, at least initially. Those schools' compliance with the proposed rule may depend on current differences in the content of school menus relative to the new standards.

Table 14, Section H presents an estimate of the cost of the rule under the alternate assumption that some schools fail to meet the proposed rule's food group requirements. This alternate estimate looks to SNDA-III's school-level compliance rates with current nutrient standards to model compliance with proposed rule food group requirements. Specifically, the estimate assumes:

1. Initial (FY 2012 and FY 2013) school-level compliance with the proposed standard for the meat group is equal to the average of the observed school-level rates of compliance with the SMI standards for protein and iron,

2. Initial school-level compliance with the proposed fruit and vegetable group standards matches the average of the observed school-level rates of compliance with SMI standards for vitamins A and C,

3. Initial school-level compliance with the fluid milk standard equals the average of the observed school-level rates of compliance with the SMI standards for protein and vitamin A,

4. Initial school-level compliance with the grains standard equals the average of the observed school-level rates of compliance with SMI standards for iron, protein, and vitamin A.

In each case, school-level compliance means the percent of schools that serve meals that meet the current or proposed requirements. For schools that do not initially comply with a proposed food group standard, we assume that they may serve the same amount from that food group in fiscal years 2012 and 2013 that they did prior to implementation of the rule. In that way, we assume a distribution of food level compliance rates based on actual recent performance. This recognizes that some schools are much closer to meeting particular food group standards than other schools. The alternative estimate assumes that these schools' average rate of compliance may rise to 100 percent, in equal increments, over the FY 2014 through 2016 period.

This assumption of less than full compliance would reduce the five year cost of the rule by \$743 million.

i. Cost Attributable to Noncompliance With Existing Meal Requirements

In subsection h, we point to results from SNDA-III that show most schools fall short on at least some SMI nutrient standards for lunch and breakfast.

The cost estimate developed in this impact analysis measures the difference in the cost of serving meals that comply with the proposed rule's requirements, and the current cost of serving meals consistent with the findings of SNDA-III. Note that in concept, some portion of that cost difference could represent the cost for schools to reach existing nutrition requirements. Arguably, any cost incurred to reach existing standards should not be considered a cost of the proposed rule.

We note, however, that an assessment of the cost to schools of changing meals to achieve current nutrition requirements is sharply limited by a lack of specific relevant data. Existing requirements for school meals consist of a limited number of food item requirements *and* a range of nutrient standards. Most schools that do not meet current standards are missing one or more *nutrient* standards—most commonly, those for total fat, saturated fat, and calories.

The proposed rule, as IOM recommended, moves more fully to a set of *food-based* standards—requiring increases in particular kinds of foods (such as fruits and vegetables), and replacement of other foods with different types (whole-grain versus refined grain products, and low fat versus full fat dairy). The proposed rule includes only four stand-alone nutrient requirements (for sodium, saturated fat, calories and *trans* fat).

The estimates presented in this analysis address the cost of providing more fruits and vegetables and replacing some or all high refined grains with whole grains—changes that could be modeled using school food purchase and cost data. In contrast, many of the kinds of changes needed to meet current standards, such as changing from frying to baking, and replacing full-fat milk with lower-fat varieties, would cost little. And for some nutrients, relatively small changes may be sufficient to reach current standards. For example, while SNDA-III shows that few schools met current requirements for total fat and saturated fat at lunch, on average schools were relatively close to meeting them. So, while just 21 percent of schools served lunches with no more than 30 percent of calories from total fat, the mean percent of energy from total fat across all schools was only 33.8 percent. For saturated fat, just 30 percent of schools met the 10 percent of total calories standard, but the mean percent of calories across all schools was just 10.9 percent. If reductions in those measures can be achieved with modest changes in menus and preparation methods, then the cost to meet them

would represent a small part of the overall cost of moving to the proposed rule's standards. At the same time, it is plausible to envision changes to meet existing standards, for vitamins A and C for example, that would cost nearly as much as the proposed rule's food group standards for fruits and vegetables.

Second, the cost of compliance with existing rules relies as much on assumptions about student acceptance of certain foods and menus as it does on the cost per nutrient. This too can be illustrated with SNDA-III data. School compliance with current SMI standards

is far lower in high schools than in elementary schools for almost all nutrients. Because "offer versus serve" (OVS) is required in high schools, meals served to high school students better reflect student preferences than meals served to elementary school students, as roughly one in five elementary schools do not use OVS.⁵⁶ Given a choice, the SNDA data indicates that students tend

⁵⁶ SNDA-III found that 78 percent of elementary schools and 93 percent of middle schools used OVS in SY 2004-2005. These percentages are the same for lunch and breakfast. USDA 2007, vol. I, Table II.11A, p. 52.

to select foods that do not satisfy current nutrient standards. That does not mean that schools cannot offer a mix of foods that students accept, but it may take a more comprehensive and costly change in school menus to gain that acceptance.

For these reasons, we do not know the likely order of magnitude of the estimated cost to reach current standards.

Table 14 below assumes that State administrative costs are not impacted by any of the alternate assumptions (a-h) listed above.

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Table 14: Cost of Proposed Rule under Alternate Assumptions

	Fiscal Year					
	2012	2013	2014	2015	2016	Total
Section A. Fruit and Vegetable Take Rates - Use IOM Estimates						
Food Costs	\$49.3	\$332.4	\$360.7	\$449.6	\$475.0	\$1,667.0
Labor Costs	48.1	324.4	352.0	438.7	463.6	1,626.8
State Admin	0.1	8.9	9.0	9.3	9.6	36.9
Total	\$97.6	\$665.7	\$721.7	\$897.6	\$948.2	\$3,330.7
Section B. IOM Fruit and Vegetable Take Rates with Labor Cost Adjustment						
Food Costs	\$49.3	\$332.4	\$360.7	\$449.6	\$475.0	\$1,667.0
Labor Costs	89.6	611.4	687.9	945.6	1,003.4	3,337.9
State Admin	0.1	8.9	9.0	9.3	9.6	36.9
Total	\$139.0	\$952.7	\$1,057.6	\$1,404.4	\$1,488.1	\$5,041.8
Section C. Using All IOM Take Rates						
Food Costs	\$83.7	\$560.2	\$624.8	\$884.2	\$925.5	\$3,078.4
Labor Costs	81.7	546.7	609.8	862.9	903.2	3,004.2
State Admin	0.1	8.9	9.0	9.3	9.6	36.9
Total	\$165.5	\$1,115.7	\$1,243.6	\$1,756.4	\$1,838.3	\$6,119.6
Section D. Cost of Whole Grains – Reduction Over Time						
Food Costs	\$91.8	\$557.3	\$532.7	\$475.5	\$506.8	\$2,164.1
Labor Costs	89.6	543.8	519.8	464.0	494.6	2,111.9
State Admin	0.1	8.9	9.0	9.3	9.6	36.9
Total	\$181.5	\$1,109.9	\$1,061.6	\$948.8	\$1,011.1	\$4,313.0
Section E. Change in Participation - 2 Percent Increase						
Food Costs	\$115.8	\$787.6	\$874.1	\$1,150.2	\$1,217.8	\$4,145.6
Labor Costs	113.0	768.6	853.1	1,122.5	1,188.4	4,045.6
State Admin	0.1	8.9	9.0	9.3	9.6	36.9
Total	\$228.9	\$1,565.1	\$1,736.2	\$2,282.0	\$2,415.9	\$8,228.1
Section F. Change in Participation – 2 Percent Decrease						
Food Costs	\$67.7	\$465.4	\$535.7	\$787.6	\$838.6	\$2,695.1
Labor Costs	66.1	454.2	522.8	768.6	818.4	2,630.1
State Admin	0.1	8.9	9.0	9.3	9.6	36.9
Total	\$134.0	\$928.5	\$1,067.5	\$1,565.6	\$1,666.7	\$5,362.2
Section G. Lower Rate of Increase in Labor Costs than Food Costs						
Food Costs	\$91.8	\$626.5	\$704.9	\$968.9	\$1,028.2	\$3,420.4
Labor Costs	67.2	458.6	515.9	709.2	752.6	2,503.4
State Admin	0.1	8.9	9.0	9.3	9.6	36.9
Total	\$159.1	\$1,093.9	\$1,229.9	\$1,687.4	\$1,790.4	\$5,960.7
Section H. Less than Full Compliance with the Proposed Rule						
Food Costs	\$68.1	\$464.9	\$586.8	\$896.1	\$1,028.2	\$3,044.1
Labor Costs	66.4	453.7	572.7	874.4	1,003.4	2,970.7
State Admin	0.1	8.9	9.0	9.3	9.6	36.9
Total	\$134.6	\$927.5	\$1,168.5	\$1,779.8	\$2,041.3	\$6,051.8

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C. Administrative Impact

1. School Food Authorities (SFA)

An initial increase in administrative staff time for training and implementation is anticipated at the SFA level. Most of these impacts will be limited to the transition to the rule's new requirements as a result of:

- Training staff on the required components of reimbursable lunches and breakfasts;
- Changes to menus and portion size may necessitate revisions to menus and recipes currently used by SFAs;
- Changes to food purchasing and commodity food use (for example, increasing purchases for fresh fruit and vegetables, whole grain products, and lower sodium products), as well as

changes in the methods of preparation of food, may be necessary for many schools;

- Changes in SFA financial structure, as SFAs may need to review finances in order to determine how to deal with any cost changes associated with the proposed requirements;
- Forging new relationships with local farmers to supply fresh produce

appealing to the tastes of school children; and

- Modifying a la carte foods and other foods at school to maintain NSLP and SBP participation rates.

The proposed rule also increases the length of State reviews of SFAs through the Coordinated Review Effort (CRE) by incorporating the requirements of School Meals Initiative (SMI) reviews, and increases their frequency to once every three years. SFAs that previously held separate CREs and SMIs may experience a decrease in burden, because they will undergo just one CRE every three years, rather than two reviews (one CRE and one SMI) every five years.

The proposed rule incorporates the provision of training and technical assistance by SAs to the SFAs. SFAs must, in turn, adjust their current training agenda to include the new requirements, as no funding has been provided in the proposed rule to accommodate new training.

FNS expects these additional burdens on SFA staff time and budgets may be offset by other benefits. For instance, new age/grade groupings would require school districts to offer different portion sizes instead of the same portions to all ages/grades. While this could be an additional burden to some SFAs, it could also reduce plate waste with use of more appropriate age/grade groupings. Moreover, it is expected that, as food service workers gain experience and become comfortable with the new requirements, administrative efforts associated with implementation may decline. Therefore, although an initial administrative impact is anticipated, FNS does not expect any significant long-term increase in administrative burden.

2. State Agencies

State Child Nutrition Agencies (SAs) play a key role in the implementation of school meal programs through their agreements and partnership with local SFAs. FNS anticipates that SAs that administer the school meals programs will work closely with SFAs to meet the requirements of the proposed rules, and to remove barriers that may hinder compliance.

Many changes associated with implementation of the proposed rule may result in an increased burden and additional required level of effort from States, such as:

- *Training and technical assistance:* SAs may provide training and technical assistance to SFAs on new calorie and meal pattern requirements, age/grade groupings, and revised nutrient requirements. Moving to a single, food-

based menu planning system may simplify the meal service for some schools and will likely streamline the meal planning process, but may require initial training to accomplish.

Although SAs may meet most of this demand by modifying current training and technical assistance efforts, we recognize that SAs may incur additional costs assisting SFAs with the transition to the proposed requirements. Our cost estimate provides for an additional 80 hours per SA in each of fiscal years 2012 and 2013, for a total of \$0.2 million.

- *Systems assistance:* SAs may assist SFAs with any changes in the meal planning process occurring as a result of this rule. This is included in our \$0.2 million estimate for training and technical assistance.

- *Food procurement and preparation:* More fruits, vegetables, whole grains, and foods that are lower in sodium may be necessary to align meals with the proposed meal patterns. SAs may also review SFA contracts with food service management companies (FSMCs). We have not estimated this cost, but expect that it may be small.

- *Monitoring and compliance:* SAs may be required to conduct CREs more frequently, once every 3 years for each SFA; nutrient analysis will be required for all SFAs and will become an additional component of each CRE (although separate SMIs will be eliminated); nutrient-based menus will be eliminated and only food-based menu planning will be permitted; menus will be reviewed from a two-week period preceding the review date; and a breakfast meal will be reviewed as part of each CRE.⁵⁷

SAs are currently required to conduct a CRE for each SFA once every 5 years; to conduct a nutrient analysis via SMI review for only those SFAs with food-based menu planning systems (although approximately 30 percent of these SFAs elect to conduct the nutrient analysis themselves); to review menus from a one-week period preceding the review date; and to review a breakfast meal only in the case of a follow-up CRE (which is only conducted in those cases in which problems are noted in the initial CRE). Total costs for each SA to complete a CRE include costs for staff labor, travel (including transportation, accommodations, and meals/incidental expenses), and possible printing costs

⁵⁷ FNS estimated in 1994 that extending the SFA review cycle from four to five years would decrease costs associated with this effort by 20 percent. (June 10, 1994, *Federal Register* Vol. 59, No. 111, p. 30234) A similar, but opposite, effect might be expected from shortening the cycle from five to three years.

for those SAs that provide CRE results to SFAs and FNS in hard copy rather than electronically.

Limited discussion with a small number of SA and FNS Regional Office officials suggest that a typical CRE or SMI review costs about \$2,000 in 2010, with about half of that cost used for staff travel. Because travel is a largely fixed cost, SAs that previously conducted separate CRE and SMI reviews should realize some savings once SMIs are ended and the nutrient analysis is made part of the CRE. That may help offset some of the cost of increased CRE frequency. A mid-sized State that now conducts 100 CRE reviews might incur annual expenses of \$200,000. Under the proposed rule, that SA could expect to conduct $\frac{2}{3}$ more CRE reviews, or roughly 167 per year. If we assume conservatively that the SA realizes no savings from elimination of SMI reviews, its review costs would increase by \$134,000 per year—an upper-bound estimate. If all SAs incurred this same expense, the total cost would be roughly \$8 million per year by FY 2013.

3. USDA/FNS

FNS will assist State Agencies by providing nutrition education, training, guidance, and technical assistance to facilitate their work with local school food professionals. This may include developing training standards, materials, updated measures for nutrition analysis, and revisions to the food buying guide.

While we expect a small increase in administrative burden for FNS under the proposed rule because of the need to provide additional training and technical assistance to SAs, and to support their role in the CRE process, this may largely be met by adapting existing efforts to the new requirements.

D. Food Service Equipment

Changes in meal pattern requirements as a result of the proposed rule may cause some SFAs to require different, or additional, equipment than that which they currently possess. For example, some SFAs may need to replace fryers with ovens or steamers. In FY 2009, FNS solicited requests from SFAs for food service equipment grants, awarding \$100 million in 2009 American Recovery and Reinvestment Act (ARRA) Equipment Grants and an additional \$25 million in one-time funds included in the FY 2010 Agriculture Appropriations Act. In response to its solicitation, FNS received a total of approximately \$600 million in grant requests from SFAs. The strong response to these grant programs indicates that schools could make productive use of an even greater

investment in kitchen equipment. However, much of that demand is associated with the routine need to replace equipment that is nearing the end of its useful life—a cost that is appropriately covered by USDA meal reimbursements and other sources of food service revenue. Although some schools may need additional upgrades to prepare meals that meet the proposed rule's standards, we do not have the data necessary to assess that need or to estimate the associated cost. The \$125 million in kitchen equipment grants distributed to schools through ARRA funds and the FY 2010 appropriation should have addressed much of the most pressing need. For these reasons, we do not include additional

incremental equipment costs as a result of the proposed rule in our estimate.

E. Implementation of Proposed Rule—SFA Resources

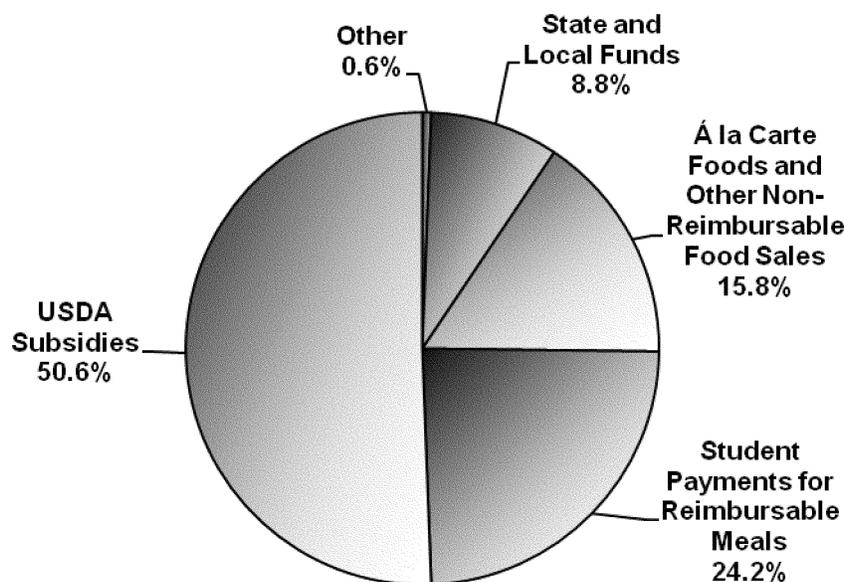
We estimate that the proposed rule may raise the average cost of producing and serving school lunches by almost 7 cents and school breakfasts by 37 cents on initial implementation. By FY 2015, when the 100 percent whole grain rich requirement takes effect, the cost per lunch may be 14 cents higher than our baseline estimate; the cost per breakfast may be 50 cents higher than our baseline.

Not all schools will face the same cost changes. Schools with menus that already emphasize fruits, non-starchy vegetables, and whole grains may need to make fewer changes, and the costs of

implementation in those schools may be lower than average. Because the per-meal costs of complying with the proposed requirements are much higher for breakfast than for lunch, the overall costs of implementation in schools that serve more school breakfasts relative to lunches may be higher than the costs faced by schools that do not serve breakfast.

SFAs have a variety of funding sources used to cover the cost of preparing and serving school meals. The SLBCS-II found that about half of average SFA revenues are provided by Federal reimbursements (cash and donated foods), about one-quarter by payments from participating families, and the remainder from other sources (See Figure 3).

Figure 3: Composition of SFA Revenues⁵⁸



Covering the increased costs estimated to implement the proposed rule may be challenging for many schools. However, some schools are already making substantial progress using available resources. USDA's HealthierUS Schools Challenge (HUSC) recognizes elementary schools that meet voluntary school meal and physical activity standards. HUSC school meal standards exceed NSLP requirements on several levels, including requirements for a variety of vegetables each week, including dark green and orange vegetables and

legumes; a variety of whole fruits, and limits on fruit juice; and whole grain and low fat milk requirements. USDA has certified more than 840 HUSC schools since 2004. HUSC schools have demonstrated an ability to operate cost-effective school meals programs that emphasize many of the same foods required by the proposed rule. These schools receive no financial assistance from USDA beyond the meal reimbursements and USDA Foods available to other schools that participate in the Federal school lunch and breakfast programs.

Most schools will have a number of options and flexibilities within available

revenue streams and operational approaches that can help to balance costs and resources.

Federal Reimbursements: As noted above, about half of all SFA revenues are from Federal reimbursements. These payments are adjusted annually for changes in food and labor costs by statute.⁵⁹ SLBCS-II found that in 2005—

⁵⁹The Healthy, Hunger-Free Kids Act of 2010 increases the Federal subsidy for reimbursable school lunches by 6 cents on implementation of final regulations to update the school meal patterns. All SFAs in compliance with the regulations would be eligible for the increased reimbursement. Further guidance on how SFAs may fulfill this legislative

Continued

⁵⁸USDA 2008, p. xii.

06, for most reimbursable lunches and in most SFAs, reported lunch production costs were less than the Federal free lunch subsidy by a small amount, with the difference greatest in SFAs that produce more meals, resulting in a lower per-meal cost.

Student Payments: School districts have the discretion to set student payments for “paid meals” and à la carte foods at levels of their choosing, so long as the resulting revenues are paid into the non-profit school food service account. Some currently set prices for these meals and foods at levels that do not cover the full cost of production, with Federal payments for free and reduced-price meals covering the difference. Schools will likely face additional incentives to adjust their pricing policies so that adequate revenue is generated to cover the cost of production.⁶⁰

State and Local Funds: A limited but nonetheless substantial portion of meal production costs are paid from State and local government sources. The contributions of these entities may need to increase to cover costs.

Operational Changes: Like other service businesses, schools may need to consider changes to their operations to increase efficiency and meet the requirements of the proposed rule. As noted above, several hundred HUSSC schools have demonstrated an ability to operate cost-effective school meals programs that meet many of the proposed rule’s requirements. These schools may offer models for others as implementation moves forward.

F. Impact on Participation

As noted in Table 12, the cost estimate in this analysis assumes no net change in student participation following introduction of the rule’s new meal pattern requirements. This assumption reflects uncertainties in a number of areas, including how schools will reflect the new requirements in menus, the acceptance of those changes by students, and potential changes in prices for reimbursable paid meals to

requirement will be forthcoming and may be addressed in a subsequent rulemaking.

⁶⁰The Healthy, Hunger-Free Kids Act of 2010, requires SFAs to gradually raise non-Federal revenues for reimbursable paid lunches, if necessary, until those revenues equaled the difference between the Federal reimbursements for free and paid lunches, to address the disparity in SFA revenue between paid and free lunches discussed above. Raising paid meal prices represents one approach by which schools may derive increased revenue, but is not a requirement of the law. Further guidance on how SFAs may fulfill this legislative requirement will be forthcoming and may be addressed in a subsequent rulemaking.

provide additional revenue. These factors are discussed below.

1. Acceptance of Meals

Any revision to the content of school meals or the method of preparation may have an effect on the acceptance of school meals. Concerns are often raised that students may react negatively to changes designed to improve nutrition. USDA launched the School Meals Initiative for Healthy Children (SMI) in 1995 to help schools improve the nutritional quality of NSLP and SBP meals. The SMI offers an opportunity to examine how students react to substantial changes in school meal patterns.

As a result of the SMI many school food service directors reported making changes in procurement and preparation practices (Abraham, 2002). For example, they reported increased purchases of low-fat/reduced-fat foods (81 percent) and fresh fruits and vegetables (75 percent). The majority reported no change in food waste. However, to the extent that there was change in the amount of food wasted, more respondents reported a reduction rather than an increase in food waste (with the exception of cooked vegetables). School food service directors report that the SMI has generally had a neutral-to-positive impact on program performance.

SNDA-III found that “[c]haracteristics of NSLP lunches offered, including percent of calories from fat, whether dessert or French fries were frequently offered, and average number of fresh fruits and vegetables offered per day, were generally not significantly associated with NSLP participation.”⁶¹ This suggests that changes in meal patterns that enhance nutrition can be well received by students. Furthermore, the increased emphasis on a healthy school nutrition environment in recent years, and greater awareness of the importance of healthy eating habits in schools, may help to support student acceptance of changes in program meals.

There is also a strong and growing school nutrition effort and infrastructure already in place. For example, Team Nutrition is an FNS initiative to support healthier meals through training and technical assistance for food service, nutrition education for children and their caregivers, and school and community support for healthy eating

⁶¹For breakfast, the study estimated that projected participation rates “were higher in schools that offered a greater percentage of calories from fat in the SBP breakfast; however, these differences were not statistically significant at conventional levels.” USDA 2007, vol. II, pp. 113 and 127.

and physical activity. Similarly, in 2004 Congress required school districts to establish local wellness policies; through these policies, schools have made changes to their school nutrition environments, improved the quality of foods offered, and students are provided with more nutritious, healthy choices. In the context of these initiatives, implementation of the proposed rule will not be an isolated endeavor, but rather may build upon a range of ongoing local, State and Federal efforts to promote children’s nutrition and health.

2. Impact of Price on Participation

FNS estimates that the average cost of preparing school meals may increase by 12 percent. SFAs may raise student prices for reimbursable paid meals to compensate for some of this increase in cost. All else being equal, increased paid meal prices may reduce NSLP paid-meal participation. Mathematica®, Inc. modeled the effect of paid meal prices on student participation as part of the SNDA-III study.⁶² All else equal, students who were not income-eligible for free or reduced-price meals were less likely to participate in the program when the full price of the meals was higher. For lunch, the model estimates a 0.11 percent decrease in participation for each 1 cent increase in paid lunch prices.⁶³ For breakfast, the model estimates a 0.12 percent decrease in participation per 1 cent increase in price.

The model’s predicted student participation rate was 54 percent in schools that charged \$2.00 for an NSLP lunch, compared to 59 percent in schools that charged \$1.50. The study also predicts lower breakfast participation in schools that charged higher prices. Predicted participation was 10.3 percent in schools that charged \$0.70 for an SBP breakfast versus 7.2 percent in schools that charged \$1.00. Since meals meeting the new requirements will be improved in nutritional content it is not clear how this factor would balance against the effects of higher meal prices. Although price changes may be a necessary option for some SFAs, FNS expects that efforts designed to maintain participation would be concurrently implemented.

G. Benefits

As noted in the preamble to this proposed rule, NSLA requires that

⁶²USDA 2007, vol. II, pp. 116–117, 123–124.

⁶³This relationship between price and participation applies to prices in the range of \$1.50 to \$2.00 in SY 2004–2005 dollars. A much bigger price increase might trigger a bigger reduction in participation.

schools serving lunches and breakfasts under its program authority ensure that those meals are consistent with the goals of the most recent *Dietary Guidelines for Americans* and the Dietary Reference Intakes. The proposed rule, by updating program regulations consistent with *Dietary Guidelines* goals and aligning the regulations with the requirements placed on schools under the statute, will ensure that school meal nutrition requirements reflect current nutrition science, increase the availability of key food groups, better meet the nutritional needs of children, and foster healthy eating habits.

In so doing, it also provides a clear means of meeting the statutory requirements through a food-based meal pattern designed with the particular circumstances and challenges of school food service in mind, to ensure that it is feasible for school foodservice operators and does not jeopardize student and school participation in the meal programs. A related benefit of the proposal is that it simplifies meal requirements to create a single, food-based approach to meal planning. This approach helps to simplify menu planning and monitoring, and streamline training and technical assistance needs.

Once implemented by schools, USDA projects that this rule will change the types and quantities of foods prepared, offered and served through the school meals programs (the sources of the costs described in this analysis). The proposed rule is expected to result in (1) increased servings of fruits and vegetables, (2) replacement of refined-grain foods with whole-grain rich foods, and (3) replacement of higher-fat dairy products with low-fat varieties. As documented in the IOM

recommendations, each of these changes corresponds to an inconsistency between the typical diets of school-aged children in the United States and the *Dietary Guidelines/MyPyramid* recommendations. In particular, the report cited an analysis of NHANES 1999–2002 data that showed that:

- Total vegetable intake was only about 40 percent of the *MyPyramid* levels, with intake of dark green and orange vegetables less than 20 percent of *MyPyramid* levels.

- Total fruit intake was about 80 percent of the *MyPyramid* levels for children ages 5–8, with far lower levels for older children.

- Intake of whole grains was less than one-quarter of *MyPyramid* levels, although total grain intake was at or above *MyPyramid* levels.

- Intake of dairy products varied by age, with the intakes of the youngest

children exceeding *MyPyramid* levels, while those of older children were below those levels. However, most dairy consumed contained 2 percent or more milk fat, while the *Dietary Guidelines* recommend fat-free or low-fat dairy products.⁶⁴

In addition, the rule would make significant changes to the level of sodium in school meals over time. Research suggests that modest population-wide reductions in dietary salt could substantially reduce cardiovascular events and medical costs.⁶⁵ More specifically, a forthcoming study suggests that reducing dietary salt in adolescents could yield substantial health benefits by decreasing the number of teenagers with hypertension and the rates of cardiovascular disease and death as these teenagers reach young and middle age adulthood.⁶⁶

The rule also makes substantial changes in the calorie targets for meals that are designed to promote healthful energy balance for the children served by these programs. For the first time, the rule sets maximum as well as minimum calorie targets, and creates a finer gradation of calorie levels by age. As a result, minimum calorie requirements for some groups are reduced by as much as 225 calories per lunch.⁶⁷ Implemented consistent with other requirements that ensure that lunches provide appropriate nutrient content, these changes in calorie levels can help to reduce the energy imbalance that contributes to obesity among the Nation's children, without compromising nutrition to support healthy growth and development.

This approach is fully consistent with the recommendations of the *Dietary Guidelines for Americans*. Recognizing that the *Dietary Guidelines* apply to a total diet, rather than a specific meal or portion of an individual's consumption, the intention of the proposed rule is to make changes to school meals nutrition requirements to promote diets more consistent with the *Guidelines* among program participants. Such diets, in turn, are useful behavioral contributors to health and well-being. As the report of the 2010 Dietary Guidelines Advisory Committee notes, "evidence is accumulating that selecting diets that comply with the *Guidelines* reduces the risk of chronic disease and promotes

health."⁶⁸ The report describes and synthesizes the evidence linking diet and different chronic disease risks, including cardiovascular disease and blood pressure, as well as the effects of dietary patterns on total mortality. Children are a subpopulation of particular focus for the Committee; the report emphasizes the increasing common evidence of chronic disease risk factors, such as glucose intolerance and hypertension, among children, and explains that "[e]vidence documents the importance of optimal nutrition starting during the fetal period through childhood and adolescence because this has a substantial influence on the risk of chronic disease with age."⁶⁹

In response, the report notes improvements in food at schools as a critical strategy to prevent obesity, and related health risks, among children. Indeed, the Committee recommends "[i]mprov[ing] foods sold and served in schools, including school breakfast, lunch, and after-school meals and competitive foods so that they meet the recommendations of the IOM report on school meals (IOM, 2009) and the key findings of the 2010 DGAC. This includes all age groups of children, from preschool through high school."⁷⁰

The linkage between poor diets and health problems such as childhood obesity are also a matter of particular policy concern, given their significant social costs. One in every three children (31.7 percent) ages 2–19 is overweight or obese.⁷¹ Along with the effects on our children's health, childhood overweight and obesity imposes substantial economic costs, and the epidemic is associated with an estimated \$3 billion in direct medical costs.⁷² Perhaps more significantly, obese children and adolescents are more likely to become obese as adults.⁷³ In 2008, medical spending on adults that was attributed to obesity increased to an estimated \$147 billion.⁷⁴

Because of the complexity of factors that contribute both to overall food consumption and to obesity, we are not able to define a level of disease or cost reduction that is attributable to the changes in meals expected to result from implementation of the rule. As the rule is projected to make substantial improvements in meals served to more

⁶⁸ Dietary Guidelines Advisory Committee, p. B1–2.

⁶⁹ Dietary Guidelines Advisory Committee, pp. B1–2, B1–3.

⁷⁰ Dietary Guidelines Advisory Committee, p. B3–6.

⁷¹ Ogden *et al.*, 2010.

⁷² Trasande *et al.*, 2009.

⁷³ Whitaker *et al.*, 1997; Serdula *et al.*, May 1993.

⁷⁴ Finkelstein *et al.*, 2009.

⁶⁴ IOM 2009, pp. 49–53.

⁶⁵ See, for example, Smith-Spangler, 2010; Bibbins-Domingo, 2010.

⁶⁶ Bibbins-Domingo, 2010b.

⁶⁷ The minimum calorie level for a lunch served to Grade 7 students is 825 calories under current standards (Grades 7–12); this would change to a range of 600 calories minimum, 700 calories maximum under the new standards (Grades 6–8).

than half of all school-aged children on an average school day, we judge that the likelihood is reasonable that the benefits of the rule exceed the costs, and that the proposal thus represents a cost-effective means of conforming NSLP and SBP regulations to the statutory requirements for school meals.

There are other, corollary benefits to improvement in school meals that are worthy of note. The changes could increase confidence by parents and families in the nutritional quality of school meals, which may encourage more families to opt for them as a reliable source of nutritious food for their children. Improved school meals can reinforce school-based nutrition education and promotion efforts and contribute significantly to the overall effectiveness of the school nutrition environment in promoting healthful food and physical activity choices. Finally, the new requirements provide a clearer alignment between Federal program benefits and national nutrition policy, which can help to reinforce overall understanding of the linkages between diet and health.

IV. Alternatives

In response to NSLA Section 9(a)(4) amended into law in 2004, USDA contracted with IOM to assemble an expert panel to undertake a review of the nutritional needs of children, the recommendations of the *Dietary Guidelines*, and IOM's Dietary Reference Intakes. USDA asked IOM to develop recommendations for updating NSLP and SBP meal patterns and nutrition requirements based on that review of need and nutrition science, with consideration given to operational feasibility and cost.

The USDA contract with IOM called for the creation of a panel with representatives from the fields of public health, epidemiology, pediatrics, child nutrition and child nutrition behavior, statistics, and economics. The contract also called for representatives with knowledge of cultural differences in food preference and eating habits, experience in menu planning, and experience in managing and operating a school lunch and breakfast program. IOM held workshops at which the panel heard presentations from invited speakers, and solicited public input. The panel also accepted public comment on its planned approach to the project.

The process undertaken by IOM was designed to consider different perspectives and competing priorities. The panel necessarily weighed the merits of alternatives as it developed a preferred option. USDA's commitment

was to implement IOM's recommendations where feasible. This commitment is driven by the statutory requirement that schools serve meals that are consistent with the goals of the *Dietary Guidelines*.⁷⁵

We did not consider alternatives that depart significantly from IOM's recommendations and cannot satisfy USDA's statutory obligation. Nevertheless, the proposed rule makes a few small changes to IOM's recommendations. In addition, the rule contains a handful of provisions that are not addressed by IOM. These proposed rule provisions are summarized below.

The final alternative discussed in this section is to retain the status quo.

a. Whole Grains

Proposed rule: Within two years of implementation of a final rule all grains offered to students must be whole grain rich (a minimum whole grain content of 51 percent).

IOM alternative: Within three years of implementation, the whole grain content of grain products offered to students must average at least 50 percent.

The proposed rule aligns the dates of the whole grain transition with the first intermediate sodium target for ease of program operation. The IOM alternative introduces additional administrative disruption, and delays the benefits of the stronger whole grain requirement by one year. That delay, however, also postpones the added cost of the stronger requirement. The alternative would reduce the five year cost of the proposed rule by an estimated \$510 million.

b. Sodium Targets

Proposed rule: Reduce sodium content of school meals to the levels specified by IOM within ten years of a final rule. Set three intermediate sodium targets, 2 years, 4 years, and 10 years after implementation of a final rule.

IOM alternative: Reach sodium targets by 2020. Set intermediate targets every 2 years.

Given the time necessary to publish proposed and final rules, reaching IOM's recommended sodium target by 2020 would leave relatively little time for phased implementation. The proposed rule's 10-year schedule is intended to win greater student acceptance. It also allows industry and schools added time to reformulate their products and school recipes between intermediate target dates. A rapid reduction in the sodium content of school meals would likely reduce

participation in the lunch and breakfast programs, and thus undermine the goal of improved student nutrition.⁷⁶ Added time may also allow the market to respond to increased demand for lower sodium foods, reducing upward pressure on prices and the costs of compliance with the rule. We have not quantified these risks to student participation or food prices.⁷⁷

c. Offer Versus Serve at Breakfast

Proposed rule: Students may decline one item at breakfast, but they must take at least one fruit or fruit juice or non-starchy vegetable.

IOM alternative: Students may decline one item at breakfast, but they must take at least one fruit or fruit juice.

The proposed rule recognizes that some schools offer vegetables at breakfast. The cost effects of this change are minimal.

d. Require Schools To Identify Reimbursable Meals

Proposed rule: Schools are required to identify the components of the day's reimbursable meals at or near the start of the serving line.

Alternative: Schools are not required to identify the components of the day's reimbursable meals.

This provision is intended to help students select a reimbursable meal and avoid a la carte charges. The provision is also meant to educate students on the content of a balanced, healthy meal. The school revenue and cost effects of this provision are small.

e. Crediting of Specific Foods

Proposed rule: Schools may credit tomato paste based on volume served. Schools may not credit snack-type fruit or vegetable products (such as fruit leather), nor may they credit formulated grain-fruit products.

Alternative: Schools can only credit tomato paste based on its calculated whole tomato equivalent. Schools may credit snack-type fruit and vegetable products and formulated grain-fruit products.

Allowing schools to credit tomato paste based on volume served is consistent with the treatment of similar products. Disallowing the crediting of snack-type fruit or vegetable products reinforces the *Dietary Guidelines* emphasis on whole fruits and vegetables, and supports nutrition education to the extent that these foods

⁷⁶ See the preamble to the proposed rule for a more thorough discussion of this issue.

⁷⁷ Section III.B.5 examines the effect of an arbitrary two percent drop in student participation on the cost of preparing school meals, and on Federal reimbursements to schools.

⁷⁵ Section 9(a)(4) and 9(f)(1) of the NSLA (42 U.S.C. 1758(a)(4) and (f)(1)).

are not recognized by children as fruits or vegetables. In addition, the crediting of certain fruit snacks was based on an FDA standard of identity for canned fruit nectar which has been removed from the Code of Federal Regulations. The crediting of formulated grain-fruit products is disallowed because those products typically contain high levels of fortification, rather than naturally occurring nutrients, and are high in sugar and fat. The effect of these changes on school costs is minimal.

f. Low Fat Flavored Milk

Proposed rule: Low fat milk cannot be flavored. Only fat-free milk can be flavored.

Alternative: Schools may allow flavored low fat milk.

The proposed rule is based on the IOM recommendation. FNS considered allowing schools to offer flavored low fat milk if they could stay within the proposed rule's calorie ranges. This was potentially achievable since the calorie difference between plain low fat milk and flavored low fat milk is modest (about 30 calories). We ultimately rejected this alternative; allowing only fat-free milk to be offered in flavored form is intended to reduce students' fat

intakes. The difference in cost between the proposed rule and the alternative is very small (fat-free milk is less expensive than low fat milk).

g. Phase-In Implementation of IOM Recommendations

Proposed rule: All schools are expected to implement the proposed rule beginning with school year 2012–2013, with final whole grain requirements implemented by the school year 2014–2015.

Alternative: Phase-in implementation of the rule based on LEA size. LEAs with:

- More than 25,000 students would implement by SY 2012–2013;
- 10,000 to 25,000 students would implement by SY 2013–2014; and
- Less than 10,000 schools would implement by SY 2014–2015.

Final whole grain requirements in effect two years after implementation in each cohort of LEAs.

Schools vary in the extent to which they meet current nutrition requirements for reimbursable meals. Though most are reasonably successful in meeting the food group requirements under current rules, some schools may find it operationally difficult, or too

costly, to prepare, serve, and gain acceptance for meals that satisfy the new food group and subgroup requirements of the proposed rule. There is potential concern that the magnitude of the changes required could make it difficult for some schools to meet the requirements of the proposed rule by SY 2012–2013.

As an alternative, USDA could consider an approach that would phase-in the requirements of the rule so that schools that can comply most readily do so early, and those for which compliance may be more difficult would have additional time. Though we are not aware of any evidentiary basis to distinguish groups of schools that may find it more difficult to meet the proposed requirements than others, we offer as an alternative scenario the phase-in schedule adopted by Congress for the requirement to conduct direct certification under Section 104 of the Child Nutrition and WIC Reauthorization Act of 2004 (Public Law 108–265). This gave smaller LEAs more time to meet the requirements than larger ones. The cost of implementing the rule under this alternative scenario is shown in Table 15, below:

TABLE 15—COST (IN MILLIONS) OF PROPOSED RULE WITH IMPLEMENTATION PHASE-IN BASED ON LEA SIZE

	2012	2013	2014	2015	2016	Total 2012–2016
Food Costs	\$31.4	\$243.3	\$443.2	\$805.1	\$918.4	\$2,441.4
Labor Costs	30.6	237.4	432.5	785.6	896.3	2,382.5
State Admin	0.1	8.9	9.0	9.3	9.6	36.9
Total	62.1	489.6	884.8	1,600.0	1,824.4	4,860.9

A phase-in of the new meal standards would reduce estimated benefits as well as costs for those schools not yet phased-in. Participation in the school meals program is highest among elementary school students; participation decreases as students move to middle and high school (see Figure 4). One of the goals of USDA-sponsored IOM recommendations for updated meal requirements was to “foster healthy eating habits” through exposure to the school meals program.⁷⁸ But, because of the decrease in participation among older students, the school meals program has only a limited opportunity to influence the eating habits of some students. Students who are not introduced to the proposed meal requirements while still in elementary school may not benefit at all from the

potential positive impact of these changes on their diets.

h. Do Not Implement IOM Recommendations

Proposed rule: With few minor exceptions, discussed above, the proposed rule adopts IOM's recommendations.

Alternative: Do not adopt the recommendations, or postpone their implementation.

By statute, schools are required to serve NSLP and SBP meals that are consistent with the goals of the *Dietary Guidelines*.⁷⁹ Given this mandate, USDA contracted with IOM to review current meal pattern and nutrition requirements and recommend changes. IOM assembled a panel of child nutrition experts and school foodservice practitioners. That panel accepted input

from industry, interest groups, and representatives of the school foodservice community. The panel was charged with recommending program changes that reflect *Dietary Guidelines* goals but are also operationally practical and cost-efficient, to the extent possible. Although a different review might have generated a different set of recommendations, any proposal consistent with *Dietary Guidelines* goals would be obligated to recommend increases in the amounts and varieties of vegetables and fruits offered to students, the substitution of whole grains for refined grains, and limits on the fat content of milk. These changes are the principal cost drivers of the IOM recommendations (see Table 11). Alternate proposals to align program requirements with the goals of the *Dietary Guidelines* would necessarily confront these same costs, and thus

⁷⁸ IOM 2009, p. 2.

⁷⁹ Section 9(a)(4) and 9(f)(1) of the NSLA (42 U.S.C. 1758(a)(4) and (f)(1)).

would be unlikely to cost significantly less than the proposed rule.

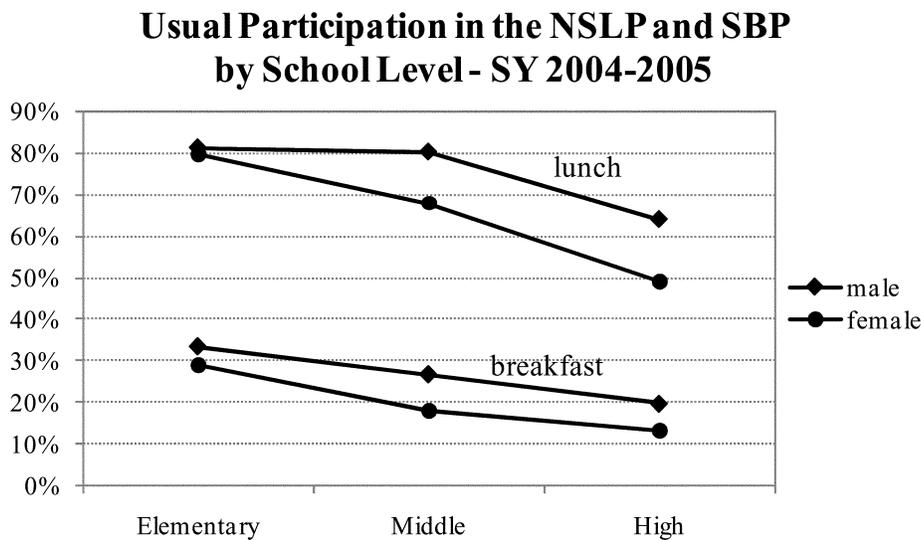
We did not consider alternatives that would move significantly away from the objective to align school meal patterns with the goals of the *Dietary Guidelines*. Such alternatives include making no

change to program rules, or delaying implementation of the proposed rule. Both of these would reduce costs relative to the proposed rule.

Taking no action would, of course, forfeit all of the benefits discussed in section III.G. Delaying implementation

would have lesser, but still significant negative consequences. As noted under alternative g, students who are not introduced to the proposed meal requirements while still in elementary school may not benefit at all from delayed implementation of the rule.

Figure 4: Usual Participation Rates in the School Lunch and Breakfast Programs⁸⁰



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VI. Appendix A

The following tables detail the major steps in the computation of food cost estimates described in the main body of the impact analysis. The tables develop both a baseline food cost estimate and an estimate under the proposed rule.

Note that the dollar values of our baseline food cost estimates are lower than the figures reported in the SLBCS-II. The primary reason that our figures differ is that we use SNDA-III rather than SLBCS-II for baseline totals of food served; we only use the SLBCS-II for unit prices.⁸¹ We chose SNDA-III as our source for food quantities because of its information on student take rates. In order to estimate the cost of the proposed rule, we need to take the rule's food group requirements, which are expressed in terms of quantities that schools must offer to students, and estimate the quantity of food actually served. The take rates from SNDA-III allow us to do that;⁸² the SLBCS-II is not designed to estimate take rates. Because of the relationship between take rates and quantities served, it would be inappropriate to mix SNDA-III take rates and SLBCS-II quantities. Because we use SNDA-III take

rates to estimate the cost of serving meals under the proposed rule, we use SNDA-III quantities to estimate our baseline.

The lower scale of our baseline food cost estimate compared to the SLBCS-II should not impact our cost estimate of the proposed rule. As long as the take rates are computed from the same source for both our baseline and proposed rule estimates, the estimated cost of an incremental change in quantities offered should not be biased.

Table A-1 contains total food and labor cost estimates for the baseline and under the proposed rule. The difference is summarized in the shaded panel at the bottom of the table. That difference is the estimated cost of the rule, as presented in Table 6 in section III.A.1.

Table A-2 shows each of the major inputs into our baseline cost estimate. The first two columns are the estimated volumes of food served per meal, expressed in grams, and weighted average prices per gram. We estimate the cost per meal of prepared and processed foods without breaking them into food group ingredients. Quantities of food served per meal are from SNDA-III; unit prices are from SLBCS-II. The product of these figures give the estimated food cost per school meal served. We inflate each of the meal components by historic and projected changes in food group specific prices to estimate per meal costs through FY 2016. Inflation factors, not shown in Table A-2, are weighted averages, computed from CPI-U data from the Bureau of Labor Statistics. The next set of columns contains projections of meals served through FY 2016. Total baseline costs, in the five rightmost columns of Table A-2, are the product of the estimated costs per meal and FNS projections of the number of meals served.

Our estimate of total cost under the proposed rule is developed in Tables A-3 and A-4. Table A-3 summarizes the steps that we took to estimate a per-meal food cost in FY 2012, the year in which the rule is expected to take effect. Table A-4 takes that FY 2012 figure and projects total costs through FY 2016.

Table A-3 begins with a set of food group quantities per meal consistent with proposed rule meal pattern requirements. There is a considerable amount of work behind these numbers that cannot be summarized in a simple table. The first three columns of numbers in Table A-3 represent the quantities of food that may be served to students, by grade level, on a per-meal basis. These figures include estimated quantities by food group and for prepared and processed foods. The process that we used to develop these figures is described in detail in section III.B.2. The key steps in that process (not shown in Table A-3) are summarized as follows:

- Begin with the food group specific quantities that must be offered to students under the proposed rule.

- Multiply quantities that must be offered by anticipated student take rates to generate estimated "target" amounts that may be served.

- Assume that schools will offer the same amount of prepared and processed ("combination") foods as they reported serving in SY 2004–2005 (from SNDA-III). Estimate the amount of creditable servings of vegetables, refined grains, whole grains, and meat or meat alternate satisfied by these combination foods and subtract those creditable amounts from our food group targets.

- The differences between targeted servings and amounts satisfied by combination foods must be satisfied with non-combination single-item servings of those foods.

Some of the food group targets satisfied by single-item servings are negative; see the refined grain figures for all grade groups, and the meat or meat alternate figure for middle schools in Table A-3. This means that the combination foods more than satisfy the serving targets for those foods. We use the negative numbers to compute the value of that excess and subtract it from our proposed rule cost estimate.

Table A-3's fourth column of numbers is weighted average prices per unit of food served for FY 2012. Note that the prices by food group are different for lunch and breakfast; we estimate different weighted average prices based on the different mix of foods served at breakfast and lunch. Our price figures use data from the SLBCS-II, and are inflated with FNS-computed factors constructed with CPI-U data (not shown in Table A-3). The product of our food group serving targets and estimated unit prices give estimated food group component costs per meal (the three columns under the "Weighted Average Price—Dollar Cost per Meal" header). To this point, all of the figures are specific to elementary, middle, and high schools. The last column in Table A-3 uses the percent distribution of meals served by grade level to estimate an overall weighted average cost per meal by food group.

Table A-4 resembles Table A-2. It takes the weighted average prices per meal for combination foods and single-item foods for FY 2012, projects them through FY 2016 using food group specific inflation factors, then multiplies those inflated per meal figures by FNS projections of meals served. The final estimated cost of meals served under the proposed rule is displayed in the last five columns of the table.

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⁸¹ Another small part of the difference in cost is our omission of items such as snack chips, drinks other than milk and fruit juice, condiments, and salad dressing; these items are served in addition to the foods that help satisfy the NSLP and SBP

meal requirements. We exclude them from both the baseline and the proposed rule estimates under the assumption that they will contribute similarly to each estimate and will have no effect on the difference in cost.

⁸² The SNDA-III dataset was designed to allow the computation of take rates by food item in order to support a nutrient analysis of school meals.

Table A-1: Cost of Proposed Rule – Summary

Cost Effect Summary

		Fiscal Year Costs (millions)					
Cost Category		2012 ¹	2013	2014	2015	2016	2012 - 2016
Current Rule	Breakfast	\$241.5	\$1,623.5	\$1,698.8	\$1,777.7	\$1,860.4	\$7,201.9
	Labor ²	235.7	1,584.3	1,657.8	1,734.8	1,815.5	7,028.2
	Lunch	868.2	5,803.7	6,058.2	6,318.3	6,590.5	25,638.9
	Labor ²	847.3	5,663.7	5,912.0	6,165.9	6,431.5	25,020.4
	Total	\$2,192.7	\$14,675.2	\$15,326.8	\$15,996.8	\$16,697.9	\$64,889.4
Proposed Rule	Breakfast	\$303.8	\$2,043.4	\$2,154.9	\$2,343.1	\$2,453.9	\$9,299.0
	Labor ²	296.5	1,994.1	2,102.9	2,286.6	2,394.7	9,074.7
	Lunch	897.7	6,010.3	6,307.0	6,721.9	7,025.3	26,962.1
	Labor ²	876.1	5,865.3	6,154.8	6,559.7	6,855.8	26,311.7
	Total	\$2,374.1	\$15,913.1	\$16,719.6	\$17,911.2	\$18,729.6	\$71,647.6
Difference	Food :	\$91.8	\$626.5	\$704.9	\$968.9	\$1,028.2	\$3,420.4
	Labor :	89.6	611.4	687.9	945.6	1,003.4	3,337.9
	State Agency Administration ³ :	0.1	8.9	9.0	9.3	9.6	36.9
	Total :	\$181.5	\$1,246.8	\$1,401.9	\$1,923.8	\$2,041.3	\$6,795.2

Notes:

1. FY 2012 is a 3 month figure. The rule is assumed to take effect at the beginning of SY 2012-2013
2. The SLBCS II estimated that labor costs are 44.5 percent of total reported SFA costs; food costs are 45.6 percent of the total. The labor costs shown here are equal to food costs multiplied by (.445/.456).
3. Added State agency administrative costs include training and technical assistance to SFAs, monitoring and compliance, and associated reporting and recordkeeping.

Table A-2: Detail of Baseline (Current Rule) Food Cost Estimate – Prices per Meal, Participation, and Total Projected Food Cost

Current Rule

Meal	Food Item	Average Meal Served ¹ grams per meal	Weighted Average Price ² dollar cost per gram	Weighted Average Price (inflated to) dollar cost per meal						Participation meals served (millions)						Total Food Cost (\$ millions) for number of months					
				FY2012	FY2013	FY2014	FY2015	FY2016	FY2012	FY2013	FY2014	FY2015	FY2016	FY2012	FY2013	FY2014	FY2015	FY2016	FY2012	FY2013	FY2014
Breakfast																					
Grades K-12																					
	Milk	211.73	\$0.0008	\$0.1776	\$0.1805	\$0.1834	\$0.1865	\$0.1895	332	2,167	2,201	2,237	2,272	2,272	\$58.9	\$391.0	\$403.8	\$417.1	\$430.7		
	Fruit	20.36	0.0018	0.0362	0.0375	0.0389	0.0403	0.0418	332	2,167	2,201	2,237	2,272	2,272	12.0	81.3	85.6	90.2	95.0		
	Fruit Juice	90.92	0.0013	0.1212	0.1260	0.1311	0.1363	0.1417	332	2,167	2,201	2,237	2,272	2,272	40.2	273.1	288.5	304.8	322.1		
	Grain	51.40	0.0046	0.2361	0.2438	0.2518	0.2600	0.2685	332	2,167	2,201	2,237	2,272	2,272	78.4	528.3	554.3	581.5	610.1		
	Meat/Meat Alternate	11.63	0.0042	0.0487	0.0501	0.0515	0.0530	0.0545	332	2,167	2,201	2,237	2,272	2,272	16.2	108.6	113.4	118.5	123.8		
	Vegetable	1.04	0.0019	0.0019	0.0021	0.0022	0.0024	0.0025	332	2,167	2,201	2,237	2,272	2,272	0.6	4.5	4.9	5.3	5.7		
	Prepared & Processed Foods	25.63	0.0041	0.1058	0.1092	0.1128	0.1164	0.1202	332	2,167	2,201	2,237	2,272	2,272	35.1	236.7	248.3	260.4	273.1		
	Total K-12	412.70		\$0.7276	\$0.7493	\$0.7717	\$0.7948	\$0.8187							\$241.5	\$1,623.5	\$1,698.8	\$1,777.7	\$1,860.4		
Lunch																					
Grades K-12																					
	Milk	215.25	\$0.0008	\$0.1786	\$0.1815	\$0.1845	\$0.1875	\$0.1906	856	5,532	5,582	5,626	5,671	5,671	\$152.9	\$1,004.2	\$1,029.9	\$1,055.2	\$1,081.2		
	Fruit	59.53	0.0017	0.1024	0.1064	0.1106	0.1149	0.1194	856	5,532	5,582	5,626	5,671	5,671	87.7	588.8	617.3	646.5	677.1		
	Fruit Juice	16.35	0.0015	0.0245	0.0254	0.0265	0.0275	0.0286	856	5,532	5,582	5,626	5,671	5,671	20.9	140.8	147.7	154.8	162.3		
	Grain	22.72	0.0025	0.0572	0.0602	0.0634	0.0667	0.0702	856	5,532	5,582	5,626	5,671	5,671	49.0	333.2	353.9	375.5	398.4		
	Meat/Meat Alternate	7.74	0.0038	0.0298	0.0306	0.0314	0.0323	0.0332	856	5,532	5,582	5,626	5,671	5,671	25.5	169.2	175.4	181.6	188.1		
	Vegetable	66.66	0.0022	0.1447	0.1525	0.1607	0.1693	0.1784	856	5,532	5,582	5,626	5,671	5,671	123.9	843.6	896.9	952.6	1,011.9		
	Prepared & Processed Foods	139.70	0.0034	0.4770	0.4924	0.5083	0.5247	0.5416	856	5,532	5,582	5,626	5,671	5,671	408.3	2,723.9	2,837.1	2,952.0	3,071.6		
	Total K-12	527.95		\$1.0142	\$1.0491	\$1.0853	\$1.1230	\$1.1620							\$868.2	\$5,803.7	\$6,058.2	\$6,318.3	\$6,590.5		

notes:

1. Average grams per meal served is calculated using SNDA-III (SY 2004-2005)
2. Price is calculated using SLBCS II data (SY 2005-2006) and inflated to FY 2012 using the Bureau of Labor Statistics CPI-U.

Table A-3: Detail of Proposed Rule Food Cost Estimate – Base Year Quantities and Prices

Proposed Rule

Meal	Food Item	Unit	Number of Units to meet Proposed Recommendations ¹			Weighted Average Price ²			Percent of Participants by School Grade ³			Weighted Average Price dollar cost per meal	
			Grades K-5	Grades 6-8	Grades 9-12	Grades K-5	Grades 6-8	Grades 9-12	Grades K-5	Grades 6-8	Grades 9-12		
			units per meal	units per meal	units per meal	dollar cost per unit	dollar cost per meal	dollar cost per meal					
						FY2012	FY2012	FY2012	FY2012	FY2012	FY2012	FY2012	
Breakfast	Milk	cup	0.9002	0.8111	0.8061	\$0.2050	\$0.1846	\$0.1663	56.64%	22.08%	21.28%	\$0.1764	
	Fruit	cup equivalent	0.4619	0.4479	0.3877	0.3630	0.1677	0.1626	56.64%	22.08%	21.28%	0.1608	
	Fruit Juice	cup equivalent	0.3658	0.3658	0.3658	0.3317	0.1213	0.1213	56.64%	22.08%	21.28%	0.1213	
	Non Whole Grains	oz equivalent	0.5010	0.3902	0.3225	0.1624	0.0814	0.0634	56.64%	22.08%	21.28%	0.0712	
	Whole Grains	oz equivalent	0.7066	0.6598	0.6934	0.2172	0.1535	0.1433	56.64%	22.08%	21.28%	0.1506	
	Meat/Meat Alternate	oz equivalent	0.5609	0.4534	0.8605	0.2032	0.1140	0.0921	56.64%	22.08%	21.28%	0.1221	
	Vegetable	cup equivalent	0.0000	0.0000	0.0000	0.3162	0.0000	0.0000	56.64%	22.08%	21.28%	0.0000	
	Prepared & Processed Foods	gram	21.980	28.837	39.656	0.0041	0.0908	0.1191	56.64%	22.08%	21.28%	0.1126	
	Total						\$0.9132	\$0.8682	\$0.9690				\$0.9151
	Lunch	Milk	cup	0.9092	0.8085	0.7811	\$0.2023	\$0.1839	\$0.1635	56.64%	22.08%	21.28%	\$0.1739
Fruit		cup equivalent	0.2759	0.2145	0.4294	0.3494	0.0964	0.0750	56.64%	22.08%	21.28%	0.1031	
Fruit Juice		cup equivalent	0.0658	0.0658	0.0658	0.3720	0.0245	0.0245	56.64%	22.08%	21.28%	0.0245	
Non Whole Grains ⁴		oz equivalent	-0.4667	-0.6420	-0.5173	0.0835	-0.0390	-0.0536	56.64%	22.08%	21.28%	-0.0431	
Whole Grains		oz equivalent	0.7126	0.6950	0.8610	0.1117	0.0796	0.0776	56.64%	22.08%	21.28%	0.0827	
Meat/Meat Alternate ⁴		oz equivalent	0.0504	-0.0775	0.1305	0.1337	0.0067	-0.0104	56.64%	22.08%	21.28%	0.0052	
Vegetables													
Dark Green		cup equivalent	0.0790	0.0763	0.0792	0.3713	0.0293	0.0283	56.64%	22.08%	21.28%	0.0291	
Orange		cup equivalent	0.0809	0.0784	0.0813	0.5195	0.0420	0.0407	56.64%	22.08%	21.28%	0.0418	
Legumes		cup equivalent	0.0847	0.0633	0.0857	0.7214	0.0611	0.0457	56.64%	22.08%	21.28%	0.0578	
Starchy	cup equivalent	0.1552	0.1494	0.1550	0.3345	0.0519	0.0500	56.64%	22.08%	21.28%	0.0515		
Other	cup equivalent	0.1032	0.0838	0.3020	0.3829	0.0395	0.0321	56.64%	22.08%	21.28%	0.0541		
Prepared & Processed Foods ⁴	gram	128.676	145.885	150.386	0.0034	0.4394	0.4981	56.64%	22.08%	21.28%	0.4681		
Total						\$1.0154	\$0.9715	\$1.2174				\$1.0487	

notes:

- Quantities shown here are estimates of the amounts that will be served to students after implementation of the proposed rule. They are the amounts that must be offered to students under the proposed rule multiplied by estimated student take-up rates.
- Price is calculated using SLBCS II data (SY 2005-2006) and inflated to FY 2012 using the Bureau of Labor Statistics CPI-U.
- The percentage splits of NSLP participants were calculated using SNDA III (SY2004-2005) data.
- The proposed rule cost estimate takes the observed quantity of prepared and processed food served from the baseline and uses that as the basis for the proposed rule estimate. That quantity of prepared and processed foods contains program-creditable amounts of vegetables, meat/meat alternate, whole grains, and refined grains. The difference between the program-creditable quantities satisfied by prepared and process foods, and the targeted quantities required by the proposed rule, are the figures shown in the vegetable, meat/meat alternate, whole grain, and refined grain rows of this table. Negative numbers in the refined grains and meat/meat alternate rows mean that prepared and processed foods from the baseline contain more than the targeted quantities required by the proposed rule. The proposed rule targets for refined grains (in all grade levels) and for meat/meat alternate (in middle school) are more than fully satisfied by prepared and processed foods. The amounts in excess of those targets are displayed as negative numbers. The methodology is described in greater detail in the regulatory impact analysis.

Proposed Rule

Meal	Food Item	Total Food Cost (\$ millions) for number of months														
		Weighted Average Price (inflated to dollar cost per meal)						Participation meals served (thousands)								
		FY2012	FY2013	FY2014	FY2015	FY2016	FY2012	FY2013	FY2014	FY2015	FY2016	FY2012	FY2013	FY2014	FY2015	FY2016
	Breakfast															
	Grades K-12															
	Milk	\$0.1764	\$0.1793	\$0.1823	\$0.1853	\$0.1883	332	2,167	2,201	2,237	2,272	\$58.6	\$388.6	\$401.3	\$414.4	\$428.0
	Fruit	0.1608	0.1667	0.1728	0.1792	0.1857	332	2,167	2,201	2,237	2,272	53.4	361.2	380.5	400.7	422.1
	Fruit Juice	0.1213	0.1262	0.1312	0.1364	0.1419	332	2,167	2,201	2,237	2,272	40.3	273.4	288.9	305.2	322.4
	Grains	0.2218	0.2291	0.2435	0.2901	0.2996	332	2,167	2,201	2,237	2,272	73.7	496.3	536.0	648.9	680.8
	Meat/Meat Alternate	0.1221	0.1256	0.1291	0.1328	0.1365	332	2,167	2,201	2,237	2,272	40.5	272.1	284.2	296.9	310.2
	Vegetable	0.0000	0.0000	0.0000	0.0000	0.0000	332	2,167	2,201	2,237	2,272	-	-	-	-	-
	Prepared & Processed Foods	0.1126	0.1162	0.1199	0.1238	0.1278	332	2,167	2,201	2,237	2,272	37.4	251.7	264.0	276.9	290.4
	Total K-12	\$0.9151	\$0.9431	\$0.9789	\$1.0476	\$1.0799						\$303.8	\$2,043.4	\$2,154.9	\$2,343.1	\$2,453.9
	Lunch															
	Grades K-12															
	Milk	\$0.1739	\$0.1767	\$0.1797	\$0.1826	\$0.1856	856	5,532	5,582	5,626	5,671	\$148.9	\$977.8	\$1,002.8	\$1,027.5	\$1,052.7
	Fruit	0.1031	0.1071	0.1113	0.1156	0.1201	856	5,532	5,582	5,626	5,671	88.2	592.6	621.2	650.6	681.4
	Fruit Juice	0.0245	0.0255	0.0265	0.0275	0.0286	856	5,532	5,582	5,626	5,671	21.0	140.8	147.7	154.9	162.3
	Grains	0.0396	0.0417	0.0480	0.0743	0.0782	856	5,532	5,582	5,626	5,671	33.9	230.6	268.2	417.8	443.3
	Meat/Meat Alternate	0.0052	0.0054	0.0055	0.0057	0.0058	856	5,532	5,582	5,626	5,671	4.5	29.8	30.8	31.9	33.1
	Vegetable	0.2343	0.2469	0.2601	0.2741	0.2888	856	5,532	5,582	5,626	5,671	200.6	1,365.7	1,452.0	1,542.2	1,638.1
	Prepared & Processed Foods	0.4681	0.4832	0.4988	0.5149	0.5315	856	5,532	5,582	5,626	5,671	400.7	2,673.2	2,784.2	2,897.0	3,014.3
	Total K-12	\$1.0487	\$1.0865	\$1.1299	\$1.1947	\$1.2387						\$897.7	\$6,010.3	\$6,307.0	\$6,721.9	\$7,025.3

**Initial Regulatory Flexibility Analysis
Proposed Rule: Nutrition Standards in
the National School Lunch and School
Breakfast Programs**

[RIN 0584-AD59]

Agency: Food and Nutrition Service, USDA.

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

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

Reasons That Action Is Being Considered

Section 103 of the Child Nutrition and WIC Reauthorization Act of 2004 inserted Section 9(a)(4) into the National School Lunch Act requiring the Secretary to promulgate rules revising nutrition requirements, based on the most recent *Dietary Guidelines for Americans*, that reflect specific recommendations for increased consumption of foods and food ingredients offered in school meal programs. This proposed rule amends Sections 210 and 220 of the regulations that govern the National School Lunch Program (NSLP) and the School Breakfast Program (SBP). The proposed rule implements recommendations of the National Academies' Institute of Medicine (IOM). Under contract to the United States Department of Agriculture (USDA), IOM proposed changes to NSLP and SBP meal pattern requirements consistent with the 2005 *Dietary Guidelines* and IOM's Dietary Reference Intakes. The proposed rule advances the mission of the Food and Nutrition Service (FNS) to provide children access to food, a healthful diet, and nutrition education in a manner that inspires public confidence.

Objectives of, and Legal Basis for, the Proposed Rule

Under Section 9(a)(4) and Section 9(f)(1) of the NSLA, schools that participate in the NSLP or SBP must offer lunches and breakfasts that are consistent with the goals of the most recent *Dietary Guidelines for Americans*. Current nutrition requirements for school lunches and breakfasts are based on the 1995 *Dietary Guidelines* and the 1989 RDAs. (School lunches and breakfasts were not updated when the 2000 Dietary Guidelines were issued because those recommendations did not require significant changes to the school meal patterns.) The 2005 Dietary Guidelines provide more prescriptive and specific nutrition guidance than earlier releases and require significant changes to school meal requirements.

Number of Small Entities to Which the Proposed Rule Will Apply

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

- There are currently about 19,000 School Food Authorities (SFAs) participating in NSLP and SBP. More than 99 percent of these have fewer than 50,000 students.⁸³ About 26 percent of SFAs with fewer than 50,000 students are private. However, private school SFAs account for only 3 percent of all students in SFAs with enrollments under 50,000.⁸⁴

- Nearly 102,000 schools and residential child care institutions participate in the NSLP. These include more than 90,000 public schools, 6,000 private schools, and about 5,000 residential child care institutions (RCCIs).⁸⁵ We focus on the impact at the SFA level in this document, rather than the school level, because SFAs are

⁸³ FNS 742 School Food Verification Survey, School Year 2009–2010. This number is approximate, not all SFAs are required to submit the 742 form.

⁸⁴ *Ibid.* RCCIs include but are not limited to juvenile detention centers, orphanages, and medical institutions. We do not have information on the number of children enrolled in these institutions.

⁸⁵ FNS program data for FY 2010.

responsible for the administration of the NSLP and the SBP.

- Food service management companies (FSMCs) that prepare school meals or menus under contract to SFAs are affected indirectly by the proposed rule. Thirteen percent of public school SFAs contracted with FSMCs in school year (SY) 2004–2005.⁸⁶ Of the 2,460 firms categorized as “food service contractors” under NAICS code 72231, 96 percent employ fewer than 500 workers.⁸⁷

Projected Reporting, Recordkeeping and Other Compliance Requirements

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

**School Food Authorities (SFA)/Schools
Increased Cost To Produce School Meals**

It is estimated that the proposed rule will raise the average cost of producing and serving school lunches by almost 7 cents and school breakfasts by 37 cents on initial implementation. By FY 2015, when the 100 percent whole grain rich requirement takes effect, the cost per lunch will be 14 cents higher than our baseline estimate; the cost per breakfast will be 50 cents higher. Across all SFAs we estimate that the total cost of compliance will be \$6.8 billion over five years. Although about 99 percent of SFAs enroll fewer than 50,000 students, they enroll only about 80 percent of all students. If they serve about 80 percent of all meals (we do not have data on meals served by SFA size) then these small entities would incur roughly 80 percent of estimated costs.

Increased costs of producing school meals as a result of the proposed rule are not expected to fall disproportionately on smaller SFAs. We estimate the cost of the proposed rule on a per meal basis. Schools that face average labor and food costs, and have menus typical of the average school will incur costs directly proportional to their size. We estimate that those costs will equal our estimated cost per meal multiplied by the number of meals served.

The most important factors that will separate schools with higher than

⁸⁶ U.S. Department of Agriculture, Food and Nutrition Service, Office of Research, Nutrition and Analysis, School Nutrition Dietary Assessment Study-III, Vol. I, 2007, p. 34 <http://www.fns.usda.gov/ora/MENU/Published/CNP/FILES/SNDIII-Vol1.pdf>

⁸⁷ *Ibid.*

average per-meal costs from those with lower than average costs are not necessarily associated with the size of the SFA. For instance, schools with menus that already emphasize fruits, non-starchy vegetables, and whole grains will need to make fewer changes, and the costs of implementation in those schools may be lower than average. Also, because the per-meal cost of complying with the proposed requirements is much higher for breakfast than for lunch, the overall costs of implementation in schools that serve the most school breakfasts relative to lunches will be higher than the costs faced by schools that do not serve breakfast.

Increased Cost of Administering School Meals Programs

An initial increase in administrative staff time for training and implementation is anticipated at the SFA level. The proposed rule increases the length of State reviews of SFAs through the Coordinated Review Effort (CRE) by incorporating the requirements of School Meals Initiative (SMI) reviews, and increases their frequency to once every three years. SFAs that previously had separate CREs and SMIs may experience a decrease in burden, because they will undergo just one CRE every three years, rather than two reviews (one CRE and one SMI) every five years.

The proposed rule incorporates the provision of training and technical assistance by SAs to the SFAs. SFAs must, in turn, adjust their current training agenda to include the new requirements, as no funding has been provided in the proposed rule to accommodate new training.

In total, these administrative changes, in the form of recordkeeping and reporting burden arising from the proposed rule, are estimated to result in a net change of 8.2 hours for each of about 7,000 SFAs per year. The additional 8.2 hours of record keeping and reporting burden to SFAs per year would not rise to the level of a significant impact for RFA purposes.⁸⁸

Increased Equipment Costs

SFAs may need to purchase new equipment to prepare and serve meals that comply with the proposed standards. For example, some SFAs may

need to replace fryers with ovens or steamers. In FY 2009, FNS solicited requests from SFAs for food service equipment grants, awarding \$100 million in 2009 American Recovery and Reinvestment Act (ARRA) Equipment Grants and an additional \$25 million in one-time funds included in the FY 2010 Appropriations Act. In response to their solicitations for these funds, State agencies received a total of approximately \$600 million in grant requests from SFAs. The strong response to these grant programs indicates a substantial demand for investment in kitchen equipment.

We do not have the data necessary to measure the remaining unmet demand in smaller SFAs or in SFAs that did not receive grants. However, much of that demand is driven by the routine need to replace equipment that is nearing the end of its useful life—a cost that is appropriately covered by USDA meal reimbursements and other sources of food service revenue. For recipient SFAs, the grants temporarily freed some of those revenue sources for other priorities. In the absence of additional Congressional action, SFAs must again turn to those sources to meet their ongoing equipment needs.

Options for Addressing Increased Costs

Most schools will have a number of options and flexibilities within available revenue streams and operational approaches that can help to balance costs and resources. The primary resources available to SFAs are listed here.

1. **Federal Reimbursements:** About half of all SFA revenues are from Federal reimbursements. These payments are adjusted annually for changes in food and labor costs by statute. SLBCS-II found that in 2005–06, for most reimbursable lunches and in most SFAs, reported lunch production costs were less than the Federal free lunch subsidy by a small amount, with the difference greatest in SFAs that produce more meals, resulting in a lower per-meal cost.

2. **Student Payments:** School districts have the discretion to set student payments for “paid meals” and à la carte foods at levels of their choosing, so long as the resulting revenues are paid into the non-profit school food service account. Some currently set prices for these meals and foods at levels that do not cover the full cost of production, with Federal payments for free and reduced-price meals covering the difference. Schools will likely face additional incentives to adjust their pricing policies so that adequate

revenue is generated to cover the cost of production.

3. **State and Local Funds:** A limited but nonetheless substantial portion of meal production costs are paid from State and local government sources. The contributions of these entities may need to increase to cover costs.

4. **Operational Changes:** Like other service businesses, schools may need to consider changes to their operations to increase efficiency and meet the requirements of the proposed rule. Several hundred schools recognized as part of the HealthierUS School Challenge (HUSC) have demonstrated an ability to operate cost-effective school meals programs that meet many of the proposed rule’s requirements. These schools may offer models for others as implementation moves forward.

We recognize that small SFAs, like others, will face substantial costs and potential challenges in implementing the proposed rule. These costs are not significantly greater for small SFAs than for larger ones, as implementation costs are driven primarily by factors other than SFA size. Nevertheless, we do not discount the special challenges that may face some smaller SFAs. As a group, small SFAs may have less flexibility to adjust resources in response to immediate budgetary needs. The time between publication of the proposed and final rules offers these SFAs some opportunity, however, for advance planning.

Food Service Management Companies

FSMCs are potentially indirectly affected by the proposed rule. FSMCs that provide school meals under contract to SFAs will need to alter those products to conform to the proposed changes in meal requirements. In addition, FSMCs may find new opportunities to work with SFAs that currently do not contract for food service assistance, a “beneficial impact” of the regulation. Consistent with SBA guidance, which notes that “[t]he courts have held that the RFA requires an agency to perform a regulatory flexibility analysis of small entity impacts only when a rule directly regulates them”,⁸⁹ we do not attempt to quantify the economic effect of the proposed rule on FSMCs.

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

FNS is unaware of any such Federal rules or laws.

⁸⁸ SBA’s “A Guide for Government Agencies” identifies several examples of significant impact: A rule that provides a strong disincentive to seek capital; 175 staff hours per year for recordkeeping; impacts greater than the \$500 fine (in 1980 dollars) imposed for noncompliance; new capital requirements beyond the reach of the entity; and any impact less cost-efficient than another reasonable regulatory alternative.

⁸⁹ SBA, “A Guide for Government Agencies”, p. 20.

Significant Alternatives

The proposed rule establishes a single effective date that applies to all local educational agencies (LEAs), regardless of size. Schools vary in the extent to which they meet current nutrition requirements for reimbursable meals. Though most are reasonably successful in meeting the food group requirements under current rules, some schools may find it operationally difficult, or too costly, to prepare and serve meals that satisfy the new requirements of the proposed rule by SY 2012–2013.

Though we are not aware of any evidentiary basis to distinguish groups of schools that may find it more difficult to meet the proposed requirements than others, the regulatory impact analysis considers as an alternative the phase-in adopted by Congress for the requirement to conduct direct certification under Section 104 of the Child Nutrition and WIC Reauthorization Act of 2004 (Public Law 108–265). LEAs with more than 25,000 students could be required to implement by SY 2012–2013, those with 10,000 to 25,000 students by SY 2013–2014, and those with less than 10,000 students by SY 2014–2015. Final whole grain requirements would become effective two years after implementation in each cohort of LEAs. Such an approach would give smaller LEAs more time to meet the requirements than larger ones and reduce the cost and impact of the rule during the first five years of implementation.

It would also, however, reduce the potential benefits of providing more nutritious meals to the children in those schools. Participation in the school meals program is highest among elementary school students; participation decreases as students move to middle and high school. One of the stated goals of IOM was to “foster healthy eating habits” through exposure to the school meals program. Because of the decrease in participation among older students, the school meals program has only a limited opportunity to influence the eating habits of some students. Students in smaller SFAs who are not introduced to the proposed meal requirements while still in elementary school may not benefit at all from delayed implementation of the rule. Because a phased implementation would deny some students the benefits of healthier school meals, this alternative schedule was not proposed.

List of Subjects

7 CFR Part 210

Grant programs—education, Grant programs—health, Infants and children,

Nutrition, Penalties, Reporting and record keeping requirements, School breakfast and lunch programs, Surplus agricultural commodities.

7 CFR Part 220

Grant programs—education, Grant programs—health, Infants and children, Nutrition, Reporting and record keeping requirements, School breakfast and lunch programs.

Accordingly, 7 CFR Parts 210 and 220 are proposed to be amended as follows:

PART 210—NATIONAL SCHOOL LUNCH PROGRAM

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

Authority: 42 U.S.C. 1751–1760, 1779.

2. In § 210.2:

- a. Revise the definition of *Food component*;
- b. Revise the definition of *Food item*;
- c. Amend the definition of *Lunch* by removing the words “applicable nutrition standards and portion sizes” and adding in their place the words “meal requirements”;
- d. Remove the definition of *Menu item*;
- e. Remove the definition of *Nutrient Standard Menu Planning/Assisted Nutrient Standard Menu Planning*;
- f. Revise the definition of *School week*; and
- g. Add the definition of *Whole grains*.

The revisions and additions read as follows:

§ 210.2 Definitions.

* * * * *

Food component means one of the five food groups which comprise reimbursable meals. The five food components are: Meats/meat alternates, grains, vegetables, fruits, and fluid milk.

* * * * *

Food item means a specific food offered within the five food components: Meats/meat alternates, grains, vegetables, fruits, and fluid milk.

* * * * *

School week means the period of time used to determine compliance with the meal requirements in § 210.10. The period shall be a normal school week of five consecutive days; however, to accommodate shortened weeks resulting from holidays and other scheduling needs, the period shall be a minimum of three consecutive days and a maximum of seven consecutive days. Weeks in which school lunches are offered less than three times shall be combined with either the previous or the coming week.

* * * * *

Whole grains means grains that consist of the intact, ground, cracked, or flaked grain seed whose principal anatomical components—the starchy endosperm, germ and bran—are present in the same relative proportions as they exist in the intact grain seed. Whole grain-rich products must conform to FNS guidance to count toward the grains component.

* * * * *

3. Revise § 210.10 to read as follows:

§ 210.10 Meal requirements for lunches and requirements for afterschool snacks.

(a) *General requirements.* (1) *General nutrition requirements.* Schools must offer nutritious, well-balanced, and age-appropriate meals to all the children they serve to improve their diets and safeguard their health.

(i) *Requirements for lunch.* School lunches offered to children age 5 or older must meet, at a minimum, the meal requirements in paragraph (b) of this section. Schools must follow a food-based menu planning approach and produce enough food to offer each child the quantities specified in the meal pattern established in paragraph (c) of this section for each age/grade group served in the school. In addition, school lunches must meet the dietary specifications in paragraph (f) of this section. Schools offering lunches to children ages 1 to 4 and infants must meet the meal pattern requirements in paragraph (p) of this section.

(ii) *Requirements for afterschool snacks.* Schools offering afterschool snacks in afterschool care programs must meet the meal pattern requirements in paragraph (o) of this section. Schools must plan and produce enough food to offer each child the minimum quantities under the meal pattern in paragraph (o) of this section. The component requirements for meal supplements served under the Child and Adult Care Food Program authorized under part 226 of this chapter also apply to afterschool snacks served in accordance with paragraph (o) of this section.

(2) *Unit pricing.* Schools must price each meal as a unit. Schools need to consider participation trends in an effort to provide one reimbursable lunch and, if applicable, one reimbursable afterschool snack for each child every school day. If there are leftover meals, schools may offer them to the students but cannot get reimbursement for them. Schools must identify, near or at the beginning of the serving line(s), the food items that constitute the unit-priced reimbursable school meal(s).

(3) *Production and menu records.* Schools or school food authorities, as

applicable, must keep production and menu records for the meals they produce. These records must show how the meals offered contribute to the required food components and food quantities for each age/grade group every day. Labels or manufacturer specifications for food products and ingredients used to prepare school meals must indicate zero grams of *trans* fat per serving (less than 0.5 grams). Schools or school food authorities must maintain records of the latest nutritional analysis of the school menus conducted by the State agency. Production and menu records must be maintained in accordance with FNS guidance.

(b) *Meal requirements for school lunches.* School lunches for children

ages 5 and older must reflect food and nutrition requirements specified by the Secretary. Compliance with these requirements is measured as follows:

(1) *On a daily basis:* (i) Meals offered to each age/grade group must include the food components and food quantities specified in the meal pattern in paragraph (c) of this section;

(ii) Food products or ingredients used to prepare meals must contain zero grams of *trans* fat per serving or a minimal amount of naturally-occurring *trans* fat; and

(iii) Meals selected by each student must have the number of food components required for a reimbursable meal and include at least one fruit or vegetable.

(2) *Over a 5-day school week:* (i) Average calorie content of meals offered to each age/grade group must be within the minimum and maximum calorie levels specified in paragraph (f) of this section;

(ii) Average saturated fat content of the meals offered to each age/grade group must be less than 10 percent of total calories; and

(iii) Average sodium content of the meals offered to each age/grade group must not exceed the maximum level specified in paragraph (f) of this section.

(c) *Meal pattern for school lunches.* Schools must offer the food components and quantities required in the lunch meal pattern established in the following table:

Meal Pattern	Lunch Meal Pattern		
	Grades K-5	Grades 6-8	Grades 9-12
	Amount of Food ^a Per Week (Minimum Per Day)		
Fruits (cups) ^b	2.5 (0.5)	2.5 (0.5)	5 (1)
Vegetables (cups) ^b	3.75 (0.75)	3.75 (0.75)	5 (1)
Dark green	0.5 ^c	0.5 ^c	0.5 ^c
Orange	0.5 ^c	0.5 ^c	0.5 ^c
Legumes	0.5 ^c	0.5 ^c	0.5 ^c
Starchy	1 ^e	1 ^d	1 ^d
Other	1.25 ^c	1.25 ^c	2.5 ^c
Grains (oz eq) ^e	9-10 (1)	9-10 (1)	12-13 (2)
Meats/Meat Alternates (oz eq)	8-10 (1)	9-10 (1)	10-12 (2)
Fluid milk (cups) ^f	5 (1)	5 (1)	5 (1)
Other Specifications: Daily Amount Based on the Average for a 5-Day Week			
Min-max calories (kcal) ^{gh}	550-650	600-700	750-850
Saturated fat (% of total calories) ^g	< 10	< 10	< 10
Sodium (mg) ⁱ	≤ 640	≤ 710	≤ 740
<u>Trans</u> fat	Nutrition label or manufacturer specifications must indicate zero grams of <u>trans</u> fat per serving.		

^aFood items included in each group and subgroup and amount equivalents. Minimum serving is 1/8 cup.

^bOne cup of fruits and vegetables usually provides 2 servings; 1/4 cup of dried fruit counts as 1/2 cup of fruit; 1 cup of leafy greens counts as 1/2 cup of vegetables. No more than half of the fruit offerings may be in the form of juice. All juice must be pasteurized, 100% full strength.

^cLarger amounts of these vegetables may be served.

^dA maximum of 1 cup of starchy vegetables may be served per week. Starchy vegetables include white potatoes, corn, green peas, and lima beans.

^eAt least half of grains offered must be whole grain-rich. Aiming for a higher proportion of whole grain-rich foods is encouraged. Two years post implementation of the final rule, all grains must be whole grain-rich.

^fFluid milk must be low-fat (1% milk fat, unflavored) or fat-free (unflavored or flavored).

^gThe average daily amount for a 5-day school week must fall within the minimum and maximum levels

^hDiscretionary sources of calories (solid fats and added sugars) may be added to the meal pattern if within the specifications for calories, saturated fat, trans fat, and sodium.

ⁱSodium targets are to be reached 10 years after implementation of the final rule. Intermediate targets have been established to ensure that action to reduce the sodium content of school meals over the 10-year period maintains student participation rates.

(1) *Age/grade groups.* Schools must plan menus for students using the following age/grade groups: grades K–5 (ages 5–10), grades 6–8 (ages 11–13), and grades 9–12 (ages 14–18). If an unusual grade configuration in a school prevents the use of these established age/grade groups, students in grades K–5 and grades 6–8 may be offered the same food quantities at lunch provided that the calorie and sodium standards for each age/grade group are met. No customization of the established age/grade groups is allowed.

(2) *Food components.* Schools must offer students in each age/grade group

the food components specified in paragraph (c) of this section.

(i) *Meats/meat alternates component.* Schools must offer meats/meat alternates daily as part of the lunch meal pattern. The quantity of meats/meat alternates must be the edible portion as served. This component must be served in a main dish or in a main dish and only one other food item. Schools without daily choices in this component should not serve any one meat alternate or form of meat (for example, ground, diced, pieces) more than three times in the same week. If a portion size of this component does not meet the daily requirement for a

particular age/grade group, schools may supplement it with another meats/meat alternates to meet the full requirement. Schools may adjust the daily quantities of this component provided that a minimum of one ounce is offered daily and the total weekly requirement is met over a five-day period.

(A) *Enriched macaroni.* Enriched macaroni with fortified protein as defined in Appendix A to this part may be used to meet part of the meats/meat alternates requirement when used as specified in Appendix A to this part. An enriched macaroni product with fortified protein as defined in Appendix A to this part may be used to meet part

of the meats/meat alternates component or the grains component but not as both food components in the same lunch.

(B) *Nuts and seeds.* Nuts and seeds and their butters are allowed as meat alternates in accordance with program guidance. Acorns, chestnuts, and coconuts may not be used because of their low protein and iron content. Nut and seed meals or flours may be used only if they meet the requirements for Alternate Protein Products established in Appendix A to this part. Nuts or seeds may be used to meet no more than one-half (50 percent) of the meats/meat alternates component with another meats/meat alternates to meet the full requirement.

(C) *Yogurt.* Yogurt may be used to meet all or part of the meats/meat alternates component. Yogurt may be plain or flavored, unsweetened or sweetened. Noncommercial and/or non-standardized yogurt products, such as frozen yogurt, drinkable yogurt products, homemade yogurt, yogurt flavored products, yogurt bars, yogurt covered fruits and/or nuts or similar products are not creditable. Four ounces (weight) or ½ cup (volume) of yogurt equals one ounce of the meats/meat alternates requirement.

(ii) *Fruits component.* Schools must offer fruits daily as part of the lunch menu. Fruits that are fresh; frozen without sugar; canned in light syrup, water or fruit juice; or dried may be offered to meet the requirements of this paragraph. All fruits are credited based on their volume as served, except that ¼ cup of dried fruit counts as ½ cup of fruit. Only pasteurized, full-strength fruit juice may be used, and may be credited to meet no more than one-half of the fruits component.

(iii) *Vegetables component.* Schools must offer vegetables daily as part of the lunch menu. Fresh, frozen, or canned vegetables and dried legumes may be offered to meet this requirement. All vegetables are credited based on their volume as served, except that 1 cup of leafy greens counts as ½ cup of vegetables. Pasteurized, full-strength vegetable juice may be used to meet no more than one-half of the vegetable requirement. Cooked dry beans or peas may be counted as either a vegetable or as a meat alternate but not as both in the same meal. Vegetable offerings at lunch must include the following vegetable subgroups in the quantities specified in the meal pattern in paragraph (c) of this section:

(A) *Dark green vegetables.* This subgroup includes bok choy, broccoli, collard greens, dark green leafy lettuce, kale, mustard greens, romaine lettuce, spinach, turnip greens, and watercress;

(B) *Orange vegetables.* This subgroup includes acorn squash, butternut squash, carrots, pumpkin, and sweet potato;

(C) *Legumes (dry beans).* This subgroup includes black beans, black-eyed peas, garbanzo beans, green peas, kidney beans, lentils, lima beans, soy beans, split peas, and white beans;

(D) *Starchy vegetables.* This subgroup includes corn, green peas, lima beans, and white potatoes. Green peas and fresh, frozen, or canned (not dried) lima beans are considered part of this subgroup and part of the legumes subgroup, but must be counted in one subgroup only in the same meal; and

(E) *Other vegetables.* This subgroup includes all other fresh, frozen, and canned vegetables, cooked or raw, including tomatoes, tomato juice, iceberg lettuce, green beans, and onions.

(iv) *Grains component.* (A) *Enriched or whole grains.* All grains must be enriched or whole grain-rich, or made with enriched or whole grain meal or flour, in accordance with the most recent grains guidance from FNS.

(B) *Daily and weekly servings.* The grains requirement is based on minimum daily servings plus total servings over a five-day school week. Half of the grains offered during the school week must meet the whole grain-rich criteria specified in FNS guidance. Two years post implementation of the final rule all grains offered during the school week must meet the whole grain-rich criteria specified in FNS guidance. The whole grain-rich criteria may be updated to reflect additional information provided voluntarily by industry on the food label or a whole grains definition by the Food and Drug Administration. Schools serving lunch 6 or 7 days per week must increase the weekly grains quantity by approximately 20 percent (1/5th) for each additional day. When schools operate less than 5 days per week, they may decrease the weekly quantity by approximately 20 percent (1/5th) for each day less than five. The servings for biscuits, rolls, muffins, pastas, cereals, and other grains varieties are specified in program guidance.

(C) *Desserts.* Schools may count up to one grain-based dessert per day towards meeting the grains requirement as specified in the Grains/Bread Instruction issued by FNS.

(v) *Fluid milk component.* Fluid milk must be offered daily in accordance with paragraph (d) of this section.

(3) *Food components in outlying areas.* Schools in American Samoa, Puerto Rico and the Virgin Islands may serve vegetables such as yams,

plantains, or sweet potatoes to meet the grains component.

(4) *Adjustments to the school menus.* Schools must adjust future menu cycles to reflect production and how often the food items are offered. Schools may need to change the foods offered given the students' selections and may need to modify the recipes and other specifications to make sure that the meal requirements are met.

(5) *Standardized recipes.* All schools must develop and follow standardized recipes. A standardized recipe is a recipe that was tested to provide an established yield and quantity using the same ingredients for both measurement and preparation methods. Standardized recipes developed by USDA/FNS are in the Child Nutrition Database. If a school has its own recipes, they may seek assistance from the State agency or school food authority to standardize the recipes. Schools must add any local recipes to their local database as outlined in FNS guidance.

(6) *Processed foods.* The Child Nutrition Database includes a number of processed foods. Schools may use purchased processed foods that are not in the Child Nutrition Database. Schools or the State agency must add any locally purchased processed foods to their local database as outlined in FNS guidance. The State agencies must obtain the levels of calories, saturated fat, and sodium in the processed foods.

(7) *Menu substitutions.* Schools should always try to substitute nutritionally similar foods.

(d) *Fluid milk requirement.* (1) *Types of fluid milk.* (i) Schools must offer students a variety of fluid milk. Milk must be fat-free or low-fat. Milk with higher fat content is not allowed. Fat-free fluid milk may be flavored or unflavored, and low-fat fluid milk must be unflavored. Lactose-free fluid milk may also be offered.

(ii) All fluid milk served in the Program must be pasteurized fluid milk which meets State and local standards for such milk. All fluid milk must have vitamins A and D at levels specified by the Food and Drug Administration and must be consistent with State and local standards for such milk.

(2) *Inadequate fluid milk supply.* If a school cannot get a supply of fluid milk, it can still participate in the Program under the following conditions:

(i) If emergency conditions temporarily prevent a school that normally has a supply of fluid milk from obtaining delivery of such milk, the State agency may allow the school to serve meals during the emergency period with an alternate form of fluid milk or without fluid milk.

(ii) If a school is unable to obtain a supply of any type of fluid milk on a continuing basis, the State agency may approve the service of meals without fluid milk if the school uses an equivalent amount of canned milk or dry milk in the preparation of the meals. In Alaska, Hawaii, American Samoa, Guam, Puerto Rico, and the Virgin Islands, if a sufficient supply of fluid milk cannot be obtained, "fluid milk" includes reconstituted or recombined fluid milk, or as otherwise allowed by FNS through a written exception.

(3) *Fluid milk substitutes.* If a school chooses to offer one or more substitutes for fluid milk for non-disabled students with medical or special dietary needs, the nondairy beverage(s) must provide the nutrients listed in the following table. Fluid milk substitutes must be fortified in accordance with fortification guidelines issued by the Food and Drug Administration. A school need only offer the nondairy beverage(s) that it has identified as allowable fluid milk

substitutes according to the following chart.

Nutrient	Per cup (8 fl oz)
Calcium	276 mg.
Protein	8 g.
Vitamin A	500 IU.
Vitamin D	100 IU.
Magnesium	24 mg.
Phosphorus	222 mg.
Potassium	349 mg.
Riboflavin	0.44 mg.
Vitamin B-12	1.1 mcg.

(4) *Restrictions on the sale of fluid milk.* A school participating in the Program, or a person approved by a school participating in the Program, must not directly or indirectly restrict the sale or marketing of fluid milk (as identified in paragraph (d)(1) of this section) at any time or in any place on school premises or at any school-sponsored event.

(e) *Offer versus serve.* School lunches must offer daily the five food components specified in the meal pattern in paragraph (c) of this section. Under offer versus serve, students in senior high (as defined by the State educational agency) must be allowed to decline two items at lunch but must select at least one fruit or vegetable. Students below the senior high level may participate in offer versus serve at the discretion of the school food authority. The price of a reimbursable lunch does not change if the student does not take a food item or requests smaller portions. Schools may not require a student to take the entrée, which is a combination of foods or a single food item that is offered as the main course.

(f) *Dietary specifications.* (1) *Calories.* School lunches offered to each age/grade group must meet, on average over the school week, the minimum and maximum calorie levels specified in the following table:

	Calorie ranges for lunch		
	Grades K-5	Grades 6-8	Grades 9-12
Min-max calories (kcal) ^{a b}	550-650	600-700	750-850

^a The average daily amount for a 5-day school week must fall within the minimum and maximum levels.

^b Discretionary sources of calories (solid fats and added sugars) may be added to the meal pattern if within the specifications for calories, saturated fat, trans fat, and sodium.

(2) *Saturated fat.* School lunches offered to all age/grade groups must, on average over the school week, provide

less than 10 percent of total calories from saturated fat.

(3) *Sodium.* School lunches offered to each age/grade group must meet, on

average over the school week, the levels of sodium specified in the following table:

National School Lunch Program		Sodium Reduction: Timeline & Amount		
Age/Grade Group	Baseline: Average Current Sodium Levels in Meals As Offered ¹ (mg)	Target 1: 2 years post implementation (mg)	Target 2: 4 years post implementation (mg)	Final Target: 10 years post implementation (mg)
K-5	1,377 (elementary)	≤ 1,230	≤ 935	≤ 640
6-8	1,520 (middle)	≤ 1,360	≤ 1,035	≤ 710
9-12	1,588 (high)	≤ 1,420	≤ 1,080	≤ 740

¹SNDA-III

(4) *Trans fat*. Food products and ingredients used to prepare school meals must contain zero grams of *trans fat* (less than 0.5 grams) per serving. Schools must add the *trans fat* specification and request the required documentation (nutrition label or manufacturer specifications) in their procurement contracts. Documentation for food products and food ingredients must indicate zero grams of *trans fat* per serving. Meats that contain a minimal amount of naturally-occurring *trans fats* are allowed in the school meal programs.

(g) *Compliance assistance*. The State agency and school food authority must provide technical assistance and training to assist schools in planning lunches that meet the meal pattern in paragraph (c) of this section and the calorie, saturated fat, sodium, and *trans fat* specifications established in paragraph (f) of this section. Compliance assistance may be offered during annual training, onsite visits, and/or administrative reviews.

(h) *State Agency responsibilities for monitoring dietary specifications*. (1) *Calories, saturated fat and sodium*. As part of the administrative review authorized under § 210.18 of this chapter, State agencies must conduct a nutrient analysis for the school(s) selected for review to evaluate the average levels of calories, saturated fat, and sodium of the lunches offered to students in grades K and above during the review period. The nutrient analysis must be conducted in accordance with the procedures established in paragraph (i)(3) of this section. If the results of the nutrient analysis indicate that the school lunches are not meeting the standards for calories, saturated fat, and sodium specified in paragraph (f) of this section, the State agency or school food authority must provide technical assistance and require the reviewed school to take corrective action to meet the established standards.

(2) *Trans fat*. During the administrative review, State agencies must verify that the food products or ingredients used by the reviewed school(s) contain zero grams of *trans fat* (less than 0.5 grams) per serving.

(i) *State agency's responsibilities for nutrient analyses*. (1) *Conducting the nutrient analyses*. State agencies must conduct a nutrient analysis of the reimbursable meals offered to children in grades K and above by a school selected for administrative review under § 210.18 of this chapter. The nutrient analysis must be conducted in accordance with the procedures established in paragraph (i)(3) of this section. The purpose of the nutrient

analysis is to determine the average levels of calories, saturated fat, and sodium in the meals offered over a school week. Unless offered as part of a reimbursable meal, foods of minimal nutritional value (see appendix B to part 210) are not included in the nutrient analysis.

(2) *Software elements*. (i) *The Child Nutrition Database*. The nutrient analysis is based on the USDA Child Nutrition Database. This database is part of the software used to do a nutrient analysis. Software companies or others developing systems for schools may contact FNS for more information about the database.

(ii) *Software evaluation*. FNS or an FNS designee evaluates any nutrient analysis software before it may be used in schools. FNS or its designee determines if the software, as submitted, meets the minimum requirements. The approval of software does not mean that FNS or USDA endorses it. The software must be able to perform a weighted average analysis after the basic data is entered. The combined analysis of the lunch and breakfast programs is not allowed.

(3) *Nutrient analysis procedures*. (i) *Weighted averages*. State agencies must include all foods offered in the reimbursable meals in the nutrient analysis. Foods items are included based on the portion sizes and projected serving amounts. They are also weighted based on their proportionate contribution to the meals offered. This means that food items offered more frequently are weighted more heavily than those not offered as frequently. State agencies calculate weighting as indicated by FNS guidance and by the guidance provided by the software.

(ii) *Analyzed nutrients*. The analysis determines the average levels of calories, saturated fat, and sodium in the meals offered over a school week. It includes all food items offered by the reviewed school over a two-week period.

(4) *Comparing the results of the nutrient analysis*. Once the procedures in paragraph (i)(3) of this section are completed, State agencies must compare the results of the analysis to the calorie, saturated fat, and sodium levels established in § 210.10 or § 220.8, as appropriate, for each age/grade group to evaluate the school's compliance with the meal requirements.

(j) *State agency's responsibilities for compliance monitoring*. Compliance with the meal requirements in paragraph (b) of this section, including dietary specifications for calories, saturated fat and sodium, will be monitored by the State agency through

administrative reviews authorized in § 210.18 of this chapter.

(k) *Menu choices at lunch*. (1) *Availability of choices*. Schools may offer children a selection of nutritious foods within a reimbursable lunch to encourage the consumption of a variety of foods. Children who are eligible for free or reduced price lunches must be allowed to take any reimbursable lunch or any choices offered as part of a reimbursable lunch. Schools may establish different unit prices for each reimbursable lunch offered provided that the benefits made available to children eligible for free or reduced price lunches are not affected.

(2) *Opportunity to select*. Schools that choose to offer a variety of reimbursable lunches, or provide multiple serving lines, must make all required food components available to all students, on every lunch line, in at least the minimum required amounts.

(l) *Requirements for lunch periods*. (1) *Timing*. Schools must offer lunches meeting the requirements of this section during the period the school has designated as the lunch period. Schools must offer lunches between 10 a.m. and 2 p.m. Schools may request an exemption from these times from the State agency.

(2) *Adequate lunch periods*. FNS encourages schools to provide sufficient lunch periods that are long enough to give all students adequate time to be served and to eat their lunches.

(m) *Exceptions and variations allowed in reimbursable meals*. (1) *Exceptions for disability reasons*. Schools must make substitutions in lunches and afterschool snacks for students who are considered to have a disability under 7 CFR 15b.3 and whose disability restricts their diet. Substitutions must be made on a case by case basis only when supported by a written statement of the need for substitution(s) that includes recommended alternate foods, unless otherwise exempted by FNS. Such statement must be signed by a licensed physician.

(2) *Exceptions for non-disability reasons*. Schools may make substitutions for students without disabilities who cannot consume the regular lunch or afterschool snack because of medical or other special dietary needs. Substitutions must be made on a case by case basis only when supported by a written statement of the need for substitutions that includes recommended alternate foods, unless otherwise exempted by FNS. Except with respect to substitutions for fluid milk, such a statement must be signed by a recognized medical authority.

(i) *Fluid milk substitutions for non-disability reasons.* Schools may make substitutions for fluid milk for non-disabled students who cannot consume fluid milk due to medical or special dietary needs. A school that selects this option may offer the nondairy beverage(s) of its choice, provided the beverage(s) meets the nutritional standards established under paragraph (d) of this section. Expenses incurred when providing substitutions for fluid milk that exceed program reimbursements must be paid by the school food authority.

(ii) *Requisites for fluid milk substitutions.* (A) A school food authority must inform the State agency if any of its schools choose to offer fluid milk substitutes other than for students with disabilities; and

(B) A medical authority or the student's parent or legal guardian must submit a written request for a fluid milk substitute identifying the medical or other special dietary need that restricts the student's diet.

(iii) *Substitution approval.* The approval for fluid milk substitution must remain in effect until the medical authority or the student's parent or legal guardian revokes such request in writing, or until such time as the school changes its substitution policy for nondisabled students.

(3) *Variations for ethnic, religious, or economic reasons.* Schools should consider ethnic and religious preferences when planning and preparing meals. Variations on an experimental or continuing basis in the food components for the meal pattern in paragraph (c) of this section may be allowed by FNS. Any variations must be consistent with the food and nutrition requirements specified under this section and needed to meet ethnic, religious, or economic needs.

(4) *Exceptions for natural disasters.* If there is a natural disaster or other catastrophe, FNS may temporarily allow schools to serve meals for reimbursement that do not meet the requirements in this section.

(n) *Nutrition disclosure.* To the extent that school food authorities identify foods in a menu, or on the serving line or through other communications with program participants, school food authorities must identify products or dishes containing more than 30 parts fully hydrated alternate protein products (as specified in appendix A of this part) to less than 70 parts beef, pork, poultry or seafood on an uncooked basis, in a manner which does not characterize the product or dish solely

as beef, pork, poultry or seafood. Additionally, FNS encourages schools to inform the students, parents, and the public about efforts they are making to meet the meal requirements for school lunches.

(o) *Afterschool snacks.* Eligible schools operating afterschool care programs may be reimbursed for one afterschool snack served to a child (as defined in § 210.2) per day.

(1) Eligible schools mean schools that:

(i) Operate school lunch programs under the Richard B. Russell National School Lunch Act; and
(ii) Sponsor afterschool care programs as defined in § 210.2.

(2) Afterschool snacks shall contain two different components from the following four:

(i) A serving of fluid milk as a beverage, or on cereal, or used in part for each purpose;

(ii) A serving of meat or meat alternate. Nuts and seeds and their butters listed in program guidance are nutritionally comparable to meat or other meat alternates based on available nutritional data. Acorns, chestnuts, and coconuts are excluded and shall not be used as meat alternates due to their low protein content. Nut or seed meals or flours shall not be used as a meat alternate except as allowed under appendix A of this part;

(iii) A serving of vegetable(s) or fruit(s) or full-strength vegetable or fruit juice, or an equivalent quantity of any combination of these foods. All fruits and vegetables are credited based on their volume as served. Juice may not be served when fluid milk is served as the only other component;

(iv) A serving of whole-grain or enriched bread; or an equivalent serving of a bread product, such as cornbread, biscuits, rolls, or muffins made with whole-grain or enriched meal or flour; or a serving of cooked whole-grain or enriched pasta or noodle products such as macaroni, or cereal grains such as enriched rice, bulgur, or enriched corn grits; or an equivalent quantity of any combination of these foods.

(3) Afterschool snacks served to infants ages birth through 11 months must meet the requirements in paragraph (o)(3)(iv) of this section. Foods offered as meal supplements must be of a texture and a consistency that are appropriate for the age of the infant being served. The foods must be served during a span of time consistent with the infant's eating habits. For those infants whose dietary needs are more individualized, exceptions to the meal pattern must be made in accordance

with the requirements found in paragraph (m) of this section.

(i) *Breastmilk and iron-fortified formula.* Either breastmilk or iron-fortified infant formula, or portions of both, must be served for the entire first year. Snacks containing breastmilk and snacks containing iron-fortified infant formula supplied by the school are eligible for reimbursement. However, infant formula provided by a parent (or guardian) and breastmilk fed directly by the infant's mother, during a visit to the school, contribute to a reimbursable snack only when the school supplies at least one component of the infant's snack.

(ii) *Fruit juice.* Juice should not be offered to infants until they are 6 months of age and ready to drink from a cup. Fruit juice served as part of the meal pattern for infants 8 through 11 months must be full-strength and pasteurized.

(iii) *Solid foods.* Solid foods of an appropriate texture and consistency are required only when the infant is developmentally ready to accept them. The school should consult with the infant's parent (or guardian) in making the decision to introduce solid foods. Solid foods should be introduced one at a time, on a gradual basis, with the intent of ensuring the infant's health and nutritional well-being.

(iv) *Infant meal pattern.* Meal supplements for infants must include, at a minimum, breastmilk or iron-fortified infant formula, or portions of both, in the appropriate amount indicated for the infant's age. For some breastfed infants who regularly consume less than the minimum amount of breastmilk per feeding, a serving of less than the minimum amount of breastmilk may be offered. In these situations, additional breastmilk must be offered if the infant is still hungry. Some infants may be developmentally ready to accept an additional food component. Meal supplements are reimbursable when schools provide all of the components in the Supplements for Infants table that the infant is developmentally ready to accept.

(4) The minimum amounts of food components to be served as meal supplements follow. Select two different components from the four listed in the Supplements for Infants table (Juice may not be served when fluid milk is served as the only other component). A serving of bread/bread alternate must be made from whole-grain or enriched meal or flour. It is required only when the infant is developmentally ready to accept it.

SUPPLEMENTS FOR INFANTS

	Birth through 3 months	4 through 7 months	8 through 11 months
Supplement (snack)	4–6 fl. oz. breastmilk ^{1,2} or formula ³ .	4–6 fl. oz. breastmilk ^{1,2} or formula ³ .	2–4 fl. oz. breastmilk ^{1,2} , formula ³ , or fruit juice ⁴ ; 0–1/2 bread ⁵ or 0–2 crackers ⁵

¹ It is recommended that breastmilk be served in place of formula from birth through 11 months.

² For some breastfed infants who regularly consume less than the minimum amount of breastmilk per feeding, a serving of less than the minimum amount of breastmilk may be offered with additional breastmilk offered if the infant is still hungry.

³ Infant formula must be iron-fortified.

⁴ Fruit juice must be full-strength and pasteurized.

⁵ Bread and bread alternates must be made from whole grain or enriched meal or flour. A serving of this component must be optional.

(p) Lunches for preschoolers and infants. (1) *Requirements for preschooler's lunch pattern.* (i) *General.* Until otherwise instructed by the Secretary, lunches for children ages 1 to 4 must meet the nutrition standards in paragraph (p)(2) of this section, the nutrient and calorie levels in paragraph (p)(3) of this section, and meal pattern in paragraph (p)(4) of this section.

(ii) *Unit pricing.* Schools must price each meal as a unit. Schools need to consider participation trends in an effort to provide one reimbursable lunch for each child every day. If there are leftover meals, schools may offer them to the students but cannot receive reimbursement for them.

(iii) *Production and menu records.* Schools must keep production and menu records for the meals they produce. These records must show how the meals contribute to the required food components and quantities every day. In addition, these records must show how the lunches contribute to the nutrition standards in paragraph (p)(2) of this section and the appropriate

calorie and nutrient requirements for the children served. Schools or school food authorities must maintain records of the latest nutritional analysis of the school menus conducted by the State agency.

(2) *Nutrition standards for preschoolers' lunches.* Children ages 1 to 4 must be offered lunches that meet the following nutrition standards for their age group:

(i) Provision of one-third of the Recommended Dietary Allowances (RDAs) for protein, calcium, iron, vitamin A and vitamin C in the appropriate levels for the ages/grades (see paragraph (p)(3) of this section).

(ii) Provision of the lunchtime energy allowances (calories) in the appropriate levels (see paragraph (p)(3) of this section);

(iii) The following dietary recommendations:

(A) Eat a variety of foods;

(B) Limit total fat to 30 percent of total calories;

(C) Limit saturated fat to less than 10 percent of total calories;

(D) Choose a diet low in cholesterol;
 (E) Choose a diet with plenty of grain products, vegetables, and fruits; and
 (F) Choose a diet moderate in salt and sodium.

(iv) The following measures of compliance:

(A) Limit the percent of calories from total fat to 30 percent of the actual number of calories offered;

(B) Limit the percent of calories from saturated fat to less than 10 percent of the actual number of calories offered;

(C) Reduce sodium and cholesterol levels; and

(D) Increase the level of dietary fiber.

(v) Compliance with the nutrition standards and the appropriate nutrient and calorie levels is determined by the State agency in accordance with the procedures in paragraph (p)(10) of this section.

(3) *Nutrient and calorie levels.* The minimum levels of nutrients and calories that lunches for preschoolers must offer are specified in the following table:

Minimum Nutrient and Calorie Levels for Lunches Traditional Food-Based Menu Planning Approach¹	
	Group II Preschool Ages 3-4
Nutrients and Energy Allowances	School Week Averages
Energy allowances (calories)	517
Total fat (as a percentage of actual total food energy)	2
Saturated fat (as a percentage of actual total food energy)	2
RDA for protein (g)	7
RDA for calcium (mg)	267
RDA for iron (mg)	3.3
RDA for Vitamin A (RE)	150
RDA for Vitamin C (mg)	14

¹Current regulations only specify minimum nutrient and calorie levels for lunches for children ages 3-4.

²The 1995 Dietary Guidelines recommend that after 2 years of age "...children should gradually adopt a diet that, by about 5 years of age, contains no more than 30 percent of calories from fat."

(4) *Meal pattern for preschoolers' lunches.* Schools must follow the traditional food-based menu planning

approach to plan lunches for children ages 1–2 and ages 3–4.
(i) *Food components and quantities.* Lunches must offer the food

components and quantities specified in the following meal pattern:
BILLING CODE 3410-30-P

Traditional Food-Based Menu Planning Approach		
Meal Plan for Lunches		
	Group I Ages 1-2 Preschool	Group II Ages 3-4 Preschool
Food Components and Food Items	Minimum Quantities	
Fluid milk (as a beverage)	6 fluid ounces	6 fluid ounces
Meat or Meat Alternates		
Lean meat, poultry, or fish	1 ounce	1 ½ ounces
Alternate Protein Products ¹	1 ounce	1 ½ ounces
Cheese	1 ounce	1 ½ ounces
Large egg	½	¾
Cooked dry beans and peas	¼ cup	⅜ cup
Peanut butter or other nut or seed butters	2 tablespoons	3 tablespoons
Yogurt, plain or flavored, unsweetened or sweetened	4 ounces or ½ cup	6 ounces or ¾ cup
The following may be used to meet no more than 50% of the requirement and must be used in combination with any of the above: Peanuts, soy nuts, tree nuts, or seeds, as listed in program guidance, or an equivalent quantity of any combination of the above meat/meat alternate (1 ounce of nuts/seeds = 1 ounce of cooked lean meat, poultry or fish)	½ ounce = 50%	¾ ounce = 50%
Vegetable or Fruit: 2 or more servings of vegetables, fruits or both	½ cup	½ cup
Grains/Breads (servings per week): Must be enriched or whole grain. A serving is a slice of bread or an equivalent serving of biscuits, rolls, <i>etc.</i> , or ½ cup of cooked rice, macaroni, noodles, other pasta products or cereal grains	5 servings per week ² – minimum of ½ serving per day	8 servings per week ² – minimum of 1 serving per day

¹Must meet the requirements in appendix A of this part.

²For the purposes of this table, a week equals five days.

BILLING CODE 3410-30-C

(ii) *Meat/meat alternate component.* The quantity of the meat/meat alternate component must be the edible portion as served. If the portion size of a food item for this component is excessive, the school must reduce that portion and supplement it with another meat/meat alternate to meet the full requirement. This component must be served in a main dish or in a main dish and only one other food item. Schools without daily choices in this component should not serve any one meat alternate or form of meat (for example, ground, diced,

pieces) more than three times in the same week. Schools may adjust the daily quantities of this component provided that a minimum of one ounce is offered daily and the total weekly requirement is met over a five-day period.

(A) *Enriched macaroni.* Enriched macaroni with fortified protein as defined in appendix A to this part may be used to meet part of the meat/meat alternate requirement when used as specified in appendix A to this part. An enriched macaroni product with fortified protein as defined in appendix

A to this part may be used to meet part of the meat/meat alternate component or the grains/breads component but not as both food components in the same lunch.

(B) *Nuts and seeds.* Nuts and seeds and their butters are allowed as meat alternates in accordance with program guidance. Acorns, chestnuts, and coconuts must not be used because of their low protein and iron content. Nut and seed meals or flours may be used only as allowed under appendix A to this part. Nuts or seeds may be used to meet no more than one-half of the meat/

meat alternate component with another meat/meat alternate to meet the full requirement.

(C) *Yogurt*. Yogurt may be used to meet all or part of the meat/meat alternate requirement. Yogurt may be plain or flavored, and unsweetened or sweetened. Noncommercial and/or non-standardized yogurt products, such as frozen yogurt, homemade yogurt, yogurt flavored products, yogurt bars, yogurt covered fruit and/or nuts or similar products are not creditable. Four ounces (weight) or ½ cup (volume) of yogurt equals one ounce of the meat/meat alternate requirement.

(iii) *Vegetable/fruit component*. Full strength vegetable or fruit juice may be used to meet no more than one-half of the vegetable/fruit requirement. Cooked dry beans or peas may be counted as either a vegetable or as a meat alternate but not as both in the same meal.

(iv) *Grains/breads component*. (A) *Enriched or whole grains*. All grains/breads must be enriched or whole grain or made with enriched or whole grain meal or flour.

(B) *Daily and weekly servings*. The requirement for the grain/bread component is based on minimum daily servings plus total servings over a five day period. Schools serving lunch 6 or 7 days per week should increase the weekly quantity by approximately 20 percent (1/5th) for each additional day. When schools operate less than 5 days per week, they may decrease the weekly quantity by approximately 20 percent (1/5th) for each day less than five. The servings for biscuits, rolls, muffins, and other grain/bread varieties are specified in the Food Buying Guide for Child Nutrition Programs (PA 1331), an FNS publication.

(C) *Minimums under the traditional food-based menu planning approach*. Schools must offer daily at least one-half serving of the grain/bread component to children in Group I and at least one serving to children in Group II. Schools which serve lunch at least 5 days a week shall serve a total of at least five servings of grains/breads to children in Group I and eight servings per week to children in Group II.

(D) *Offer versus serve*. Schools must offer all five required food items. At the school food authority's option, students in preschool may decline one or two of the five food items. The price of a reimbursable lunch does not change if the student does not take a food item or requests smaller portions.

(E) *Meal pattern exceptions for outlying areas*. Schools in American Samoa, Puerto Rico and the Virgin Islands may serve a starchy vegetable such as yams, plantains, or sweet

potatoes to meet the grain/bread requirement.

(5) *Fluid milk requirement*. Schools must offer students in age group 1–2 years and age group 3–4 years fluid milk in a variety of fat contents. Schools may offer flavored or unflavored fluid milk and lactose-free fluid milk. All fluid milk served must be pasteurized fluid milk which meets State and local standards for such milk. All fluid milk must have vitamins A and D at levels specified by the Food and Drug Administration and must be consistent with State and local standards for such milk. Schools must also comply with other applicable milk requirements in § 210.10(d)(2), § 210.10(d)(3), and § 210.10(d)(4) of this part.

(6) *Menu choices*. FNS encourages schools to offer children a selection of foods at lunch. Choices provide variety and encourage consumption. Schools may offer choices of reimbursable lunches or foods within a reimbursable lunch. Children who are eligible for free or reduced price lunches must be allowed to take any reimbursable lunch or any choices offered as part of a reimbursable lunch. Schools may establish different unit prices for each lunch offered provided that the benefits made available to children eligible for free or reduced price lunches are not affected.

(7) *Requirements for lunch periods*. (i) *Timing*. Schools must offer lunches meeting the requirements of this section during the period the school has designated as the lunch period. Schools must offer lunches between 10 a.m. and 2 p.m. Schools may request an exemption from these times only from FNS.

(ii) *Lunch periods for young children*. With State agency approval, schools are encouraged to serve children ages 1 through 4 over two service periods. Schools may divide the quantities and/or the menu items, foods, or food items offered each time any way they wish.

(iii) *Adequate lunch periods*. FNS encourages schools to provide sufficient lunch periods that are long enough to give all students enough time to be served and to eat their lunches.

(8) *Exceptions and variations allowed in reimbursable meals*. Schools must comply with the requirements in § 210.10(m) of this part.

(9) *Nutrition disclosure*. If applicable, schools must follow the provisions on disclosure of Alternate Protein Products in § 210.10(n) of this part.

(10) *State agency's responsibilities for monitoring lunches*. As part of the administrative review authorized under § 210.18(g)(2) of this chapter, State agencies must evaluate compliance with

the meal pattern requirements (food components and quantities) in paragraph (d) of this section. If the meals for preschoolers do not meet the requirements of this section, the State agency or school food authority must provide technical assistance and require the reviewed school to take corrective action. In addition, the State agency may take fiscal action as authorized in § 210.18(m) and § 210.19(c) of this part.

(11) *Requirements for the infant lunch pattern*. (i) *Definitions*. (A) *Infant cereal* means any iron-fortified dry cereal, specially formulated and generally recognized as cereal for infants, that is routinely mixed with breastmilk or iron-fortified infant formula prior to consumption.

(B) *Infant formula* means any iron-fortified formula intended for dietary use solely as a food for normal, healthy infants. Formulas specifically formulated for infants with inborn errors of metabolism or digestive or absorptive problems are not included in this definition. Infant formula, when served, must be in liquid state at recommended dilution.

(ii) *Feeding lunches to infants*. Lunches served to infants ages birth through 11 months must meet the requirements in paragraph (k)(5) of this section. Foods included in the lunch must be of a texture and a consistency that are appropriate for the age of the infant being served. The foods must be served during a span of time consistent with the infant's eating habits. For those infants whose dietary needs are more individualized, exceptions to the meal pattern must be made in accordance with the requirements found in § 210.10(m) of this part.

(iii) *Breastmilk and iron-fortified formula*. Either breastmilk or iron-fortified infant formula, or portions of both, must be served for the entire first year. Meals containing breastmilk and meals containing iron-fortified infant formula supplied by the school are eligible for reimbursement. However, infant formula provided by a parent (or guardian) and breastmilk fed directly by the infant's mother, during a visit to the school, contribute to a reimbursable lunch only when the school supplies at least one component of the infant's meal.

(iv) *Solid foods*. For infants ages 4 through 7 months, solid foods of an appropriate texture and consistency are required only when the infant is developmentally ready to accept them. The school should consult with the infant's parent (or guardian) in making the decision to introduce solid foods. Solid foods should be introduced one at a time, on a gradual basis, with the

intent of ensuring the infant's health and nutritional well-being.

(v) *Infant meal pattern.* Infant lunches must include, at a minimum, each of the food components indicated in Lunch Pattern for Infants table in the amount that is appropriate for the infant's age. For some breastfed infants who regularly consume less than the

minimum amount of breastmilk per feeding, a serving of less than the minimum amount of breastmilk may be offered. In these situations, additional breastmilk must be offered if the infant is still hungry. Lunches may include portions of breastmilk and iron-fortified infant formula as long as the total number of ounces meets, or exceeds, the

minimum amount required of this food component. Similarly, to meet the component requirements for vegetables and fruits, portions of both may be served. Infant lunches are reimbursable when schools provide all of the components in the Lunch Pattern for Infants table that the infant is developmentally ready to accept.

Lunch Pattern for Infants		
Birth through 3 months	4 through 7 months	8 through 11 months
4-6 fluid ounces of formula ¹ or breastmilk ^{2,3}	4-8 fluid ounces of formula ¹ or breastmilk ^{2,3} ; and 0-3 tablespoons of infant cereal ^{1,4} ; and 0-3 tablespoons of fruits or vegetables or both ⁴ .	6-8 fluid ounces of formula ¹ or breastmilk ^{2,3} ; and 2-4 tablespoons of infant cereal ¹ ; and/or 1-4 tablespoons of meat, fish, poultry, egg yolk, cooked dry beans or peas; or ½ - 2 ounces of cheese, or 1-4 ounces (volume) of cottage cheese; or 1-4 ounces (weight) of cheese food or cheese spread; and 1-4 tablespoons of fruits or vegetables or both.

¹Infant formula and dry infant cereal must be iron-fortified.

²Breastmilk or formula, or portions of both, may be served; however, it is recommended that breastmilk be served in place of formula from birth through 11 months.

³For some breastfed infants who regularly consume less than the minimum amount of breastmilk per feeding, a serving of less than the minimum amount of breastmilk may be offered, with additional breastmilk offered if the infant is still hungry.

⁴A serving of this component is required only when the infant is developmentally ready to accept it.

5. In § 210.18:

a. Revise paragraphs (a), (b)(2)(ii), (c), (g)(2), (i)(3)(ii), and (m); and

b. Remove paragraph (h)(2) and redesignate paragraph (h)(3), (h)(4), (h)(5), and (h)(6) as paragraphs (h)(2), (h)(3), (h)(4), and (h)(5).

The revisions read as follows:

§ 210.18 Administrative reviews.

(a) *General.* Each State agency must follow the requirements of this section to conduct administrative reviews of school food authorities serving meals under parts 210 and 220 of this chapter.

(b) * * *

(2) * * *

(i) * * *

(ii) *Performance Standard 2—Meal Requirements.* Reimbursable lunches meet the meal requirements in § 210.10 of this chapter, as applicable to the age/grade group reviewed. Reimbursable

breakfasts meet the meal requirements in § 220.8 of this chapter, as applicable to the age/grade group reviewed.

* * * * *

(c) *Timing of reviews.* State agencies must conduct administrative reviews of all school food authorities participating in the NSLP and/or SBP at least once during a 3-year review cycle. For each State agency, the first 3-year review cycle will start the school year that begins on July 1, 2012 and ends on June 30, 2013. Administrative reviews and follow-up reviews must be conducted as follows:

(1) *Administrative reviews.* At a minimum, State agencies must conduct administrative reviews of all school food authorities at least once during each 3-year review cycle, provided that each school food authority is reviewed at least once every 4 years. The on-site portion of the administrative review

must be completed during the school year in which the review was begun.

(2) *Exceptions.* FNS may, on an individual school food authority basis, approve written requests for 1-year extensions to the 3-year review cycle specified in paragraph (c)(1) of this section if FNS determines this 3-year cycle requirement conflicts with efficient State agency management of the Programs.

(3) *Follow-up reviews.* The State agency is encouraged to conduct first follow-up reviews in the same school year as the administrative review. The first follow-up review must be conducted no later than December 31 of the school year following the administrative review. Subsequent follow-up reviews must be scheduled in accordance with paragraph (i)(5) of this section.

* * * * *

(g) * * *

(2) *Performance Standard 2* (Reimbursable lunches meet the meal requirements in § 210.10 of this chapter, as applicable to the age/grade group reviewed. Reimbursable breakfasts meet the meal requirements in § 220.8 of this chapter, as applicable to the age/grade group reviewed). When reviewing meals, the State agency must:

(i) For the day of the review, observe the serving line(s) to determine whether all food components and food quantities required under § 210.10, as applicable, and § 220.8, as applicable, are offered.

(ii) For the day of the review, observe a significant number of the Program meals counted at the point of service for each type of serving line to determine whether the meals selected by the students contain the food components and food quantities required for a reimbursable meal under § 210.10, as applicable, and § 220.8, as applicable. If visual observation suggests that quantities offered are insufficient or excessive, the State agency must require the reviewed school(s) to provide documentation demonstrating that the required amounts of each food component were available for service for each day of the review period.

(iii) Review menu and production records for a minimum of ten operating days (specified by the State agency); such review must determine whether all food components and food quantities required under § 210.10, as applicable, and § 220.8, as applicable, of this chapter have been offered.

(iv) Conduct a nutrient analysis of the meals for students in age/grade groups K and above to determine whether the meals offered meet the calorie, sodium, and saturated fat requirements in § 210.10 and § 220.8 of this chapter, as applicable. The State agency must conduct the nutrient analysis in accordance with the procedures established in § 210.10(i) of this part. Until instructed by the Secretary, a nutrient analysis for the meals offered to preschoolers is not required. The State agency must also review nutrition labeling or manufacturer specifications for products or ingredients used to prepare school meals to verify they contain zero grams (less than 0.5 grams) of *trans* fat per serving.

* * * * *

(i) * * *

(3) * * *

(ii) For Performance Standard 2—10 percent or more of the total number of Program lunches or Program breakfasts observed in a school food authority are missing one or more of the food

components required under parts 210 and 220.

* * * * *

(m) *Fiscal action*. Fiscal action for violations identified during an administrative review or any follow-up reviews must be taken in accordance with the provisions in § 210.19(c) of this part.

(1) *Performance Standard I violations*. A State agency is required to take fiscal action for all violations of the critical areas of Performance Standard 1. The State agency may limit fiscal action from the point corrective action occurs back through the beginning of the review period for errors identified under paragraphs (g)(1)(i)(A), (g)(1)(i)(B) and (g)(1)(i)(C) of this section, provided corrective action occurs.

(2) *Performance Standard 2 violations*. A State agency is required to take fiscal action for violations of the critical areas of Performance Standard 2 as follows:

(i) For food component violations cited under paragraph (g)(2) of this section, the State agency must take fiscal action and require the school food authority and/or school reviewed to take corrective action for the missing component. If a corrective action plan is in place, the State agency may limit fiscal action from the point corrective action occurs back through the beginning of the review period for errors identified under paragraph (g)(2) of this section.

(ii) For repeated violations involving vegetable subgroups and milk type cited under paragraph (g)(2) of this section, the State agency must take fiscal action provided that:

(A) Technical assistance has been given by the State agency;

(B) Corrective action has been previously required and monitored by the State agency; and

(C) The school food authority remains in noncompliance with the meal requirements established in parts 210 and 220 of this chapter.

(iii) For violations involving food quantities and whole grains cited under paragraph (g)(2) of this section and for violations of calorie, saturated fat, sodium, and *trans* fat requirements cited under paragraph (g)(2)(iv) of this section, the State agency has discretion to apply fiscal action provided that:

(A) Technical assistance has been given by the State agency;

(B) Corrective action has been previously required and monitored by the State agency; and

(C) The school food authority remains in noncompliance with the meal

requirements established in parts 210 and 220 of this chapter.

* * * * *

6. In § 210.19:

a. Remove paragraphs (a)(1) and redesignate paragraphs (a)(2), (a)(3), (a)(4), (a)(5), and (a)(6) as paragraph (a)(1), (a)(2), (a)(3), (a)(4), (a)(5); and

b. Revise paragraphs (c) introductory text, (c)(1) and (c)(6) to read as follows:

§ 210.19 Additional responsibilities.

* * * * *

(c) *Fiscal action*. State agencies are responsible for ensuring Program integrity at the school food authority level. State agencies must take fiscal action against school food authorities for Claims for Reimbursement that are not properly payable, including, if warranted, the disallowance of funds for failure to take corrective action to comply with the meal requirements in parts 210 and 220 of this chapter. In taking fiscal action, State agencies must use their own procedures within the constraints of this Part and must maintain all records pertaining to action taken under this section. The State agency may refer to FNS for assistance in making a claim determination under this part.

(1) *Definition*. Fiscal action includes, but is not limited to, the recovery of overpayment through direct assessment or offset of future claims, disallowance of overclaims as reflected in unpaid Claims for Reimbursement, submission of a revised Claim for Reimbursement, and correction of records to ensure that unfiled Claims for Reimbursement are corrected when filed. Fiscal action also includes disallowance of funds for failure to take corrective action to meet the meal requirements in Parts 210 and 220 of this chapter.

* * * * *

(6) *Exceptions*. The State agency need not disallow payment or collect an overpayment when any review or audit reveals that a school food authority is approving applications which indicate that the households' incomes are within the Income Eligibility Guidelines issued by the Department or the applications contain Supplemental Nutrition Assistance Program or TANF case numbers or FDPPIR case numbers or other FDPPIR identifiers but the applications are missing the information specified in paragraph (1)(ii) of the definition of *Documentation* in § 245.2 of this chapter.

* * * * *

§ 210.21 [Amended]

7. In § 210.21, amend paragraph (e) by removing the phrase "paragraph

(m)(1)(ii) of this section” and adding in its place the phrase “§ 210.10(d)(4) of this chapter.”

8. Revise § 210.30 to read as follows:

§ 210.30 State agency and Regional office addresses.

School food authorities and schools desiring information about the Program should contact their State educational agency or the appropriate FNS Regional Office at the address or telephone number listed on the FNS Web site (<http://www.fns.usda.gov/cnd>).

9. In Appendix B to part 210:

a. Amend paragraph (b)(1) by removing from the fourth sentence the words “, and the public by notice in the Federal Register as indicated below under paragraph (b)(3) of this section;”

b. Amend paragraph (b)(2) by removing the words “as indicated under paragraph (b)(3) of this section” from the last sentence.

c. Remove paragraph (b)(3) and redesignate paragraph (b)(4) as paragraph (b)(3); and

d. Revise the first sentence of newly redesignated paragraph (b)(3) to read as follows:

* * * * *

Appendix B to Part 210—Categories of Foods of Minimal Nutritional Value.

(b) * * *

(3) Written petitions should be sent to the Chief, Nutrition Promotion and Training Branch, Child Nutrition Division, FNS, USDA, 3101 Park Center Drive, Room 632, Alexandria, Virginia 22302.* * *

* * * * *

PART 220—SCHOOL BREAKFAST PROGRAM

10. The authority citation for 7 CFR part 220 continues to read as follows:

Authority: 42 U.S.C. 1773, 1779.

11. In § 220.2:

a. Amend the definition of *Breakfast* by removing the word “nutritional” and adding in its place the word “meal”,

b. Remove the definition of *Menu item* and the definition of *Nutrient*

Standard Menu Planning/Assisted Nutrient Standard Menu Planning;

c. Revise the definition of *School week*; and

d. Add the definition of *Whole grains* and placing the definition in alphabetical order.

The revisions and additions read as follows:

§ 220.2 Definitions.

* * * * *

School week means the period of time used to determine compliance with the meal requirements in § 220.8. The period must be a normal school week of five consecutive days; however, to accommodate shortened weeks resulting from holidays and other scheduling needs, the period must be a minimum of three consecutive days and a maximum of seven consecutive days. Weeks in which school breakfasts are offered less than three times must be combined with either the previous or the coming week.

* * * * *

Whole grains means grains that consist of the intact, ground, cracked, or flaked grain seed whose principal anatomical components—the starchy endosperm, germ and bran—are present in the same relative proportions as they exist in the intact grain seed. Whole grain-rich products must conform to FNS guidance to count toward the grains component.

* * * * *

12. Revise § 220.8 to read as follows:

§ 220.8 Meal requirements for breakfasts.

(a) *General.* School food authorities must ensure that participating schools provide nutritious, well-balanced, and age-appropriate breakfasts to all the children they serve to improve their diet and safeguard their health. School breakfasts offered to children age 5 and older must meet, at a minimum, the meal requirements in paragraph (b) of this section. Schools must follow a food-based menu planning approach and produce enough food to offer each child

the quantities specified in the meal pattern established in paragraph (c) of this section for each age/grade group served in the school. In addition, school breakfasts must meet the dietary specifications in paragraph (f) of this section. Schools offering breakfasts to children ages 1 to 4 and infants must meet the meal pattern requirements in paragraph (n) of this section.

(b) *Meal requirements for school breakfasts.* School breakfasts for children ages 5 and older must reflect food and nutrition requirements specified by the Secretary. Compliance with these requirements is measured as follows:

(1) On a daily basis:

(i) Meals offered to each age/grade group must include the food components and food quantities specified in the meal pattern in paragraph (c) of this section;

(ii) Food products or ingredients used to prepare meals must contain zero grams of *trans* fat per serving or a minimal amount of naturally-occurring *trans* fat; and

(iii) Meals selected by each student must have the number of food components required for a reimbursable meal and include at least one fruit or vegetable.

(2) Over a 5-day school week:

(i) Average calorie content of the meals offered to each age/grade group must be within the minimum and maximum calorie levels specified in paragraph (f) of this section;

(ii) Average saturated fat content of the meals offered to each age/grade group must be less than 10 percent of total calories;

(iii) Average sodium content of the meals offered to each age/grade group must not exceed the maximum level specified in paragraph (f) of this section.

(c) *Meal pattern for school breakfasts.* A school must offer the food components and quantities required in the breakfast meal pattern established in the following table:

Meal Pattern	School Breakfast Program		
	Grades K-5	Grades 6-8	Grades 9-12
	Amount of Food ^a Per Week (Minimum Per Day)		
Fruits (cups) ^b	5 (1)	5 (1)	5 (1)
Vegetables (cups) ^{bc}	0	0	0
Dark green	0	0	0
Orange	0	0	0
Legumes	0	0	0
Starchy	0	0	0
Other	0	0	0
Grains ^d (oz eq)	7-10 (1)	8-10 (1)	9-10 (1)
Meats/Meat Alternates (oz eq)	5 (1)	5 (1)	7-10 (1)
Fluid milk ^e (cups)	5 (1)	5 (1)	5 (1)
Other Specifications: Daily Amount Based on the Average for a 5-Day Week			
Min-max calories (kcal) ^{fg}	350-500	400-550	450-600
Saturated fat (% of total calories) ^f	< 10	< 10	< 10
Sodium (mg) ^h	≤ 430	≤ 470	≤ 500
<u>Trans</u> fat	Nutrition label or manufacturer specifications must indicate zero grams of <u>trans</u> fat per serving.		

^aFood items included in each group and subgroup and amount equivalents. Minimum serving is 1/8 cup.

^bOne cup of fruits and vegetables usually provides 2 servings; 1/4 cup of dried fruit counts as 1/2 cup of fruit; 1 cup of leafy greens counts as 1/2 cup of vegetables. No more than half of the fruit offerings may be in the form of juice. All juice must be pasteurized, 100% full-strength.

^cFor breakfast, 1/2 cup of non-starchy vegetables may be considered equivalent to 1/2 cup fruits.

^dUpon implementation, at least half of grains offered must be whole grain-rich. Aiming for a higher proportion of whole grain-rich foods is encouraged. Two years post implementation, all grains must be whole grain-rich.

^eFluid milk must be low-fat (1% milk fat or less, unflavored) or fat-free (unflavored or flavored).

^fThe average daily amount for a 5-day school week must fall within the minimum and maximum levels.

^gDiscretionary sources of calories (solid fats and added sugars) may be added to the meal pattern if within the specifications for calories, saturated fat, trans fat, and sodium.

^h Sodium targets are to be reached 10 years after implementation of the final rule. Intermediate targets have been established to ensure that action to reduce the sodium content of school meals over the 10-year period maintains student participation rates.

(1) *Age/grade groups.* Schools must plan menus for students using the following age/grade groups: Grades K–5 (ages 5–10), grades 6–8 (ages 11–13), and grades 9–12 (ages 14–18). If an unusual grade configuration in a school prevents the use of the established age/grade groups, students in grades K–5 and grades 6–8 may be offered the same food quantities at breakfast provided that the calorie and sodium standards for each age/grade group are met. No customization of the established age/grade groups is allowed.

(2) *Food components.* Schools must offer students in each age/grade group the food components specified in meal pattern in paragraph (c). Food component descriptions in § 210.10 of this chapter apply to this Program. A serving of non-starchy vegetables may

be offered in place of fruits at breakfast. Only pasteurized full-strength fruit and vegetable juice may be used, and may be credited to meet no more than one-half of the fruits component.

(3) *Food components in outlying areas.* Schools in American Samoa, Puerto Rico and the Virgin Islands may serve a vegetable such as yams, plantains, or sweet potatoes to meet the grains component.

(4) *Production and menu records.* Schools or school food authorities, as applicable, must keep production and menu records for the meals they produce. These records must show how the meals offered contribute to the required food components and food quantities for each age/grade group every day. Labels or manufacturer specifications for food products and

ingredients used to prepare school meals must indicate zero grams of trans fat per serving (less than 0.5 grams). Schools or school food authorities must maintain records of the latest nutritional analysis of the school menus conducted by the State agency. Production and menu records must be maintained in accordance with FNS guidance.

(d) *Fluid milk requirement.* A serving of fluid milk as a beverage or on cereal or used in part for each purpose must be offered for breakfasts. Schools must offer students a variety of fluid milk. Milk must be fat-free or low-fat. Milk with higher fat content is not allowed. Fat-free fluid milk may be flavored or unflavored, and low-fat fluid milk must be unflavored. Lactose-free fluid milk may also be offered. Schools must also comply with other applicable fluid milk

requirements in § 210.10(d)(1), § 210.10(d)(2), § 210.10(d)(3), and § 210.10(d)(4) of this chapter.

(e) *Offer versus serve.* School breakfasts must offer daily the four food components specified in the meal pattern in paragraph (c) of this section. At the option of the school food authority, each school may allow

students to decline food items they do not intend to consume. Under offer versus serve, the student may decline one item at breakfast but must select at least one fruit serving, or one vegetable serving (if a vegetable is offered in place of fruit). The price of a reimbursable breakfast does not change if a student

does not take a food item or requests smaller portions.

(f) *Dietary specifications.* (1) *Calories.* School breakfasts offered to each age/grade group must meet, on average over the school week, the minimum and maximum calorie levels specified in the following table:

CALORIE RANGES FOR BREAKFAST

	Grades K–5	Grades 6–8	Grades 9–12
Minimum-maximum calories (kcal) ^{a b}	350–500	400–550	450–600

^a The average daily amount for a 5-day school must fall within the minimum and maximum levels.

^b Discretionary sources of calories (solid fats and added sugars) may be added to the meal pattern if within the specifications for calories, saturated fat, *trans* fat, and sodium.

(2) *Saturated fat.* School breakfasts offered to all age/grade groups must, on average over the school week, provide

less than 10 percent of total calories from saturated fat.

(3) *Sodium.* School breakfasts offered to each age/grade group must meet, on

average over the school week, the levels of sodium specified in the following table:

Age/Grade Group	Baseline: Average Current Sodium Levels As Offered ¹ (mg)	Sodium Reduction: Timeline & Amount		
		Target 1: 2 years post implementation (mg)	Target 2: 4 years post implementation (mg)	Final Target: 10 years post implementation (mg)
School Breakfast Program				
K-5	573 (elementary)	≤ 540	≤ 485	≤ 430
6-8	629 (middle)	≤ 600	≤ 535	≤ 470
9-12	686 (high)	≤ 640	≤ 570	≤ 500

¹SNDA-III

(4) *Trans fat.* Food products and ingredients used to prepare school meals must contain zero grams of *trans* fat (less than 0.5 grams) per serving. Schools must add the *trans* fat specification and request the required documentation (nutrition label or manufacturer specifications) in their procurement contracts. Documentation for food products and food ingredients must indicate zero grams of *trans* fat per serving. Meats that contain a minimal amount of naturally-occurring *trans* fats are allowed in the school meal programs.

(g) *Compliance assistance.* The State agency and school food authority must provide technical assistance and training to assist schools in planning

breakfasts that meet the meal pattern in paragraph (c) of this section and the calorie, saturated fat, sodium, and *trans* fat specifications established in paragraph (f) of this section. Compliance assistance may be offered during annual training, onsite visits, and/or administrative reviews.

(h) *State Agency responsibilities for monitoring dietary specifications.* (1) *Calories, saturated fat, and sodium.* As part of the administrative review authorized under § 210.18 of this chapter, State agencies must conduct a nutrient analysis for the school(s) selected for review to evaluate the average levels of calories, saturated fat, and sodium of the breakfasts offered during the review period. The nutrient

analysis must be conducted in accordance with the procedures established in section 210.10(i) of this chapter. State agencies must also review nutrition labeling or manufacturer specifications for products or ingredients used to prepare school meals to verify they contain zero grams of *trans* fat per serving. If the results of the review indicate that the school breakfasts are not meeting the standards for calories, saturated fat, sodium, or *trans* fat levels specified in paragraph (f) of this section, the State agency or school food authority must provide technical assistance and require the reviewed school to develop a corrective action plan.

(2) *Trans fat*. During an administrative review, State agencies must verify that the food products or ingredients used by the reviewed school(s) contain zero grams of *trans fat* (less than 0.5 grams) per serving.

(i) *State agency responsibilities for nutrient analysis*. State agencies must conduct a nutrient analysis of all foods offered in a reimbursable breakfast by a school selected for administrative review to determine the average levels of calories, saturated fat, and sodium in the meals offered over a school week. The analysis must be conducted in accordance with the procedures established in § 210.10(i) of this chapter.

(j) *State agency's responsibilities for compliance monitoring*. Compliance with the meal requirements in paragraph (b) will be monitored by the State agency through administrative reviews authorized in § 210.18 of this chapter.

(k) *Menu choices at breakfast*. The requirements in § 210.10(k) of this chapter apply to this Program.

(l) *Exceptions and variations allowed in reimbursable meals*. The requirements in § 210.10(m) of this chapter apply to this Program.

(m) *Nutrition disclosure*. The requirements in § 210.10(n) of this chapter apply to this Program.

(n) *Breakfasts for preschoolers and infants*. (1) *Nutrition standards for breakfasts for children age 1 to 4*. Until otherwise instructed by the Secretary, breakfasts for preschoolers, when averaged over a school week, must meet the nutrition standards and the appropriate nutrient and calorie levels in this section. The nutrition standards are:

(i) Provision of one-fourth of the Recommended Dietary Allowances (RDA) for protein, calcium, iron, vitamin A and vitamin C in the appropriate levels (*see* paragraph (n)(2) of this section);

(ii) Provision of the breakfast energy allowances (calories) for children in the appropriate levels (*see* paragraph (n)(2) of this section);

(iii) The following dietary recommendations:

- (A) Eat a variety of foods;
- (B) Limit total fat to 30 percent of total calories;
- (C) Limit saturated fat to less than 10 percent of total calories;
- (D) Choose a diet low in cholesterol;
- (E) Choose a diet with plenty of grain products, vegetables, and fruits; and
- (F) Choose a diet moderate in salt and sodium.

(iv) The following measures of compliance:

(A) Limit the percent of calories from total fat to 30 percent of the actual number of calories offered;

(B) Limit the percent of calories from saturated fat to less than 10 percent of the actual number of calories offered;

(C) Reduce sodium and cholesterol levels; and

(D) Increase the level of dietary fiber.

(v) School food authorities must follow the traditional food-based menu planning approach to plan breakfasts for preschoolers and provide daily the food components and quantities specified in paragraph (n)(3) of this section.

(vi) Schools must keep production and menu records for the breakfasts they produce. These records must show how the breakfasts contribute to the required food components and food quantities every school day. In addition, these records must show how the breakfasts contribute to the nutrition standards in paragraph (n)(1) of this section and the appropriate calorie and nutrient levels in paragraph (n)(2) of this section over the school week. Schools or school food authorities must maintain records of the latest nutritional analysis of the school menus conducted by the State agency.

(2) *Nutrient and calorie levels for breakfasts for preschoolers*. Under the traditional food-based menu planning approach, the required levels are:

Minimum Nutrient and Calorie Levels for School Breakfasts		
Traditional Food-Based Menu Planning Approach		
	Age 2¹	Ages 3-4
Nutrients and Energy Allowances	School Week Averages	
Energy allowances (calories)	325	388
Total fat (as a percentage of actual total food energy)	2	2
Saturated fat (as a percentage of actual total food energy)	2	2
RDA for protein (g)	4	5
RDA for calcium (mg)	200	200
RDA for iron (mg)	2.5	2.5
RDA for Vitamin A (RE)	100	113
RDA for Vitamin C (mg)	10	11

¹Nutrient and calorie levels start at age 2 because the "Dietary Guidelines for Americans" apply to ages 2 and older.

²The 1995 "Dietary Guidelines for Americans" recommend that after 2 years of age "children should gradually adopt a diet that, by about 5 years of age, contains no more than 30 percent of calories from fat."

(3) *Meal pattern for preschoolers*. (i) *Food items*. Schools must offer these food items in at least the portions required for each age group:

(A) A serving of fluid milk as a beverage or on cereal or used partly for both;

(B) A serving of fruit or vegetable or both, or full-strength fruit or vegetable juice; and

(C) Two servings from one of the following components or one serving from each component:

(1) Grains/breads; and/or

(2) Meat/meat alternate.

(ii) *Quantities for the traditional food-based menu planning approach.* At a minimum, schools must offer the food items in the quantities specified for the appropriate age/grade group in the following table:

Traditional Food-Based Menu Planning Approach		
Meal Plan for Breakfasts		
	Ages 1-2	Ages 3-4
Food Components and Food Items	School Week Averages	
Fluid milk (as a beverage, on cereal, or both)	4 fluid ounces	6 fluid ounces
Juice/Fruit/Vegetable: Fruit and/or vegetable; or full-strength fruit or vegetable juice	¼ cup	½ cup
Select one serving from each of the following components, two from one component, or an equivalent combination:		
Grains/Breads		
Whole grain or enriched bread	½ slice	½ slice
Whole grain or enriched bread product, such as biscuit, roll, muffin	½ serving	½ serving
Whole grain, enriched or fortified cereal	¼ cup or ⅓ ounce	⅓ cup or ½ ounce
Meat or Meat Alternates		
Meat/poultry or fish	½ ounce	½ ounce
Alternate protein products ¹	½ ounce	½ ounce
Cheese	½ ounce	½ ounce
Large egg	½	½
Peanut butter or other nut or seed butters	1 tablespoon	1 tablespoon
Cooked dry beans and peas	2 tablespoons	2 tablespoons
Nuts and/or seeds (as listed in program guidance) ²	½ ounce	½ ounce
Yogurt, plain or flavored, unsweetened or sweetened	2 ounces or ¼ cup	2 ounces or ¼ cup

¹Must meet the requirements in appendix A of this part.

²No more than 1 ounce of nuts and/or seeds may be served in any one breakfast.

(iii) *Offer versus serve.* Schools must offer all four required food items. At the school food authority's option, students in preschool may decline one of the four food items. The price of a reimbursable breakfast does not change if the student does not take a menu item or requests smaller portions.

(iv) *Exceptions and variations allowed in reimbursable breakfasts.* Schools must follow the requirements in § 210.10(m) of this chapter.

(4) *Fluid milk requirement.* A serving of fluid milk as a beverage or on cereal or used in part for each purpose must be offered for breakfasts. Schools must offer students in age group 1–2 and age group 3–4 fluid milk in a variety of fat contents. Schools may offer flavored or

unflavored fluid milk and lactose-free fluid milk. All milk served in the Program must be pasteurized fluid milk which meets State and local standards for such milk. All fluid milk must have vitamins A and D at levels specified by the Food and Drug Administration and must be consistent with State and local standards for such milk. Schools must also comply with other applicable milk requirements in § 210.10(d)(2), § 210.10(d)(3), and § 210.10(d)(4) of this chapter.

(5) *Additional foods.* Schools may offer additional foods with breakfasts to children over one year of age.

(6) *Menu choices at breakfast.* Schools must follow the requirements in § 210.10(l) of this chapter.

(7) *Exceptions and variations allowed in reimbursable meals.* Schools must follow the requirements in § 210.10(m) of this chapter.

(8) *Nutrition disclosure.* Schools must follow the requirements in § 210.10(n) of this chapter.

(9) *State agency's responsibilities for monitoring breakfasts.* As part of the administrative review authorized under § 210.18(g)(2) of this chapter, State agencies must evaluate compliance with the meal pattern requirements (food components and quantities) in paragraph (n)(3) of this section. If the meals do not meet the requirements of this section, the State agency or school food authority must provide technical assistance and require the reviewed

school to take corrective action. In addition, the State agency must take fiscal action as authorized in § 210.18(m) and 210.19(c) of this chapter.

(10) *Requirements for the infant breakfast pattern.* (i) *Feeding breakfasts to infants.* Breakfasts served to infants ages birth through 11 months must meet the requirements described in paragraph (n)(11)(iv) of this section. Foods included in the breakfast must be of a texture and a consistency that are appropriate for the age of the infant being served. The foods must be served during a span of time consistent with the infant's eating habits. For those infants whose dietary needs are more individualized, exceptions to the meal pattern must be made in accordance with the requirements found in § 210.10(m) of this chapter.

(ii) *Breastmilk and iron-fortified formula.* Either breastmilk or iron-fortified infant formula, or portions of both, must be served for the entire first year. Meals containing breastmilk and meals containing iron-fortified infant formula supplied by the school are eligible for reimbursement. However, infant formula provided by a parent (or guardian) and breastmilk fed directly by the infant's mother, during a visit to the school, contribute to a reimbursable breakfast only when the school supplies

at least one component of the infant's meal.

(iii) *Solid foods.* For infants ages 4 through 7 months, solid foods of an appropriate texture and consistency are required only when the infant is developmentally ready to accept them. The school should consult with the infant's parent (or guardian) in making the decision to introduce solid foods. Solid foods should be introduced one at a time, on a gradual basis, with the intent of ensuring the infant's health and nutritional well-being.

(iv) *Infant meal pattern.* Infant breakfasts must have, at a minimum, each of the food components indicated, in the amount that is appropriate for the infant's age. For some breastfed infants who regularly consume less than the minimum amount of breastmilk per feeding, a serving of less than the minimum amount of breastmilk may be offered. In these situations, additional breastmilk must be offered if the infant is still hungry. Breakfasts may include portions of breastmilk and iron-fortified infant formula as long as the total number of ounces meets, or exceeds, the minimum amount required of this food component. Similarly, to meet the component requirement for vegetables and fruit, portions of both may be served.

(A) *Birth through 3 months.* 4 to 6 fluid ounces of breastmilk or iron-fortified infant formula—only breastmilk or iron-fortified formula is required to meet the infant's nutritional needs.

(B) *4 through 7 months.* Breastmilk or iron-fortified formula is required. Some infants may be developmentally ready for solid foods of an appropriate texture and consistency. Breakfasts are reimbursable when schools provide all of the components in the meal pattern that the infant is developmentally ready to accept.

(1) 4 to 8 fluid ounces of breastmilk or iron-fortified infant formula; and

(2) 0 to 3 tablespoons of iron-fortified dry infant cereal.

(C) *8 through 11 months.* Breastmilk or iron-fortified formula and solid foods of an appropriate texture and consistency are required.

(1) 6 to 8 fluid ounces of breastmilk or iron-fortified infant formula; and

(2) 2 to 4 tablespoons of iron-fortified dry infant cereal; and

(3) 1 to 4 tablespoons of fruit or vegetable.

(v) *Infant meal pattern table.* The minimum amounts of food components to serve to infants, as described in paragraph (n)(11)(iv) of this section, are:

Breakfast Pattern for Infants		
Birth through 3 months	4 through 7 months	8 through 11 months
4–6 fluid ounces of formula ¹ or breastmilk ^{2,3}	4–8 fluid ounces of formula ¹ or breastmilk ^{2,3} ; and 0–3 tablespoons of infant cereal ^{1,4}	6–8 fluid ounces of formula ¹ or breastmilk ^{2,3} ; and 2–4 tablespoons of infant cereal ¹ ; and 1–4 tablespoons of fruit or vegetable or both.

¹Infant formula and dry infant cereal must be iron-fortified.

²Breastmilk or formula, or portions of both, may be served; however, it is recommended that breastmilk be served in place of formula from birth through 11 months.

³For some breastfed infants who regularly consume less than the minimum amount of breastmilk per feeding, a serving of less than the minimum amount of breastmilk may be offered, with additional breastmilk offered if the infant is still hungry.

⁴A serving of this component is required only when the infant is developmentally ready to accept it.

14. Paragraph 220.13 is amended as follows:

a. Amend paragraph (f)(2) by removing the words “§ 210.30” wherever

it appears and adding in its place the words “§ 210.29”; and

b. Revise paragraph (f)(3) to read as follows:

§ 220.13 Special responsibilities of State agencies.

* * * * *

(f) * * *

(3) For the purposes of compliance with the meal requirements in § 220.8, the State agency must follow the provisions specified in § 210.18(g)(2) of this chapter, as applicable.

* * * * *

Appendix A to Part 220 [Amended]

15. Amend Appendix A to part 220 by removing section I. Formulated Grain-Fruit Products in its entirety, and by removing the Roman numeral "II." from the words "II. Alternate Protein Products".

Dated: January 3, 2011.

Kevin Concannon,
Under Secretary, Food, Nutrition, and Consumer Services.

[FR Doc. 2011-485 Filed 1-12-11; 8:45 am]

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S. 3447/P.L. 111-377

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S. 3481/P.L. 111-378

To amend the Federal Water Pollution Control Act to clarify Federal responsibility for stormwater pollution. (Jan. 4, 2011; 124 Stat. 4128)

S. 3592/P.L. 111-379

To designate the facility of the United States Postal Service located at 100 Commerce Drive in Tyrone, Georgia, as the "First Lieutenant Robert Wilson Collins Post Office Building". (Jan. 4, 2011; 124 Stat. 4130)

S. 3874/P.L. 111-380

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S. 3903/P.L. 111-381

To authorize leases of up to 99 years for lands held in trust for Ohkay Owingeh Pueblo. (Jan. 4, 2011; 124 Stat. 4133)

S. 4036/P.L. 111-382

To clarify the National Credit Union Administration authority

to make stabilization fund expenditures without borrowing from the Treasury. (Jan. 4, 2011; 124 Stat. 4134)

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